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Committee on Industry, Research and Energy

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OPINION

of the Committee on Industry, Research and Energy

for the Committee on Agriculture and Rural Development

on the proposal for a directive of the European Parliament and of the Council on the protection of animals used for scientific purposes
(COM(2008)0543 – C6-0391/2008 – 2008/0211(COD))

Rapporteur: Esko Seppänen

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SHORT JUSTIFICATION

The objective of the Commission proposal is to lay down a new Directive revising Directive 86/609/EEC. The new draft directive is a long step forward in implementing the 3Rs principles (replacement, reduction and refinement and of animals in experiments) and relieving suffering of the animals used in experimentation. One day the scientific community will succeed in developing alternative methods for animal experiments, but the time has not come yet.

Animal testing and especially the use in research of non-human primates (NHP) is a sensitive and controversial topic owing to an increasing awareness of animal welfare among the citizens. Many animal rights NGOs use good arguments against animal testing: it is cruel, it is poor scientific practice, it cannot reliably predict the effects in humans, the costs outweigh the benefits and animals have an intrinsic right not to be used for experimentation.

Reflecting such views, the European Parliament in a Written Declaration of March 2007 urged the revision of Directive 809/609/EC "as an opportunity to: a) make ending the use of apes and wild-caught monkeys in scientific experiments an urgent priority, and b) establish a timetable for replacing the use of all primates in scientific experiments with alternatives". The draftsman also signed this declaration.

In the draft directive there is a ban on the use of Great Apes in experiments, and in the EU the last use of chimpanzees derives from the year 1999. Therefore, this is not a problem.

The problem however, is that there is a need to use smaller NHPs because, compared to humans, they have more similar (although not identical) anatomical, physiological and immunological systems than any other species and they are susceptible to diseases that may not be present in other species. Therefore, the use of primates remains unavoidable in several essential research areas for the welfare of humans.

In basic and applied research, animal testing is used, for instance in finding cure or relief in the following areas: AIDS, type 2 diabetes, tuberculosis, malaria, stroke, cancer, hepatitis, SARS, neuro-degenerative diseases (Parkinson, Alzheimer), multiple sclerosis, poliomyelitis, fertility research, dengue haemorrhagic fever and drug abuse.

To ban NHP testing in these fields will result in a significant reduction in the amount of biomedical research undertaken in Europe to the detriment of human and animal health and welfare.

In the near future, it is not possible to establish a time table for replacing NHPs with alternatives. The latest scientific knowledge about alternatives is expressed in the SCHER report "The need for non-human primates in biomedical research, production and testing of products and devices". SCHER provides the Commission with scientific advice. The same opinion is largely shared by Academia. Thus, the above cited Parliament declaration may not be correct when stating that "advanced technology and techniques provide alternative methods that are proving to be more efficient and reliable than primate experiments".

Whenever it is not possible to avoid animal experiments, it is essential to ensure that animals still used in research can have the highest protection and welfare and that experiments be tightly regulated. The draftsman agrees fully with the purpose and the scope of the Directive.

AMENDMENTS

The Committee on Industry, Research and Energy calls on the Committee on Agriculture and Rural Development, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a directive
Recital 6

Text proposed by the Commission	*Amendment*
(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.	(6) It is necessary to include specific invertebrate species within the scope of this Directive, ***where*** scientific ***peer reviewed*** evidence of the ability of such species to experience pain, suffering, distress and lasting harm ***has been established***.

Justification

For some vertebrate species protection of developmental forms is appropriate. This makes the incorrect assumption that gestation or incubation progresses at the same rate in all species. The scientifically robust approach would relate the controls to the development of the neuronal pathways associated with pain. The regulation should be based on evidence of the development of sentience and not on an arbitrary time that may vary greatly between species. Including all embryonic and foetal forms as from last third of their development is arbitrary since sentience has not been established for all of them.

Amendment 2

Proposal for a directive
Recital 7

Text proposed by the Commission	*Amendment*
(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	(7) This Directive should cover embryonic and foetal forms of vertebrate animals ***which are intended to reach birth, when it has been scientifically shown that their***

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.	***nervous system is capable of registering pain signals, where*** there is scientific evidence showing that such forms in the last third of their development have an increased risk of experiencing pain, suffering and distress, which may also affect negatively their subsequent development. Scientific evidence has also shown that procedures on embryonic and foetal forms ***of mammals*** at an earlier stage of development could result in pain, suffering, distress or lasting harm, should the developmental forms be allowed to live beyond the first two thirds of their development.

Justification

Including all embryonic and foetal forms as from last third of their development is arbitrary since sentience has not been established for all of them. In addition with such broad scope the directive will cover use of embryonated hen's eggs for vaccine production.

Amendment 3

Proposal for a directive
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) The 7th Framework Programme of the European Community for research technological development and demonstration activities (2007-2013) adopted by the European Parliament and by the European Council on 18 December 2006 includes among its priorities in biomedical research, research on the brain and related diseases, and relevant age related illnesses, research on infectious diseases, HIV/AIDS, malaria and tuberculosis and translational research on major diseases such as cancer, cardiovascular diseases, diabetes/obesity and other chronic diseases, all of which may require experimentation with non human primates.

Justification

The 7th Framework Programme funds biomedical research which may require the use of non human primates.

Amendment 4

Proposal for a directive
Recital 8 b (new)

Text proposed by the Commission	*Amendment*
	(8b) In the light of scientific progress, the use of animal experiments remains an important means of ensuring a very high quality of public health research.

Justification

In many cases animals are used for scientific purposes with a view to complying with the European criteria of quality, effectiveness and safety, complementing tests not involving animals.

Amendment 5

Proposal for a directive
Recital 10

Text proposed by the Commission	*Amendment*
(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.	(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. ***Therefore the use of animals in scientific procedures should only be considered where a non-animal alternative is not available.*** Use of animals for scientific procedures in other areas under Community competence should be prohibited.

Amendment 6

Proposal for a directive
Recital 13

Text proposed by the Commission	*Amendment*
(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.	(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 ***an appropriate*** method without any further suffering. *If adopted, the words* *- killed by **a human** method* *- killed using **a human** method* *- **humane** method(s) of killing* *shall be replaced by* *- killed by **an appropriate** method* *- killed using **an appropriate** method* *- **appropriate** method(s) of killing* *throughout the text.*

Justification

There are no humane methods of killing an animal, only appropriate methods.

Amendment 7

Proposal for a directive
Recital 16

Text proposed by the Commission	*Amendment*
(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	(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***.

raises specific ethical ***issues*** and ***justifies certain practices*** in terms of meeting their behavioural, environmental and social needs in a laboratory environment. Therefore the use of non-human primates should be allowed in those essential ***research and*** biomedical areas for the benefit of human beings for which no other replacement alternative methods are yet available, or for the preservation of the respective non-human primate species. Fundamental research in ***all*** areas of the biomedical sciences can provide important new information relevant to many human conditions. ***Fundamental research projects using non-human primates should be subjected to scientific peer review and a strict ethical evaluation, taking into account the specific characteristics of these species.***

Amendment 8

Proposal for a directive
Recital 18

Text proposed by the Commission	*Amendment*
(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***	(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. ***With a view to*** gradually ***ending*** the capturing of animals from the wild for breeding purposes, ***account should be taken of the technical and scientific feasibility of this process, studies should be carried out on its economic viability***

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.	***and its effects – both positive and negative – on animal welfare, and possible solutions should be considered to the problem of supplying the European Union in the long term. The Commission and the Member States should also take the necessary measures to support appropriate transport conditions for non-human primates on the territory of the European Union.***

Justification

Il existe de graves préoccupations quant à l'impact à la fois sur le bien-être et sur la mise en œuvre de cette disposition. En effet, la faisabilité de la création de colonies F2 n'est pas démontrée à long terme. Le calendrier proposé par la Commission ne se réfère qu'à la reproduction, sans prendre en compte ni la santé des animaux, ni l'impact scientifique et/ou économique engendré par cette proposition, ni l'indispensable approvisionnement pour l'Union européenne, sachant qu'aujourd'hui il n'y a quasi pas d'élevage en Europe. Enfin le transport de primates peut poser des difficultés qu'il convient d'anticiper et de régler.

Amendment 9

Proposal for a directive
Recital 22

Text proposed by the Commission	*Amendment*
(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.	(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 ***restricted as far as possible taking account of their scientific and public health benefits***. 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.

Justification

It is inconceivable that major research in oncology, for example, should be banned, but the development of such research must be based on solid scientific needs.

Amendment 10

Proposal for a directive
Recital 23

Text proposed by the Commission	*Amendment*
(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***.	(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 ***have been justified by an ethical review.***

Justification

The Commission's original proposal would entail an increase in the number of animals used for experimental purposes: in some cases, the number of dogs could be multiplied 20-fold. Accordingly, while not increasing the number of animals we should ensure the continuity of scientific procedures and should not impairing the follow-up of experiments.

Amendment 11

Proposal for a directive
Recital 26

Text proposed by the Commission	*Amendment*
(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	(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.	procedures involving animals, those activities should only be performed ***in establishments and*** by persons authorised by the competent authorities. The main focus should be on obtaining and maintaining an adequate level of competence which should be demonstrated before authorising those persons or renewing their authorisation.

Justification

Establishments, signifying physical installations and teams of people as well as individual personnel, should require authorisation.

Amendment 12

Proposal for a directive
Recital 27

Text proposed by the Commission	*Amendment*
(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.	(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 ***both*** to the animals ***directly concerned and their animal companions***. The establishments should operate only if they are authorised by the competent authorities.

Justification

Distress and anxiety to animals caused by witnessing their fellows being experimented upon should be avoided.

Amendment 13

Proposal for a directive
Recital 40

Text proposed by the Commission	*Amendment*
(40) To ensure that the public is informed, it is important that objective information	(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.	on the projects using live animals is ***collected and compiled***. The format of that information should not violate proprietary rights or expose confidential information ***or information relating to the safety of persons and installations***. Therefore, user establishments should ***draw up*** anonymous non-technical summaries of those projects, including the results of any retrospective assessments, and make those summaries available ***to the relevant authorities***.

Justification

The relevant authorities should receive this information with a view to filing it if necessary.

Amendment 14

Proposal for a directive
Recital 45

Text proposed by the Commission	*Amendment*
(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 in order to ensure coherent and comparable quality of the results.	(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 in order to ensure coherent and comparable quality of the results. ***In***

	addition, the remit of the European Centre for the Validation of Alternative Methods should be extended to include the coordination and promotion of the development and use of alternatives to animal experiments.

Amendment 15

Proposal for a directive
Recital 47

Text proposed by the Commission	*Amendment*
(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.	(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***, based on the results of peer-assessed scientific studies,*** should examine possible replacement of the use of animals, and in particular non-human primates, as a matter of priority where it is possible, taking into account the advancement of science.

Justification

Such a review can only be justified on the basis of scientific evidence.

Amendment 16

Proposal for a directive
Article 2 – paragraph 2

Text proposed by the Commission	*Amendment*
2. This Directive shall apply to ***the following animals:***	2. This Directive shall apply to live non-human vertebrate animals, including independently feeding larval forms and embryonic or foetal forms ***of mammals*** as from the last third of their normal development.
(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.

Justification

We cannot include all embryonic forms in advance, particularly where the protocols do not result in the birth of a viable form. Retaining this article unchanged would have a disastrous effect on the evaluation of batches of human and veterinary vaccines, many of which are produced on embryonated hens' eggs, but in particular it would hinder the development of interesting alternative methods in toxicology and development biology base on the use of fish eggs (independently feeding larval forms).

Amendment 17

Proposal for a directive
Article 2 – paragraph 3

Text proposed by the Commission	*Amendment*
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***.	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 ***which are intended to reach birth and have been scientifically shown to possess a nervous system capable of registering pain signals***.

Justification

The directive should apply only to the categories mentioned in this paragraph which are certain to reach birth.

Amendment 18

Proposal for a directive
Article 3 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. 'competent authority' means the authority or authorities designated by

	each Member State as being responsible for supervising the enforcement of this Directive.

Justification

This definition is missing.

Amendment 19

Proposal for a directive
Article 4 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. Where a method of testing not involving the use of animals exists***, provides equally relevant information*** and may be used in place of a procedure, Member States shall ensure that the alternative method is used.

Justification

In line with efforts to promote product safety and a high quality of public health, the alternative method must meet the same requirements as regards the relevance of the scientific data.

Amendment 20

Proposal for a directive
Article 4 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Member States shall provide funding for training, research, development and implementation of replacement methods.

Amendment 21

Proposal for a directive
Article 5 – point 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) the improvement of the production

conditions and welfare of animals reared for agricultural purposes.

Justification

Animal experimentation also takes place for agricultural purposes (to improve production systems, to evaluate and improve welfare during rearing), on the understanding that acts relating to agricultural practices as defined in Article 2(4) are not covered by the scope of the directive. It is essential to take into account the ultimate objectives of agricultural research in supporting the competitiveness of European agriculture.

Amendment 22

Proposal for a directive
Article 6 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. Competent authorities may grant exemptions from paragraph 1 on the basis of scientific justification that the purpose of the procedure cannot be achieved by the use of a humane method of killing ***or that other methods providing better animal protection have been developed***.

Amendment 23

Proposal for a directive
Article 6 a (new)

Text proposed by the Commission	*Amendment*
	Article 6a
	National measures
	This Directive shall not prevent Member States from applying or adopting stricter national measures seeking to improve the well-being and protection of animals used for scientific purposes.

Amendment 24

Proposal for a directive
Article 8 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Non-human primates shall not be used in procedures, with the exception of those procedures meeting the following conditions:	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;	(a) the procedure has one of the purposes referred to in points (1), (2)(a), (3) and (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.	(b) there is a scientific justification ***from the competent national authority or ethical review body*** that the purpose of the procedure cannot be achieved by the use of other species than non-human primates.

Justification

NHP use should not be restricted to research related to life threatening or debilitating diseases. This restriction will exclude much academic research, as well as basic research not yet linked to a specific disease. In some instances, for instance in the discovery of medicines for diseases such as HIV/AIDS, Alzheimer's disease, Parkinson's disease (which may or may be not be categorised as life threatening or severely debilitating), or for the safety and quality testing of some vaccines, non human primates are currently the only animals that can provide certain critical information. The exceptions in (b) should be granted in the national institutional framework according to the subsidiarity principle.

Amendment 25

Proposal for a directive
Article 8 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) the procedure is necessary for significant fundamental research justified by its potential for improved human

health and quality of the human condition.

Justification

Fundamental research which could lead to therapies and procedures of benefit to human health and well-being must not be excluded. Nor should such benefits exclude areas such as reproductive and other important health benefits which may not be categorised as "life threatening or debilitating".

Amendment 26

Proposal for a directive
Article 8 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Commission shall develop a strategy to establish a high-level group to review annually the use of non-human primates in procedures.

Amendment 27

Proposal for a directive
Article 9 – paragraph 2

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

Justification

Animals taken from the wild experience considerable additional suffering in comparison with purpose-bred animals. Only in the rarest cases should their use be contemplated.

Amendment 28

Proposal for a directive
Article 10

Text proposed by the Commission	*Amendment*
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***.	1. ***No later than [5 years from the entry into force of this Directive], the Commission shall submit a technical feasibility study of the requirements set out in paragraph 1a, detailing the consequences for animal welfare.***
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.	***1a. In the light of the results of the study referred to in paragraph 1, and if justified on scientific, economic and ethical grounds,*** 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.	2. Competent authorities may grant exemptions from paragraph 1 on the basis of a scientific justification ***or linked to animal welfare***.

Justification

There are serious concerns both about this provision's impact on animal welfare and its implementation. There is no evidence of the long-term feasibility of creating F2 colonies.

The timetable proposed by the Commission refers only to reproduction, and does not take into account either the health of the animals or the scientific and/or economic impact of this proposal, nor yet the European Union's vital need for supplies, given that there is practically no breeding in Europe today.

Amendment 29

Proposal for a directive
Article 13 – paragraph 1

Text proposed by the Commission	*Amendment*
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	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.	entailing the use of an animal, is recognised by Community legislation ***and internationally accepted***. 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.

Amendment 30

Proposal for a directive
Article 14 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that all procedures are carried out under general or local anaesthesia.	***deleted***

Justification

Many studies require the animal to be observed in its normal activities and cannot be conducted under local or general anaesthesia (studies of digestion, the immune system, stress, animal welfare, etc.).

Amendment 31

Proposal for a directive
Article 14 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
2. ***By way of derogation from paragraph 1,*** procedures may be carried out without anaesthesia in the following conditions:	2. Procedures may be carried out without anaesthesia in the following conditions:

Justification

Many studies require the animal to be observed in its normal activities and cannot be conducted under local or general anaesthesia (studies of digestion, the immune system, stress, animal welfare, etc.).

Amendment 32

Proposal for a directive
Article 15 – paragraph 1

Text proposed by the Commission	*Amendment*
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***.	1. Member States shall ensure that all procedures are classified as 'up to mild', 'moderate' ***or*** 'severe' ***in accordance with Annex VIIa.***

Amendment 33

Proposal for a directive
Article 15 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. Member States shall ensure that the procedures classified as "severe" ***are subject to an enhanced scientific and ethical evaluation procedure supported by the establishment of clearly defined limit points*** if the pain, suffering or distress is likely to be prolonged.

Justification

The ban proposed would call into question the possibility of carrying out studies in a number of fields (cancer research, infectious diseases, chronic inflammatory diseases). On the other hand, there must be strong scientific justification and a system of limit points must be put in place.

Amendment 34

Proposal for a directive
Article 15 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Commission shall establish the criteria for classification of procedures.	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).	***The criteria for classification of procedures must be established by the Commission by [within three months of the date of entry into force of this Directive].***

Justification

It is not acceptable that such a key procedural element is not in force at the same time that the directive.

Amendment 35

Proposal for a directive
Article 16 – paragraph 1

Text proposed by the Commission	*Amendment*
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:	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 ***which, in scientific terms, is entirely different from the previous procedure,*** only when all of the following conditions are met:
(a) the previous procedure was classified as ***'up to mild'***;	(a) the previous procedure was classified as ***'up to moderate'***;
(b) it is demonstrated that its general state of health and well-being has been fully restored;	(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'**.**	(c) the further procedure is classified as ***'up to moderate'*** or 'non-recovery'***;***

	(ca) a prior veterinary inspection is undertaken before the possible re-use.

Amendment 36

Proposal for a directive
Article 19 – introductory part

Text proposed by the Commission	*Amendment*
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:	Member States may allow animals used or intended to be used in procedures to be ***placed in normal breeding conditions*** or re-homed provided that the following conditions are met:

Justification

The term 'normal breeding conditions' is more appropriate to the behaviour and physiological characteristics of species of agronomic interest (domestic species selected by man on the basis of specific criteria) for which it is not possible to speak of 'setting free'.

Amendment 37

Proposal for a directive
Article 20 – paragraph 1 – introductory part

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

Justification

The competent authority must be able to delegate its power of authorisation. This is what happens in several Member States. The Directive must respect the organisation of the national authorisation systems.

Amendment 38

Proposal for a directive
Article 20 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	3. All authorisations of persons shall be granted for a limited period of time, not exceeding ***seven*** 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.***Member States shall guarantee the mutual recognition of this competence and of the authorisation.***

Justification

The aim is to minimise the administrative burden.

Amendment 39

Proposal for a directive
Article 22 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where an establishment no longer complies with requirements set out in this Directive, the competent authority shall suspend or withdraw its authorisation.	1. Where an establishment no longer complies with requirements set out in this Directive, the competent authority shall suspend or withdraw its authorisation. ***Member States shall establish an appropriate mechanism for appeals against suspension or withdrawal of authorisation.***

Justification

There needs to be a mechanism to appeal decisions in order to ensure a fair and reasonable process.

Amendment 40

Proposal for a directive
Article 23 – paragraph 2

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

Justification

No way for authorities to ensure that results are consistent.

Amendment 41

Proposal for a directive
Article 25 – paragraph 2

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

Amendment 42

Proposal for a directive
Article 26 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The permanent ethical review body shall fulfil the following tasks:	1. The permanent ethical review body ***that reviews protocols and procedures*** shall fulfil the following tasks:

Justification

Coherence with the text and with the tasks assigned to the ethical review bodies.

Amendment 43

Proposal for a directive
Article 26 – paragraph 1 – point d – introductory part

Text proposed by the Commission	*Amendment*
(d) review annually all projects which are of more than 12 months duration, focusing in particular on:	(d) review annually all projects ***classified as "severe" or on non-human primates and every three years the other projects*** which are of more than 12 months duration, focusing in particular on:

Justification

The larger universities typically each have in excess of 300 separate projects. To review each one every year would be a full-time task for the ethical review body, requiring so much time that the stipulated members of that body would be unable to carry out their main jobs – which would have a harmful effect both on animal welfare and science. It would be appropriate to do this annual review only for projects rated "severe" for the others a review each 3 years would be appropriate.

Amendment 44

Proposal for a directive
Article 26 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
The records shall be ***submitted*** to the competent authority upon request.	The records shall be ***made available*** to the competent authority upon request. ***Member States shall pay particular attention to the collection, collation and publication of records relating to projects classified as severe or on non-human primates in order to provide information which can improve animal welfare and further the 3Rs.***

Amendment 45

Proposal for a directive
Article 27 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. ***Without prejudice to the principle of replacement, reduction and refinement,*** Member States shall ensure that breeding ***establishments of non-human primates in the Community*** 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. ***The Commission and the Member States shall take the necessary measures to support appropriate conditions of transport and shall draw up a common strategy to sustain the indispensable presence of non-human primates on Community territory.***

Amendment 46

Proposal for a directive
Article 29 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the number and the species of animals bred, acquired, supplied, released or re-homed;	(a) the number and the species of ***vertebrate*** animals bred, acquired, supplied, released or re-homed;

Justification

The inclusion of all mature and immature invertebrates of the relevant orders would be simply impossible to fulfil.

Amendment 47

Proposal for a directive
Article 32 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall, as far as the care	1. Member States shall, as far as the care

and accommodation of animals is concerned, ensure the following:	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;	(a) all animals are provided with accommodation, an environment, freedom of movement, food, water and care which are appropriate to their health and well-being ***and which allow them to satisfy their ethological as well as physical needs***;
(b) any restrictions on the extent to which an animal can satisfy its physiological and ethological needs are limited to a minimum;	(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;	(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;	(d) the well-being and state of health of animals are observed by a competent person ***at least once a day*** to prevent pain or avoidable suffering, distress or lasting harm;
(e) arrangements are made to ensure that any defect ***or*** suffering discovered ***is*** eliminated as quickly as possible.	(e) arrangements are made to ensure that any defect ***in equipment causing*** suffering ***is*** discovered ***and*** eliminated as quickly as possible.

Justification

The new standards should be implemented as soon as possible. The existing standards were accepted as being in need of revision 1998; a Council of Europe Working Group then took 8 years to develop the new standards and to get agreement from all stakeholders including industry, breeders, academia and regulators. A further 2 years has now passed. Further delay in their implementation would be outrageous. The proposed transition period for adopting housing standards would mean some animals continue to be kept in housing which has long been known to be substandard.

Amendment 48

Proposal for a directive
Article 32 – paragraph 2

Text proposed by the Commission	*Amendment*
2. For the purposes of points (a) and (b) of paragraph 1, Member States shall apply the care and accommodation ***standards*** set out	2. For the purposes of points (a) and (b) of paragraph 1, Member States shall apply the care and accommodation ***guidelines*** set out

in Annex IV as from the dates provided for in that Annex.	in Annex IV as from the dates provided for in that Annex.

Justification

These guidelines (Appendix A of Convention ETS No 123 of the Council of Europe) constitute a framework that is recognised and applied by the scientific community. However, they should not become standards. It is in fact essential that the care and accommodation conditions of animals be adapted to the scientific objective in question, which strict application of the provisions referred to would not permit.

Amendment 49

Proposal for a directive
Article 32 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States may allow exemptions to paragraph 2 for animal welfare reasons.	3. Member States may allow exemptions to paragraph 2 for ***justified scientific reasons, veterinary reasons or*** animal welfare reasons.

Justification

The exemptions to paragraph 2 must be assessed with regard not only to animal welfare considerations but also to scientific and/or veterinary reasons.

Amendment 50

Proposal for a directive
Article 33 – paragraph 3 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Member States shall take the necessary measures to ensure that the inspections do not jeopardise the scientific quality of the projects and the welfare of the animals, and do not take place under conditions that fail to comply with the other regulations in force.

Amendment 51

Proposal for a directive
Article 34 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission may undertake controls of the infrastructure and operation of national inspections in Member States.	1. The Commission may undertake controls of the infrastructure and operation of national inspections in Member States ***to ensure that severity classifications are applied correctly and uniformly in the EU territory***.

Justification

The revised Directive must enshrine the principles of transparency and accountability.

Amendment 52

Proposal for a directive
Article 35 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that projects are not carried out without a prior authorisation by the competent authority.	1. Member States shall ensure that projects are not carried out without a prior authorisation by the competent authority ***or, by delegation, by the permanent ethical review body that reviews protocols and procedures***.

Justification

The bodies required to review protocols and procedures are the permanent ethical review bodies. The existence of a single competent authority, which would be centralised and thus remote, would cause major delays for research. Member States should develop their review bodies on their respective territories in order to perform this role.

Amendment 53

Proposal for a directive
Article 35 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Granting of authorisation shall be subject to favourable ethical evaluation by	2. Granting of authorisation shall be subject to favourable ethical evaluation by

the competent authority.	the competent authority ***or, by delegation, by the permanent ethical review body that reviews protocols and procedures***.

Justification

The permanent ethical review bodies carry out the reviews.

Amendment 54

Proposal for a directive
Article 35 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. No formal authorisation shall be necessary for projects required by law, but such projects should be subject to favourable ethical evaluation.

Justification

Projects required by law are automatically authorised. These projects should, however, be subject to favourable ethical evaluation. The issues at stake are compliance with the principle of equal treatment and guaranteeing that due consideration is given to animal welfare.

Amendment 55

Proposal for a directive
Article 36 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The ***user establishment*** shall submit an application for the project authorisation, which shall include the following:	1. The ***scientific director or the person in charge of the establishment where the project is to be carried out*** shall submit an application for the project authorisation, which shall include the following:

Justification

It is important to take account of the fact that it often happens in academic research that a number of laboratories have common experimentation establishments.

Amendment 56

Proposal for a directive
Article 36 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) a scientifically justified statement that the research project is indispensable and ethically defensible and that the purposes of the project cannot be achieved using other methods or procedures.

Justification

This information is essential in order to assess the application.

Amendment 57

Proposal for a directive
Article 37 – paragraph 2 – point d

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

Justification

It is impossible to carry out a harm-benefit analysis on the basis of objective, scientifically recognised criteria, and such a requirement disregards the nature of science. The knowledge gained from a scientific experiment cannot be foreseen in advance, and history shows that in many cases the usefulness of certain results for the development of specific applications for human beings, animals or the environment does not become clear until years later. The ethical assessment should therefore examine whether the project is ethically defensible. This corresponds to the tried-and-tested procedure used in Germany.

Amendment 58

Proposal for a directive
Article 37 – paragraph 3 – introductory part

Text proposed by the Commission	*Amendment*
3. The competent authority carrying out the ethical evaluation shall consider ***experts*** in particular in the following areas:	3. The competent authority carrying out the ethical evaluation shall consider ***corresponding expertise*** in particular in the following areas:

Justification

The ethical evaluation should draw on independent expertise. So far, the Commission proposal does not take into account that this expertise may also be available within the Committee on Ethics and that the confidentiality of the corresponding information must be guaranteed.

Amendment 59

Proposal for a directive
Article 37 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Ethical evaluation shall be performed in a transparent manner***,*** by integrating ***the opinion of*** independent ***parties***.	4. Ethical evaluation shall be performed in a transparent manner by integrating independent ***expertise whilst safeguarding intellectual property and confidential information and also the safety of goods and persons.***

Amendment 60

Proposal for a directive
Article 38 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) harm inflicted on animals including the numbers and species of animals used and the ***severity of*** the procedures;	(b) harm inflicted on animals including the numbers and species of animals used and the ***nature, level and duration of the harm inflicted on animals during*** the procedures;

Amendment 61

Proposal for a directive
Article 40 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Subject to safeguarding confidential information, the non-technical project summary shall provide the following:	1. Subject to safeguarding confidential information, ***including that of the establishment and its staff,*** 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;	(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.	(b) a demonstration ***that there has been*** compliance with the requirement of replacement, reduction and refinement.

Amendment 62

Proposal for a directive
Article 40 – paragraph 4

Text proposed by the Commission	*Amendment*
4. ***Member States shall make publicly available the*** non-technical project summaries of authorised projects and any updates to them.	4. ***The*** non-technical project summaries of authorised projects and any updates to them ***shall be sent, on request, to the competent authorities, which shall make them publicly available***.

Justification

The aim is to avoid administrative bottlenecks, whilst clearly establishing that public access to this information is possible.

Amendment 63

Proposal for a directive
Article 41 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Project authorisations shall be granted	3. Project authorisations shall be granted

for a period not exceeding ***four*** years.	for a period not exceeding ***five*** years.

Justification

The aim is to avoid imposing an excessive administrative burden.

Amendment 64

Proposal for a directive
Article 41 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States may allow the authorisation of multiple projects when those projects are required by law.	4. Member States may allow the authorisation of multiple projects ***under one group authorisation*** when those projects are required by law.

Justification

Clarification of the wording.

Amendment 65

Proposal for a directive
Article 42 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The competent authority may amend or renew the project authorisation on the request of the user establishment.	1. The competent authority may amend or renew the project authorisation on the request of the user establishment ***or the scientific director of the project***.

Justification

It is important to take account of the fact that it often happens in academic research that a number of laboratories have common experimentation establishments.

Amendment 66

Proposal for a directive
Article 42 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Any ***amendment or*** renewal of a project authorisation shall be subject to a further favourable ethical evaluation.	2. Any renewal of a project authorisation ***that involves severe procedures or non-human primates, or a moderate or greater increase in animal harm*** shall be subject to a further favourable ethical evaluation ***and authorisation by the competent authority***.

Justification

This would be a very serious burden as it covers even minor amendments to licenses with no or minimal welfare impact.

Amendment 67

Proposal for a directive
Article 42 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The competent authority may withdraw the project authorisation where the project is not carried out in accordance with the project authorisation.	3. The competent authority may withdraw the project authorisation where the project is not carried out in accordance with the project authorisation ***and may cause a deterioration in animal welfare***.

Amendment 68

Proposal for a directive
Article 43 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	***deleted***

Justification

A time limit must apply to all applications for animal experiments. 'Constructive approval' where this deadline has been exceeded must also apply to all applications. Otherwise the transparency and legality of the procedure would not be guaranteed.

In the case of complex applications for animal experiments, a time limit of 30 or even 60 days is not sufficient to allow authorities and bodies to carry out an appropriate assessment. A time limit of 90 days for all applications has proved effective in Germany and has been enforced there for many years.

Amendment 69

Proposal for a directive
Article 45

Text proposed by the Commission	*Amendment*
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.	The Commission and Member States shall contribute ***financially and by any other appropriate means,*** to the development and***, where appropriate, scientific*** validation of alternative approaches ***intended to*** 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.

Justification

In recent years considerable progress has been made towards replacing, reducing and refining the use of animals in procedures through dedicated research, sharing of best practice and through validation studies conducted according to international standards. Efforts in this field should be increased in order to promote animal welfare and reduce animal suffering.

Amendment 70

Proposal for a directive
Article 45 a (new)

Text proposed by the Commission	*Amendment*
	Article 45a
	The Commission shall, by [one year after entry into force of this Directive], strengthen the role of the European Centre for the Validation of Alternative Methods and create new facilities to advance the development and use of alternatives to animal procedures including the use of animals in basic and applied biomedical and veterinary research.
	The European Centre for the Validation of Alternative Methods shall coordinate with the national reference laboratories referred to in Article 46 in order to:
	(a) develop strategies to advance the replacement, reduction and refinement of the use of animals in basic and applied biomedical and veterinary research, and regulatory testing;
	(b) conduct and commission research in order to develop new replacement, reduction and refinement techniques;
	(c) provide advice, guidance and information on the application of the 3Rs (replacement, reduction and refinement) to competent authorities, the scientific community, the public and relevant stakeholders;
	(d) coordinate pre-validation and validation studies in order to further the replacement, reduction and refinement of the use of animals in regulatory testing;
	(e) facilitate the scientific endorsement and regulatory acceptance of alternatives to animal tests used for regulatory purposes.

Justification

In recent years considerable progress has been made towards replacing, reducing and refining the use of animals in procedures through dedicated research, sharing of best practice and through validation studies conducted according to international standards. Efforts in this field should be increased in order to promote animal welfare and reduce animal suffering.

A more wide-ranging and coordinated approach is needed to further the aims of Article 45, coordinate approach to research, and the development of alternatives in all areas of animal use, as well as to manage validation studies, expanding on the role and facilities of the existing infrastructure (ECVAM).

Amendment 71

Proposal for a directive
Article 46 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. Each Member State shall, by *[one year after entry into force of this Directive],* ***ensure access to one or more accredited European*** reference ***centre(s)*** for the validation of alternative methods replacing, reducing and refining the use of animals.

Justification

It is neither cost effective nor feasible from the perspective of qualified human resources for every member state to establish its own reference laboratory. It is sufficient to require access to centres on an EU-wide basis. It would also encourage the sharing of best practice.

Amendment 72

Proposal for a directive
Article 46 – paragraph 4 – point d

Text proposed by the Commission	*Amendment*
(d) provide scientific and technical assistance to the relevant authorities ***of*** the Member States for the acceptance and implementation of alternative methods;	(d) provide scientific and technical assistance to the relevant authorities ***within and between*** the Member States for the acceptance and implementation of alternative methods;

Justification

Best practices should be international property.

Amendment 73

Proposal for a directive
Article 49 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. Member States shall collect, 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.	Member States shall ***make*** that statistical information ***publicly available and submit it*** to the Commission by [three years from transposition date] and thereafter ***at intervals not exceeding two years***.

Amendment 74

Proposal for a directive
Article 53

Text proposed by the Commission	*Amendment*
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.	53. The Commission shall review this Directive by [***five 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.

Justification

A review which takes place after 10 years from the entry into force of the Directive would be unable to keep pace with technological and scientific progress.

Amendment 75

Proposal for a directive
Annex I

Text proposed by the Commission	*Amendment*
• Cyclostomes	
• Cephalopods	• Cephalopods
• Decapod crustaceans	

Justification

There has never been any scientific proof of the sensitivity of invertebrates other than cephalopods.

Amendment 76

Proposal for a directive
Annex II – point 8

Text proposed by the Commission	*Amendment*
8. Rabbit (Oryctolagus cuniculus)	***deleted***

Justification

With regard to rabbits, it is essential that further experimentation be permitted for agronomic purposes (genetic improvement of production animals, quality of the meat, welfare of farmed animals, etc.). It would also be discriminatory to require that the same species be bred in separate farms depending on whether it is intended for research purposes or for production purposes.

Amendment 77

Proposal for a directive
Annex II – point 11 a (new)

Text proposed by the Commission	*Amendment*
	***11a. Zebrafish (Danio danio*)**

Justification

With regard to the zebrafish (danio danio), this is a laboratory species with very many genetic

variants which now differs significantly from the original wild species and, particularly for food safety reasons, should come from establishments breeding them for experimental purposes.

Amendment 78

Proposal for a directive
Annex IV – point 1 – introductory part

Text proposed by the Commission	*Amendment*
1. THE PHYSICAL FACILITIES	1. THE PHYSICAL FACILITIES
	The accommodation conditions shall be tailored to the scientific objective.

Amendment 79

Proposal for a directive
Annex IV – point 3 – introductory part

Text proposed by the Commission	*Amendment*
3. CARE	3. CARE
	The care shall be tailored to the scientific objective.

Amendment 80

Proposal for a directive
Annex IV – point 3 – point 3.5 – point a

Text proposed by the Commission	*Amendment*
(a) Uncontaminated drinking water shall ***always*** be available to all animals.	(a) ***Sufficient*** uncontaminated drinking water shall be available to all animals.

Justification

Many experiments investigating behavioural physiology use liquids (water, juice, etc.) as reinforcement (i.e. as a 'reward') for animals used in procedures. This is necessary in order to condition behaviour. Consequently, the animals may not 'always' have access to liquids in such experiments. A sufficient supply of water is of course nevertheless guaranteed.

Amendment 81

Proposal for a directive
Annex VII a (new)

Text proposed by the Commission	*Amendment*
	ANNEX VIIa
	General Definitions of Degrees of Severity referred to in Article 15(1)
	In general:
	Unless the contrary is known or established it shall be assumed that procedures that cause pain in humans also cause pain in animals.
	No pain or mild stress/pain: Severity Grade 1
	Interventions and manipulations in animals for experimental purposes as a result of which the animals experience no pain or mild pain, suffering and injury, or no anxiety or mild anxiety and no significant impairment of their general condition.
	Examples:
	- studies with differing feed compositions or with unphysiological diet, without manifest clinical signs or symptoms;
	- withdrawal of blood samples; injection (s.c., i.m., i.p., i.v.) of a drug;
	- one single retrobulbar blood sample or several retrobulbar blood samples at intervals of > 14 days (alternating punctures), under brief anaesthesia;
	- subcutaneously channelled venous catheters;
	- NMR measurements (nuclear spin resonance), with or without sedation of the animals;
	- test of contrast media by means of exploratory echography;
	- application of substances with known

innocuous effects (vehicle-control);

- tolerability studies which give rise to transient, mild, local or systemic reactions and, owing to the method of administration or sample collection, impose no significant stress on the animals;

- bronchoscopy, broncho-alveolar lavage or pulmonary-function test in anaesthetized animals;

- models with ECG recordings in the conscious dog;

- open-field test, labyrinth tests, the staircase test;

- circadian-rhythm model.

Moderate Stress: Severity Grade 2

Interventions and manipulations in animals for experimental purposes which subject the animals to a brief episode of moderate stress, or a moderately long to long-lasting episode of mild stress (pain, suffering, or injury, extreme anxiety, or significant impairment of general condition).

Examples:

- models with telemetric heart-rate measurements in the conscious animal by means of catheters/transmitters implanted in the abdominal cavity;

- surgical treatment or castration of female animals under anaesthesia;

- studies with unphysiological diet, with manifest clinical signs or symptoms;

- implantation of gene-technologically altered embryos in foster-mother mice;

- spontaneous diabetes mellitus;

- genetically engineered mouse strains with oncogenes, if the experiment is prematurely terminated according to defined criteria (that is, if the study is finished before the tumour exceeds a pre-

defined size);

- obese mouse with diabetes mellitus;

- repetitive daily withdrawal of blood samples from the tail vein of the rat over five days;

- repeated retrobulbar blood samples under brief anaesthesia (at the most three times within 14 days, alternating, and on the last occasion preterminally);

- surgical interventions:

- implantation of catheters in the abdominal aorta or bile duct,

- implantation of minipumps intravenously,

- acute toxicity tests, acute tolerability studies; range-finding studies, chronic toxicity/carcinogenicity tests; toxicokinetic tests,

- petit-mal model (i.e. for epilepsy studies),

- collection of cerebrospinal fluid via cannula (microdialysis) in the rat.

Severe stress: Severity Grade 3

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

Examples:

- bacteria: models with infections for screening new antibiotics;

- transmitted rheumatoid arthritis;

- auto-immunely induced arthritis;

- genetically engineered mouse strains

with oncogenes, without premature termination of the experiment;

- joint transplantations;

- transplantation of a functional internal organ (i.e. kidney, pancreas transplantation);

- models with induction of clinically manifest cardiac insufficience;

- lethal infectious and neoplastic disease without premature euthanasia;

- knock-out mice with massive deficiency symptoms.

PROCEDURE

Title	Protection of animals used for scientific purposes
References	COM(2008)0543 – C6-0391/2008 – 2008/0211(COD)
Committee responsible	AGRI
Opinion by Date announced in plenary	ITRE 4.12.2008
Associated committee(s) - date announced in plenary	19.2.2009
Rapporteur Date appointed	Esko Seppänen 2.12.2008
Discussed in committee	11.2.2009
Date adopted	9.3.2009
Result of final vote	+: 37 –: 2 0: 0
Members present for the final vote	Jan Březina, Jorgo Chatzimarkakis, Giles Chichester, Pilar del Castillo Vera, Den Dover, Lena Ek, Norbert Glante, Umberto Guidoni, Fiona Hall, David Hammerstein, Erna Hennicot-Schoepges, Mary Honeyball, Romana Jordan Cizelj, Anne Laperrouze, Pia Elda Locatelli, Eluned Morgan, Reino Paasilinna, Atanas Paparizov, Francisca Pleguezuelos Aguilar, Anni Podimata, Miloslav Ransdorf, Herbert Reul, Teresa Riera Madurell, Paul Rübig, Catherine Trautmann, Claude Turmes, Adina-Ioana Vălean, Dominique Vlasto
Substitute(s) present for the final vote	Alexander Alvaro, Pilar Ayuso, Ivo Belet, Françoise Grossetête, Marie-Noëlle Lienemann, Erika Mann, Vittorio Prodi, Esko Seppänen, Vladimir Urutchev, Lambert van Nistelrooij
Substitute(s) under Rule 178(2) present for the final vote	Ulrike Rodust