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***I
REPORT

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))

Committee on Agriculture and Rural Development

Rapporteur: Neil Parish

Symbols for procedures

*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
***I	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission.)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics*.** In the case of amending acts, passages in an existing provision that the Commission has left unchanged, but that Parliament wishes to amend, are highlighted in **bold**. Any deletions that Parliament wishes to make in passages of this kind are indicated thus: [...]. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). Suggested corrections of this kind are subject to the agreement of the departments concerned.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

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))

(Codecision procedure: first reading)

The European Parliament,

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

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

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

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

1. Approves the Commission proposal as amended;

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

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

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

Justification

The wording is too general and would bring under regulation very large numbers of animals

that would not benefit, in a welfare sense, from such regulation.

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

Justification

Inclusion of all embryonic and foetal forms is arbitrary given the lack of conclusive scientific evidence of sentient capacity.

Amendment 3

Proposal for a directive
Recital 8

Text proposed by the Commission	*Amendment*
(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.	(8) ***The*** use of live animals continues to be necessary to protect human health, animal health and the environment***, within current scientific limitations. However this directive represents an important step towards achieving the goal of the full replacement of procedures on live animals***

for scientific purposes as soon as it is scientifically possible to do so. To meet that end, this directive seeks to facilitate and promote the advancement of alternative methods and to ensure a high level of protection for animals used in procedures. This directive should be reviewed regularly in light of evolving scientific and animal protection measures.

Amendment 4

Proposal for a directive
Recital 8 a (new)

Text proposed by the Commission	*Amendment*
	(8a) In light of scientific progress, the use of animal experiments remains an important means of ensuring a very high standard 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 9

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

implementing this Directive.	***Commission shall ensure a high level of transparency in relation to the use of animals and in terms of reporting to the public on the implementation of animal protection measures and progress made towards replacing animal methods.***

Amendment 6

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 ***fundamental knowledge, since this may*** ultimately ***have benefits for e.g.*** human or animal health, or the environment. ***The use of animals in scientific procedures should therefore only be considered where a non-animal alternative is not available.*** Use of animals for scientific procedures in other areas under Community competence should be prohibited.

Justification

The history of medical progress is littered with examples where the pursuit of fundamental knowledge turned out to be of great utility in the future though that utility was not recognised at the time of the study.

Amendment 7

Proposal for a directive
Recital 11 a (new)

Text proposed by the Commission	*Amendment*
	(11a) In accordance with the objectives of the Community Action Plan on the Protection and Welfare of Animals 2006 – 2010 (COM(2006)0013)[1] the Commission should endeavour to promote the welfare of animals used for scientific purposes internationally, and in particular to seek promotion of the replacement, reduction and refinement of animal procedures through the World Organisation for Animal Health (OIE), and by seeking to add animal welfare standards to the criteria assessed in order to establish compliance with Good Laboratory Practice (GLP).

[1] OJ C 49 of 28.02.2006.

Justification

The Communication from the Commission on a Community Action Plan on the Protection and Welfare of Animals 2006-2010 lists promotion of high animal welfare standards in the EU and at the international level as one of its primary objectives. Promotion of the replacement, reduction and refinement of animal procedures through the World Organisation for Animal Health would not only further this objective, but would protect EU industry by raising animal welfare standards in third countries.

Amendment 8

Proposal for a directive
Recital 12

Text proposed by the Commission	*Amendment*
(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	(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.	use the minimum number of animals that would provide reliable results and choose the species with the lowest degree of neurophysiological sensitivity that are optimal for the extrapolation into target species.

Justification

No need to have always a statistical relevance, sometimes a small number of animals is enough for a scientific relevance.

Amendment 9

Proposal for a directive
Recital 14

Text proposed by the Commission	*Amendment*
(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.	(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 ***a trained and*** authorised person with a humane method that is considered appropriate to the species.

Amendment 10

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 raises specific ethical and practical problems in terms of meeting their	(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.***	behavioural, environmental and social needs in a laboratory environment. Furthermore, the use of non-human primates is of the highest concern to the public. Therefore the use of non-human primates should only be allowed in those essential biomedical areas for the benefit of human beings for which no other replacement alternative methods are yet available, or for the preservation of the respective non-human primate species. Fundamental research in some areas of the biomedical sciences can provide important new information relevant***, at some future stage,*** to many life-threatening and debilitating human conditions.

Justification

The emphasis on relevance of procedures to serious human clinical conditions would preclude much fundamental research that, at the time it is carried out, has no direct association with relief of serious human conditions, but which may in due course be central to clinical advances.

Amendment 11

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***	(18) In order to gradually end the capturing of animals from the wild for breeding purposes, ***a thorough scientific evaluation should be conducted as soon as possible to***

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.	***the feasibility of limiting the animals used to those from self-sustaining colonies.*** Establishments breeding and supplying non-human primates should therefore have a strategy in place to support and facilitate the progressive move towards that goal.

Justification

A proper scientific analysis is required before this is set as a legal requirement.

Amendment 12

Proposal for a directive
Recital 21

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

Amendment 13

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

Amendment 14

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 ***to only*** those procedures where ***the cumulative*** pain, distress and suffering ***are ethically justified***

Amendment 15

Proposal for a directive
Recital 24

Text proposed by the Commission	*Amendment*
(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.	(24) At the end of ***an authorised*** 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 ***of*** those animals in order to ***promote*** successful re-homing as well as to avoid unnecessary distress to the animals and to guarantee public safety.

Amendment 16

Proposal for a directive
Recital 25

Text proposed by the Commission	*Amendment*
(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.	(25) Animal tissue and organs are used for the development of in vitro methods. To implement the principle of reduction, ***it is desirable for*** Member States ***to*** establish programmes for sharing the organs and tissue of animals that are killed using humane methods.

Justification

The establishment of programmes for sharing the organs and tissue of animals cannot be made compulsory, given how complex this would be to implement. However, a recommendation to this effect can be made.

Amendment 17

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 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.	(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 ***in establishments, and*** by persons***,*** authorised by the competent authorities. The main focus should be on obtaining and maintaining an adequate level of competence which should be demonstrated before authorising those persons or renewing their authorisation. ***Authorisation by a competent authority and proof of the successful completion of relevant training courses should be mutually recognised by all Member States.***

Amendment 18

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	(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***

they are authorised by the competent authorities.	***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 19

Proposal for a directive
Recital 29

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

Amendment 20

Proposal for a directive
Recital 30

Text proposed by the Commission	*Amendment*
(30) In order to enable the competent authorities to monitor compliance with this Directive, each establishment should maintain accurate records on the numbers	(30) In order to enable the competent authorities to monitor compliance with this Directive, each establishment should***, where possible,*** maintain accurate records

of animals, their origins and fate.	on the numbers of animals, their origins and fate.

Amendment 21

Proposal for a directive
Recital 31

Text proposed by the Commission	*Amendment*
(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.	(31) Non-human primates with highly developed social skills, ***as well as dogs and cats,*** 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.

Amendment 22

Proposal for a directive
Recital 34

Text proposed by the Commission	*Amendment*
(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.	(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 ***subject always to developments based on new scientific evidence***.

Amendment 23

Proposal for a directive
Recital 38

Text proposed by the Commission	*Amendment*
(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.	(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 that use. The likely harm to the animals should be balanced against the expected benefits of the project. Therefore, an ethical evaluation***independent of those in charge of the study*** should be carried out as part of the authorisation process of projects involving the use of live animals. Effective implementation of an ethical evaluation should also allow for an appropriate assessment of the use of any new scientific experimental techniques as they emerge.

Amendment 24

Proposal for a directive
Recital 39

Text proposed by the Commission	*Amendment*
(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.	(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 ***might be*** necessary to carry out a retrospective assessment. Since projects may vary significantly in terms of complexity, length, as well as the delay for obtaining the results, it is necessary that the decision as to whether retrospective assessment should be carried out takes those aspects fully into account.

Amendment 25

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 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.	(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 ***the competent authority with data, which may be qualitative and/or quantitative, concerning the use of live animals*** and make ***such data*** publicly available.

Justification

Amendment 26

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	(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.	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 co-ordination and promotion of the development and use of alternatives to animal experiments.***

Amendment 27

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 28

Proposal for a directive
Article 2 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
1. This Directive shall apply ***where*** animals are used or intended to be used in	1. This Directive shall apply ***to the accommodation and husbandry of*** animals

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

Justification

There should be control over the accommodation and husbandry of all animals to be used in experiments. However, the inclusion of routine breeding, and of animals used by humane killing for scientific purposes, in the licensing and reporting requirements would cause a major increase in authorisations and record keeping, and therefore in costs, with no benefit to animal welfare.

Amendment 29

Proposal for a directive
Article 2 – paragraph 1 - subparagraph 2

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

Amendment 30

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

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

Justification

Some fish and amphibian species produce vast numbers (more than 10,000 per female) of larval or embryonic forms. To count and record such numbers would entail a vast amount of work and make the statistics on the numbers of animals used meaningless for these species.

Amendment 31

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

Text proposed by the Commission	*Amendment*
(b) live invertebrate animals***, including independently feeding larval forms,*** of those species listed in Annex I.	(b) live invertebrate animals of those species ***of orders*** listed in Annex I.

Amendment 32

Proposal for a directive
Article 2 – paragraph 4 – introductory part

Text proposed by the Commission	*Amendment*
4. This Directive shall not apply to the following :	4. ***Other than the general checks on breeding facilities***, this Directive shall not apply to the following :

Amendment 33

Proposal for a directive
Article 2 – paragraph 4 – point d

Text proposed by the Commission	*Amendment*
(d) practices that ***are not invasive***	(d) practices that ***do not cause pain, suffering, distress or lasting harm.***

Justification

The current wording is unclear and could lead to confusion. The amendment makes the article consistent with the rest of the text.

Amendment 34

Proposal for a directive
Article 3 – paragraph 1

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

Justification

Amendment 35

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

Amendment 36

Proposal for a directive
Article 3 – point 6 b (new)

Text proposed by the Commission	*Amendment*
	(6b) 'ethical approach' means the approach which precedes experimentation and consists of assessing the scientific

and societal grounds for using animals, with reference to humankind's duty to respect animals as living, sentient beings;

Justification

These definitions should be added because they relate to concepts that are at the core of project authorisations.

Amendment 37

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

Text proposed by the Commission	*Amendment*
	(6c) 'competent person' means any person who is considered by a Member State to be competent to perform the relevant function described in this Directive;

Amendment 38

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

Text proposed by the Commission	*Amendment*
	(6d) 'husbandry' means all those activities required to breed and maintain phenotypically normal animals, whether for scientific or other purposes, but which do not themselves constitute experiments;

Amendment 39

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

Text proposed by the Commission	*Amendment*
	(6e) 'practice' means any non-experimental activity or any scientific activity which does not constitute an experiment;

Amendment 40

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

Text proposed by the Commission	*Amendment*
	(6f) 'properly anaesthetised' means deprived of sensation by means of anaesthesia, whether local or general, which is as effective as those used in good veterinary practice;

Amendment 41

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

Text proposed by the Commission	*Amendment*
	(6g) 'protocol' means a series of procedures that constitute an experiment with a defined objective;

Amendment 42

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

Text proposed by the Commission	*Amendment*
	(6h) 'regulated procedure' means any experimental or other scientific procedure, which is likely to have the effect of causing a protected animal pain, suffering, distress or lasting harm;

Amendment 43

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

Text proposed by the Commission	*Amendment*
	(6i)) 're-use' means the use of an animal already used in a procedure, when a different animal on which no procedure has previously been carried out could also be used;

Amendment 44

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

Text proposed by the Commission	*Amendment*
	(6j) 'confidential information' means information, the non-consensual release of which could prejudice the legitimate commercial or other interests of its owner or a third party.

Amendment 45

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

Justification

The term testing is undefined and, in normal scientific usage, is different from experimental research. It would also exclude training, education and forensic inquiries As drafted this phrase would require the use of non-animal alternative methods even if they were scientifically invalid. Member States are free to decide whether and subject to what conditions the use of human embryonic and foetal cells is allowed and whether such testing methods are to be regarded as ethically defensible alternatives to animal testing.

Amendment 46

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

Text proposed by the Commission	*Amendment*
	3a. Member States shall ensure that funding is provided for training and research on, and development and implementation of, scientifically satisfactory methods or testing strategies that do not entail the use of animals

Justification

In recognition of the primary objective of the Directive, amendments to Article 4 are proposed to make explicit the obligation on Member States to pursue, through the acts of the competent authority, the objective of Article 4. An obligation to provide funding for, training on and promotion of alternative methods is imposed to ensure that the aims of the Directive are achieved as swiftly as possible.

Amendment 47

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

Text proposed by the Commission	*Amendment*
	3b. Member States shall ensure that the aim of paragraph 1 is pursued by the competent authority when considering the authorisation of projects.

Justification

Amendment 48

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

Text proposed by the Commission	*Amendment*
	3c. Member States shall ensure training is provided on the use of scientifically satisfactory methods or testing strategies that do not entail the use of animals, to appropriate persons and establishments, and promote such methods or testing strategies.

Justification

Amendment 49

Proposal for a directive
Article 5 – paragraph 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

It is necessary to highlight the importance of agricultural purposes in terms of their agricultural, food and environmental dimensions.

Amendment 50

Proposal for a directive
Article 5 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. the protection of human health in the context of workers' or consumers' exposure to chemicals;

Justification

The current list of procedures does not explicitly include measures needed to protect human health in the context of workers' and consumers' exposure to chemicals.

Amendment 51

Proposal for a directive
Article 5 – paragraph 5

Text proposed by the Commission	*Amendment*
(5) research aimed at preservation of the species;	(5) research aimed at preservation, ***health and welfare*** of the species;

Amendment 52

Proposal for a directive
Article 6 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
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.	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 ***an*** appropriate humane method of killing as set out in that Annex ***or by such other methods as are scientifically demonstrated to be at least as humane. Where a more humane method of killing is possible and readily available, it may be used even if it is not included in Annex V***.

Justification

When more humane methods of killing are developed, this will allow them to be used immediately instead of waiting several years for Annex V to be updated

Amendment 53

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***. ***Notwithstanding any exemption, animals shall be killed with a minimum of pain, suffering and distress.***

Amendment 54

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 55

Proposal for a directive
Article 7 – paragraph 1 – point b b (new)

Text proposed by the Commission	*Amendment*
	(bb) as far as possible, the animals used should be bred specifically for testing purposes;

Justification

With a view to protecting the species covered by the Washington Agreement on the Protection of Species, where possible the use of specially bred animals should be authorised.

Amendment 56

Proposal for a directive
Article 8 – paragraph 1 – introductory phrase

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

Justification

The decisive criterion which should be used to determine whether species need special protection in the context of testing is not their classification, but rather the animals' high level of neurophysiological sensitivity and cognitive development.

Amendment 57

Proposal for a directive
Article 8 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(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) ***or*** (5) of Article 5;

Justification

There is no scientific justification for the special status granted to NHPs, so that basic research should be allowed, without being restricted to experiments designed to achieve specific medical research objectives. Due account must be taken of the fact that European and international approval guidelines for biotechnological active agents stipulate that studies must be carried out on NHPs before human testing can begin. The current wording would create problems for the entire European biotechnology industry in connection with the development of new active agents and force that industry to relocate development activities.

Amendment 58

Proposal for a directive
Article 8 – paragraph 1 – point b

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

Amendment 59

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

Text proposed by the Commission	*Amendment*
	2a. Every two years, and for the first time two years after the entry into force of this Directive, the Commission shall, in consultation with Member States, conduct a review of the use of non-human primates in procedures and publish the results thereof. The review shall examine the impact of developments in technological, scientific and animal-welfare knowledge, and set targets for the implementation of validated replacement methods.

Justification

A new paragraph is inserted to introduce a review of the use of non-human primates in procedures which is to be conducted by the Commission every two years. Reviews are conducted at regular intervals to ensure that implementation of the Directive keeps pace with technological and scientific developments.

Amendment 60

Proposal for a directive
Article 10 – paragraph 1 – subparagraph -1 (new)

Text proposed by the Commission	*Amendment*
	(-1) The Commission shall carry out an animal welfare assessment and a feasibility evaluation of implementation of the requirements set out in paragraph 2, five years after the entry into force of this Directive.

Justification

A feasibility study has therefore to be conducted as it was not established yet. A better alternative would be to look at the feasibility of establishing self-sustaining colonies to ensure

they can supply animals of sufficient quality to support EU research needs.

Amendment 61

Proposal for a directive
Article 10 – paragraph 1 – subparagraph 2

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

Amendment 62

Proposal for a directive
Article 10 – paragraph 2

Text proposed by the Commission	*Amendment*
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 ***veterinary justification for reasons of animal welfare or on the basis of a*** scientific justification.

Justification

It is important to include veterinary justification, as specialists in this field are capable of assessing all criteria linked to animal welfare.

Amendment 63

Proposal for a directive
Article 11 a (new)

Text proposed by the Commission	*Amendment*
	Article 11a

	Training
	For higher education and training purposes, the cadavers, tissue and organs of animals may be used only if they come from animals slaughtered in accordance with the provisions of Council Regulation (EC) No .../2009 [on the protection of animals at the time of killing][1].
	[1] OJ L .... [COM(2008)0553].

Amendment 64

Proposal for a directive
Article 12 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that procedures are always carried out in ***user*** establishments.	1. Member States shall ensure that procedures are always carried out in establishments ***as defined in Article 3***.

Amendment 65

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

Justification

Anaesthesia is appropriate for only a small minority of procedures and so it is unwise to have anaesthesia as the default requirement. 'Wherever appropriate' is necessary because it clarifies that not all procedures will benefit from some form of pain–relieving strategy (i.e. the majority where there is no pain in the first place).

Amendment 66

Proposal for a directive
Article 14 – paragraph 2 – point ca (new)

Text proposed by the Commission	*Amendment*
	(ca) where analgesics are used to prevent or control potentially severe pain.

Justification

There are many situations where pain is appropriately controlled by the use of analgesics not anaesthetics.

Amendment 67

Proposal for a directive
Article 14 – paragraph 3

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

Amendment 68

Proposal for a directive
Article 14 – paragraph 5

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

humane method.	method.

Justification

There is no need to include 'considerable' – it should be standard post surgical practice and exceptions are already covered. Normal pre- and post surgical procedure are applied when there is no risk of pain

Amendment 69

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 conformity with Annex VIIa.***

Justification

The criteria for classification of procedures have to be established. The lack of definition of the severity bands within the current draft Directive leaves it impossible to interpret the impact of other Articles in the Directive. It is essential that these definitions be agreed forthwith so that the concomitant terms in the Directive can be appropriately interpreted.

Amendment 70

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 ***scientifically justified, and ethically monitored*** if the pain, suffering or distress is likely to be prolonged. ***Such procedures must be exceptional and shall be subject to particular harm/benefit analysis and***

scrutiny by the competent authority.

Justification

The ban on "prolonged" "severe" procedures appears to preclude any "severe" category procedures, and could be highly restrictive.

Amendment 71

Proposal for a directive
Article 15 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
4. The Commission shall ***establish*** the criteria for classification of procedures.	4. The Commission shall, ***within 12 months from the date of entry into force of this Directive, complete*** the criteria for classification of procedures ***as referred to in Annex VII a on the basis of international classifications and in line with best practices developed within the European Union***.

Justification

Annex VIIa is a general framework. More precise guidelines governing the classification of procedures need to be developed.

Amendment 72

Proposal for a directive
Article 16 – introductory part

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

Justification

The wording does not adequately clarify the important distinction between "continued use" of pre-prepared animals that can and (in the interests of the 3Rs) should be used multiple times, and "reuse" in an entirely new procedure. This is a sufficiently important point to warrant absolute clarity

Amendment 73

Proposal for a directive
Article 16 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the previous procedure was classified as 'up to ***mild***';	(a) the previous procedure was classified as 'up to ***moderate***';

Amendment 74

Proposal for a directive
Article 16 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(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'. ***The repeated use of animals shall be accompanied by veterinary examinations.***

Justification

Amendment 75

Proposal for a directive
Article 16 – paragraph 2

Text proposed by the Commission	*Amendment*
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***	2. By way of derogation from paragraph 1, the competent authority, on the basis of scientific justification, may allow re-use of an animal ***where the previous procedure***

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'.	***performed on the animal is classified as'up to moderate'*** and the further procedure is classified as ***'up to moderate'*** or as 'non-recovery'.

Justification

Current restriction will result in dramatic increase in numbers of animals used for experimental purposes.

Amendment 76

Proposal for a directive
Article 17 – paragraph 3

Text proposed by the Commission	*Amendment*
3. An animal shall be killed by a humane method when it is likely to remain in lasting pain or distress.	3. ***At the end of an authorised procedure*** an animal shall be killed by a humane method when it is likely to remain in lasting pain or distress.

Justification

It is not clear whether the control refers only at the end of an authorised procedure or whether any level of chronic pain would be cause for ending that procedure.

Amendment 77

Proposal for a directive
Article 18

Text proposed by the Commission	*Amendment*
Member States shall ***establish*** programmes for the sharing of organs and tissues of animals killed by a humane method.	Member States shall ***encourage the establishment of*** programmes for the sharing of organs and tissues of animals killed by a humane method.

Amendment 78

Proposal for a directive
Article 19 – introductory phrase

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 ***released into their original habitat, returned to a husbandry system appropriate to the species,*** or re–homed provided that the following conditions are met:

Justification

It may be appropriate to set free wild and other animals (such as bats or deer) used in behavioural, conservation or environmental studies of that species, subject to assessment at ethical review. For agricultural animals (such as dairy cows, pigs), the return should be to a standard system of husbandry.

Amendment 79

Proposal for a directive
Article 19 – point c

Text proposed by the Commission	*Amendment*
(c) the maximum possible care has been taken to safeguard the well-being of the animal.	(c) the maximum possible care has been taken to safeguard the well-being of the animal***, including an assessment of the animal's behaviour and its ability to adapt to highly variable environmental conditions***.

Amendment 80

Proposal for a directive
Article 19 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) the animals concerned are not genetically modified experimental animals or non-human primates.

Justification

The release of experimental animals in the wild or domestic population as a general request is not appropriate. On the one hand, such an approach is contradictory to any kind of sense of responsibility to the experimental animal. Furthermore, this request would not be compatible with the guidelines in the German law on animals and nature conservation.

Amendment 81

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 82

Proposal for a directive
Article 20 – paragraph 2 – subparagraph 1

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

Justification

For clarity – we should avoid requiring that the procedure be carried out just to demonstrate competence.

Amendment 83

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, not exceeding five years. Member States shall ensure that the renewal of an authorisation of persons is only granted on the basis of ***evidence*** of the requisite competence. ***Member States shall ensure the mutual recognition of education and training qualifications and authorisation to conduct designated procedures.***

Justification

The word "demonstrate" has a scientific implication of practical testing. While it is entirely appropriate for first time applicants to "demonstrate" competence, forcing all applicants at each licence renewal to "demonstrate" their competence in a practical sense would be inappropriate. Mutual recognition of professional qualifications is very important to support free movement of well-qualified lab scientists. It will also enhance the opportunities for collaborative projects to be run across Member States.

Amendment 84

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 ***have the power to*** suspend or withdraw its authorisation***, or take appropriate remedial action or require such action to be taken. There shall be appropriate procedures for licensees to appeal against any such decision***.

Justification

All establishments will intermittently fail in some aspect of the requirements, usually minor and technical. The competent authority therefore needs to have the ability to select the most appropriate action in the interests of the welfare of the animals concerned, and discretion over whether to impose a penalty. The licence-holder must have the right of appeal against any such decision by the competent authority.

Amendment 85

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.

Amendment 86

Proposal for a directive
Article 24 – paragraph 2 (new)

Text proposed by the Commission	*Amendment*
	2a. Without prejudice to the generality of paragraph 1, each breeding, supplying and user establishment shall ensure that there is at least one trained person available at all times to look after the animals' welfare.

Justification

It is obvious that animals subjected to invasive procedures may require care (whether veterinary or otherwise) at any time of day or night. It is not possible to predict when a need for care may arise, or to confine it within business hours. Professional veterinary guidance

requires that veterinary surgeons are available to provide emergency cover on a 24-hour basis for all their clients. In the laboratory context, as in other contexts, this necessitates that there is someone who in practice is able to summon the veterinary surgeon.

Amendment 87

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 88

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

Text proposed by the Commission	*Amendment*
1. The permanent ethical review body shall fulfil the following tasks:	1. ***Having regard to the objectives of this Directive, and in particular Article 4,*** the permanent ethical review body shall fulfil the following tasks :

Justification

It is to ensure that the function of the permanent ethical review body is executed with the due regard to the primary objectives of the Directive.

Amendment 89

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 those on non-human primates, and every 3 years all 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.

Amendment 90

Proposal for a directive
Article 26 – paragraph 1 – point d – indent 2a (nouveau)

Text proposed by the Commission	*Amendment*
	- the scientific progress of the project

Amendment 91

Proposal for a directive
Article 26 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. Member States shall ensure that the records of any advice given to the establishment by the permanent ethical review body and decisions taken regarding that advice are kept. The records shall be ***made available*** to the competent authority upon request. ***Member States shall pay particular attention to the collection, collation and publication of records relating to projects classified as "severe"***

or those on non-human primates in order to provide information which can improve animal welfare and further the principles of replacement, reduction and refinement.

Amendment 92

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

Justification

The EU has no jurisdiction to control non-EU suppliers. In addition the transport of non-human primates can raise concerns; therefore the European Union should bring its support to the transport, in optimal conditions of concerned species. Moreover, a common strategy to ensure an indispensable development of non-human primates on the European territory would a plus of efficiency for this text.

Amendment 93

Proposal for a directive
Article 27 – paragraph 2

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

Amendment 94

Proposal for a directive
Article 29 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that all breeding, supplying and user establishments keep records of the following:	1. Member States shall ***where possible*** ensure that all breeding, supplying and user establishments keep records of the following:

Justification

Quite difficult for each animal, in the case of rodents, for instance.

Amendment 95

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 96

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

Text proposed by the Commission	*Amendment*
(e) the name and address of the ***recipient of*** animals;	(e) the name and address of the ***the establishment receiving the*** animals;

Amendment 97

Proposal for a directive
Article 30 – paragraph 2 – subparagraph 1

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

Amendment 98

Proposal for a directive
Article 30 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
The file shall be established at birth and shall cover ***detailed*** reproductive, medical and social information on the individual animal.	The file shall be established at birth and shall cover ***any relevant*** reproductive, medical and social information on the individual animal.

Amendment 99

Proposal for a directive
Article 32 – paragraph 1 – point a

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

Justification

Amendment 100

Proposal for a directive
Article 32 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(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;

Justification

Amendment 101

Proposal for a directive
Article 32 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(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 ***avoidable*** defect or suffering discovered is eliminated as quickly as possible.

Amendment 102

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 103

Proposal for a directive
Article 33 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
2. National inspections shall be carried out by the competent authority ***at least twice*** a year.	2. National inspections shall be carried out by the competent authority ***on average once*** a year***, with the competent authority adapting the frequency of inspection on the basis of a risk analysis for each establishment***.

Justification

The Commission does not appear to have found any failings in this area. There is therefore no justification for such a measure. The obligation to have establishments inspected twice a year, one of which would be unannounced, is neither feasible nor desirable. As in other areas of inspection, it would be more appropriate to require the competent authority to adapt the frequency of inspection on the basis of a risk analysis.

Amendment 104

Proposal for a directive
Article 33 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States shall ensure that the	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.	frequency and the extent of inspections are adequate to the number and species of animals housed, to the compliance record of the establishment with this Directive and, in the case of user establishments, to the number and types of projects carried out in those establishments. ***Member States shall take the necessary measures to ensure that the inspections do not jeopardise the scientific quality of the projects and the welfare of the animals, and do not take place under conditions that fail to comply with the other regulations in force.***

Amendment 105

Proposal for a directive
Article 33 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Records of all inspections shall be kept for at least five years.	4. Records of all inspections shall be kept for at least five years. ***In addition, inspection records shall be kept by each Member State's competent authority, including records detailing any failure to meet the requirements of this Directive.***

Amendment 106

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 ***and to ensure that severity classifications are applied correctly and uniformly within the territory of the EU***.

Justification

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

Amendment 107

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

Justification

Prior authorisation should be restricted to projects involving higher severity classifications or NHP.

Amendment 108

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

Justification

The scientific justification and ethical justification for a project are so closely linked that a review body could not properly and evaluate the ethical considerations without the scientific considerations. It is important therefore that the review body have expertise in both areas and considers both jointly.

Amendment 109

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

Justification

The proposal of the commission does not fit for academic research where most projects are performed in common establishments by scientists depending from an array of different institutions. In contrasts to what happens in industry, the establishment does not necessary depend on the same authority. In addition many projects are performed, for technical reasons in different establishments.

Amendment 110

Proposal for a directive
Article 36 –paragraph 1 – point ca (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 examine the application for authorisation.

Amendment 111

Proposal for a directive
Article 37 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the project is scientifically justified ***or***	(a) the project is scientifically justified***,***

required by law; ***indispensable and ethically defensible***;

Justification

In order to ensure that animal experiments are conducted only if they are indispensable, ethically defensible and represent the only alternative, there must be an ethical evaluation prior to a project being authorised. Member States should be responsible for drawing up the procedural details.

Amendment 112

Proposal for a directive
Article 37 – paragraph 1 – point b

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

Amendment 113

Proposal for a directive
Article 37 – paragraph 1 – point c

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

Justification

Amendment 114

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

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

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.

Amendment 115

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

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 the fact that this expertise may also be available within the Committee on Ethics and that the confidentiality of the corresponding information must be guaranteed.

Amendment 116

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***	4. Ethical evaluation shall be performed in a transparent manner by integrating

opinion of independent ***parties***.	independent ***expertise whilst safeguarding intellectual property and confidential information as well as the safety of goods and persons***.

Amendment 117

Proposal for a directive
Article 38 – paragraph 1 – subparagraph 1

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

Justification

It should be up to an ethical committee to decide whether a retrospective ethical evaluation is required, depending on objective criteria, whatever species is involved.

Amendment 118

Proposal for a directive
Article 38 – paragraph 2 – introductory sentence

Text proposed by the Commission	*Amendment*
2. ***Retrospective assessment*** shall ***evaluate*** the following:	2. ***The review*** shall ***establish*** the following:

Justification

The review gathers important information on completed projects and should therefore be conducted by the permanent ethical review body for each project. The decision on whether a review of a project should also be conducted by the authority should be made by the authority on a case-by-case basis. This procedure is optimum and efficient, without being overly bureaucratic.

Amendment 119

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

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

Justification

Amendment 120

Proposal for a directive
Article 38 – paragraph 4

Text proposed by the Commission	*Amendment*
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.	4. All projects involving only procedures classified as "up to ***moderate***" shall be exempted from the requirement for a retrospective assessment.

Justification

Amendment 121

Proposal for a directive
Article 40 – paragraph 1 – introductory phrase

Text proposed by the Commission	*Amendment*
Subject to safeguarding confidential information, the non-technical project summary shall provide the following	Subject to safeguarding confidential information, ***establishment and personnel details,*** the non-technical project summary shall provide the following:

Justification

Establishment and personal details should be safeguarded.

Amendment 122

Proposal for a directive
Article 40 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) a demonstration ***of compliance with the requirement*** of replacement, reduction and refinement.	(b) a demonstration ***that the principles*** of replacement, reduction and refinement have been ***observed where practicable***.

Justification

It is not uniformly possible to "comply" with all three of the 3Rs – if replacement were a "requirement" then no procedures could take place. However the 3Rs must be promoted, and should be adopted wherever possible.

Amendment 123

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

Amendment 124

Proposal for a directive
Article 41 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Project authorisations shall be granted for a period not exceeding ***four*** years.	3. Project authorisations shall be granted for a period not exceeding ***five*** years.

Justification

Many projects and funds for them (including EU Framework funds) are for 5 year durations and unnecessary disruption would ensue if renewed authorisation were required mid–project. Moreover, it is highly burdensome with minimal benefit to have retrospective review after a 4 year project if there is to be a mid–project review at 3 years.

Amendment 125

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 when those projects are required by law***, or when standardised procedures are applied, the ethical assessment of which has already produced a positive result***.

Justification

Article 41(3) fixes the maximum project duration at four years. There is no longer the possibility of simplified renewal. Article 41(4): a simplified authorisation procedure is only possible in the case of regulatory testing which is required by law. This leads to unequal treatment of basic research.

Amendment 126

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 person in charge of the project***.

Amendment 127

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

Justification

The ethical evaluation is a process, and as such cannot be favourable or unfavourable. It is the ethical opinion, i.e. the result, which is favourable or unfavourable.

Amendment 128

Proposal for a directive
Article 42 – paragraph 2a (new)

Text proposed by the Commission	*Amendment*
	2a. Amendments to mild or moderate procedures that do not increase the severity of the procedure may be made by the permanent ethical review body but must be communicated to the competent authority within one week of such change.

Amendment 129

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 standards***.

Amendment 130

Proposal for a directive
Article 43 – paragraph 1

Text proposed by the Commission	*Amendment*
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***.	1. Member States shall ensure that the decision to grant an authorisation is taken and communicated to the user establishment at the latest within ***60*** 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.

Justification

The time limit for authorisations to be granted by the competent authorities is unclear. A maximum limit for the authority to reach a decision is stipulated.

Delayed decisions will give rise to constructive authorisation only in exceptional cases. In other cases, testing cannot begin and indeterminate delays are caused. A failure to process applications for animal experiments must not penalise the applicant but must, in case of doubt, lead to the testing procedure being authorised.

Amendment 131

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

There must be a maximum time limit applicable to all applications for animal experiments in order to ensure that the procedure is fast, transparent and fair. The time limit should be increased to 60 days in order to ensure there is sufficient time for decisions to be made even in the case of complex applications.

Amendment 132

Proposal for a directive
Article 44 – paragraph 1

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

Amendment 133

Proposal for a directive
Article 44 – paragraph 2

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

Amendment 134

Proposal for a directive
Article 44 – paragraph 2a (new)

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

Amendment 135

Proposal for a directive
Article 44 – paragraph 2b (new)

Text proposed by the Commission	*Amendment*
	2b. Before applying for a project authorisation, a person intending to carry out a procedure must take all reasonable steps to ascertain whether data relevant to the proposed project already exists and, if so, to access such data (including contributing towards the cost thereof), and Member States shall similarly verify whether such data exists before granting an authorisation.

Amendment 136

Proposal for a directive
Article 44 – paragraph 2c (new)

Text proposed by the Commission	*Amendment*
	2c. Member States shall not authorise a procedure where a person has not taken

reasonable steps to comply with paragraph 2b.

Amendment 137

Proposal for a directive
Article 44 – paragraph 2d (new)

Text proposed by the Commission	*Amendment*
	2d. Where relevant data is reasonably available, Member States shall only grant authorisation for a project where this is necessary for the protection of the public.

Amendment 138

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

Amendment 139

Proposal for a directive
Article 45a (new)

Text proposed by the Commission	*Amendment*
	Article 45a
	European Centre for the Validation of Alternative Methods
	1. The remit of the European Centre for the Validation of Alternative Methods shall be extended so that it includes the co-ordination and promotion of the development and use of alternatives to animal procedures including applied and basic biomedical research and veterinary research and regulatory testing by performing the following functions:
	a) coordinate research undertaken to facilitate the development of alternatives to animal procedures by the National Centres for Alternative Methods described in Article 46;
	b) conduct research to facilitate the development of alternatives to animal procedures;
	c) commission research in fields likely to yield information that will facilitate the replacement, reduction or refinement of animal procedures;
	d) in consultation with relevant stakeholders, create and implement strategies to replace, reduce and refine animal procedures;
	e) make available information on alternatives to animal procedures through regular reporting to the public, to stakeholders and to Member State authorities;
	f) provide databases to facilitate the exchange of relevant information including information on available alternative methods and information contributed voluntarily by researchers

which would otherwise remain unpublished, but which could prevent duplication of unsuccessful animal studies;

(g) coordinate pre-validation and validation studies undertaken by the National Centres for Alternative Methods in accordance with Article 46 of this Directive;

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

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

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

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

Amendment 140

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],* ***nominate a centre responsible for supporting the development, validation and promotion*** of ***alternatives to animal tests used for regulatory purposes, and facilities to develop and promote the use of alternatives to animal procedures undertaken for other purposes, such as basic and applied biomedical and***

veterinary research.

Amendment 141

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

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

Amendment 142

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

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

Amendment 143

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 ***and to user establishments, within and between*** the Member States***,*** for the acceptance and implementation of alternative methods;

Amendment 144

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

Text proposed by the Commission	*Amendment*
(e) provide training on the use of alternative methods to persons referred to in Article 20(1).	(e) provide training on the use of alternative methods to persons referred to in Article 20(1) ***and, if required, to user establishments***.

Amendment 145

Proposal for a directive
Article 46 – paragraph 4 – point e a (new)

Text proposed by the Commission	*Amendment*
	ea) communicate developments on alternative methods and inform the public of positive and negative outcomes.

Amendment 146

Proposal for a directive
Article 49 – paragraph 2 – subparagraph 1

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.

Amendment 147

Proposal for a directive
Article 49 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
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 148

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.	The Commission shall review this Directive by [***5 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

Considering the pace of scientific development and increasing understanding of the ability of animals to suffer mean that the directive should be reviewed sooner.

Amendment 149

Proposal for a directive
Article 53 a (new)

Text proposed by the Commission	*Amendment*
	Article 53a
	Thematic review
	The Commission shall, in consultation with Member States and any relevant stakeholders, conduct a thematic review

	of the use of animals in procedures every two years commencing two years after the entry into force of this Directive. The review shall examine the impact of developments in technological, scientific and animal welfare knowledge, and set targets for the implementation of validated replacement methods.

Justification

A review which takes place ten years after entry into force of the Directive would be unable to keep pace with the technological and scientific progress. Consequently a series of thematic, regular reviews is proposed to allow a more focussed approach to the use of animals in specific areas of research and testing.

Amendment 150

Proposal for a directive
Annex I - Title

Text proposed by the Commission	*Amendment*
Invertebrate ***Species*** referred to in Article 2 (2)	Invertebrate ***Orders*** referred to in Article 2 (2)

Amendment 151

Proposal for a directive
Annex I – line 1

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

Justification

Including cyclostomes will have a huge bureaucratic impact and impact on reported numbers of experimental animals, with no benefit for animal welfare.

Amendment 152

Proposal for a directive
Annexe I

Text proposed by the Commission	*Amendment*
Decapod crustaceans	Decapod crustaceans ***of the infraorders Brachyura and Astacidea***

Justification

If invertebrates are indeed to be included within the scope of the Directive, Annex I needs to be updated in order to better reflect scientific opinion. The report of the EFSA scientific panel on Animal Health and Welfare only refers to the large or "walking" decapods such as crabs and lobsters as exhibiting "complex behaviour", "some degree of awareness", "a pain system" and "considerable learning ability". A clear distinction between the large or "walking" decapods such as crabs (infraorder Brachyura) and lobsters (infraorder Astacidea) and other decapods is therefore proposed.

Amendment 153

Proposal for a directive
Annex II – point 8

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

Justification

The rabbit is considered to be a production animal (domestic species bred by farmers, the products of which are intended for human consumption) in a number of southern European countries. It is essential to ensure the possibility of testing on such animals bred for agricultural purposes and not testing purposes as it would be discriminatory to require that the same species be bred on separate farms, depending on whether it is intended for research purposes or for production purposes.

Amendment 154

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

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

Justification

The zebrafish (danio danio) is a laboratory species with very many genetic variants which now differs significantly from the original wild species.

Amendment 155

Proposal for a directive
Annex III – line 3 - column 2

Text proposed by the Commission	*Amendment*
7 years after transposition of Directive	***10 years*** after transposition of Directive

Justification

Given that the feasibility and continuity of supply are not yet established at this point, it is proposed to extend the timelines for switch to 10 years for all species (except marmosets) and to include a mid-term feasibility review.

Amendment 156

Proposal for a directive
Annex III – line 4 - column 2

Text proposed by the Commission	*Amendment*
7 years after transposition of Directive	***10*** years after transposition of Directive

Amendment 157

Proposal for a directive
Annex IV – subtitle (new)

Text proposed by the Commission	*Amendment*
	The care and accommodation conditions should be tailored to the scientific objective.

Justification

The accommodation conditions for the test animal should be in line with the scientific objectives of the project, which sometimes require specific test conditions. For example, for certain tests on species of agronomic interest it is essential that the animal is kept in normal breeding conditions.

Amendment 158

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 159

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 160

Proposal for a directive
Annex V – table 5 – 'Overall rating' column – Carbon dioxide

Text proposed by the Commission	*Amendment*
1 - if sole agent	***5***
5 - if animal unconscious	

Justification

This method causes no suffering for rodents, provided that the carbon dioxide is introduced

gradually. It seems therefore excessive to classify it as unsatisfactory when used alone, given too that many laboratories are now equipped for, and have mastered, this practice, which they judge to be satisfactory.

Amendment 161

Proposal for a directive
Annex VIIa (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 should be assumed that procedures that cause pain in humans also cause pain in animals.
	No pain or mild pain: Severity Grade 1
	Interventions and manipulations in animals for experimental purposes as a result of which the animals experience no pain or short term mild pain, suffering, injury, or mild distress with no significant impairment of their general condition.
	Examples:
	- studies with differing feed compositions or with unphysiological diet, with minor clinical signs or symptoms.
	- withdrawal of blood samples or injection (s.c., i.m., i.p., i.v.) of a drug.
	- superficial tissue biopsy under anaesthesia
	- non-invasive scanning techniques, with or without sedation or anaesthesia of the animals
	- tolerability studies which give cause to expect short term, minor, local or systemic reactions
	- Electrocardiogram (ECG) recordings in

conscious animals

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

- experiments under general anaesthesia without recovery

Moderate: Severity Grade 2

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

Examples:

- surgery under anaesthesia and appropriate analgesia

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

- studies with unphysiological diet, with clinical signs or

- symptoms of untreated diabetes mellitus

- frequent repeated blood sampling or administration of substances

- induction of anxiety in animal models

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

- seizure models e.g. epilepsy studies

- non-lethal animal models of cancer e.g. xenograft studies

Severe: Severity Grade 3

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

condition.

Examples:

- bacterial or viral lethal infections

- chronic models of rheumatoid arthritis

- genetically modified animals with lethal phenotypes (e.g. oncogenes), without early termination of the experiment

- organ transplantation (e.g. kidney, pancreas)

- chronic models of severe neurological diseases, e.g. Parkinsons disease

EXPLANATORY STATEMENT

Scope of the new directive

As the current directive (86/609/EEC) has been interpreted differently in the various Member States, the first objective of the proposal is to re-establish a level playing field throughout the EU, for industry and the research community and "at the same time strengthening the protection of animals still used in scientific procedures".

As for the current directive, the proposal covers the protection of animals used for scientific purposes related to human or animal health or animal welfare. The main differences between the proposition and the current directive are:

- The new directive will make it compulsory to carry out ethical reviews and require that experiments where animals are used be subject to authorisation; it also requires an eventual retrospective assessment. A Permanent ethical review body is created and each Member State shall establish a national animal welfare and ethics committee,

- Specific invertebrate species and foetuses in their last trimester of development and also larvae and other animals used in basic research, education and training are now included;

- Animals may only be used in procedures where those animals have been bred specifically for use in procedure, the directive also requires that only animals of second or older generations be used, subject to transitional periods to avoid taking animals from the wild and exhausting wild populations,

- Alternatives to testing on animals must be used when available and the number of animals used in projects be reduced to a minimum. Member States will be required to improve the breeding, accommodation and care measures and methods used in procedures so as to eliminate or reduce to a minimum any possible pain, suffering, distress or lasting harm caused to animals. These measures are based on the three "R" principle of replacing, reducing and refining the use of animals in experiments,

- All procedures are carried out under general or local anaesthesia and all procedures are classified in function of the degree of potential pain, suffering, distress etc.

Rapporteur's position

The Draft Commission report strongly supports the development of a more animal welfare friendly approach to the issue of the use of animals in scientific experimentation. This demonstrates the commission's commitment towards the end goal of the abolition of animal experimentation.

The European Union should be working towards this goal and the European Parliament has made it clear that it believes that more should be done towards the final objective of removing animals from scientific experiments altogether.

However, whilst this remains the end goal, we are not yet in a position to end animal experimentation altogether. There remains a huge gap in the development of alternative, non animal testing methods and whilst this remains the case, it would be unwise and potentially disastrous for human health to mandate a date beyond which animal testing or testing on certain categories of animals, such as non human primates, can no longer be carried out. Public opinion polls tend to support this approach.

The Commission report therefore aims to improve animal welfare conditions within the framework of continuing to allow animal experimentation. However in many instances the wording is ambiguous and may have the opposite effect to that which the Commission is seeking.

The Commission proposal is also not clear with regards to when animals can be used or the obligations on facilities carrying out tests. If left unaltered, the draft proposal is ambiguous enough that it may mean that it becomes virtually impossible for tests to be carried out within the European Union. European research is already hugely competitive and whilst ensuring that we maintain and improve the already high animal welfare standards, we must also ensure that our research industry can remain globally competitive. Otherwise we risk exporting the industry outside of the EU to areas that do not possess the same high commitment to animal welfare.

This report therefore seeks to clarify where animal testing is acceptable from a moral and scientific perspective and exactly how and under what rules tests can be carried out. Whilst it remains the goal to ultimately end testing on non human primates this can not happen until we are in a position to ensure that research into life threatening and debilitating diseases can continue through alternative testing methods.

In addition, to minimise the amount of animal testing undertaken throughout the EU the issue of data sharing and duplication of animal tests must be addressed. This is a contentious area however the industry can not hide behind their intellectual property whilst animals needlessly face experiments. Therefore data should be shared in order to minimise animal testing wherever possible.

This directive should be uniformly applied across the EU.

Rapporteur's position - specific points

The inclusion of foetal forms in this directive through article 2 is a step too far and will increase bureaucracy without significant increases in animal welfare.
Some fish and amphibian species produce vast numbers (more than 10,000 per female) of larval or embryonic forms. To record such numbers would entail a vast amount of work and make the statistics on the numbers of animals used meaningless for these species.

The current wording of Article 6 implies that there are no humane methods of killing other than those listed in Annex V, which is scientifically flawed. Indeed, some of the current proposals in Annex V will have an adverse welfare impact, particularly as the Annex can not be updated quickly enough to keep up to date with scientific developments in this area.

Article 8 bans the use of NHPs except in certain circumstances. This needs to be clarified as the current wording appears to prohibit all basic research on NHPs.

The recommendation in Article 10 only to source non-human primates from self sustaining colonies of F2 primates (the second generation bred in captivity) is a noble aim and one which in the long term will ensure that fewer animals are taken from the wild. However, the proposal is not practical within the timescale that the Commission has envisioned. Self sustaining F2 colonies have not been successfully established anywhere in the world and there is the possibility that many male primates in the F1 category will need to be euthanized in order to allow for the development of sustainable F2 colonies.

A feasibility study should therefore be conducted ahead of any mandated move towards establishing a policy of only sourcing from F2 self sustaining colonies.

A glaring omission in the Commission report is the lack of definition of severity classifications. The Commission identifies a number of severity clauses, "up to mild" "moderate" and "severe" governing how experiments can be undertaken, however it does not define what the classifications are. This must be clarified. The Swiss system of classifications appears to be the clearest of existing classifications and is therefore proposed.

The ban on prolonged, severe procedures in Article 15 could mean that projects on rheumatoid arthritis or chronic pain related to cancers and other neurological diseases could be stopped.

While the principle of restricting the re-use of animals in experiments is positive, the Commission proposal in Article 16 may lead to many more animals being used in experiments. This is particularly the case if re-use is not possible on an animal that has undergone a procedure which was categorised as "up to mild." Some procedures involve the training or preparation of an animal followed by the actual experiment. For example, a primate might have to be trained to use a touch-screen to select particular images, so that brain processes can be studied. Such training can take up to a year ahead of the experiment. In other cases the preparation might involve anaesthesia, a surgical operation and recovery (eg to implant a radio monitor for blood pressure). Many of these preparatory procedures are classed as "moderate". Re-using such a prepared animal in further procedures allows research to be done faster, more efficiently and often generates better data.

However, an animal that has undergone a "severe" procedure should not be re-used. In contrast those previously subjected to a "moderate" procedure should be permitted to undergo a further "moderate" procedure. In pharmacokinetic studies which consist on checking the effect of a new compound, the number of dogs would increase 20 times under the current proposed wording.

In article 20, the mutual recognition of professional qualifications is very important to support the free movement of well qualified lab scientists. It will also enhance the opportunities for collaborative projects to be run across member states.

In article 26, it would be appropriate to do an annual review for all projects rated as "severe,"

but for other projects a review every three years would be appropriate. In addition, the decision for retrospective review for procedures other than severe of for Non-human primates should be left with the ethical review.

Given the shortage of the world supply of NHPs, the EU has no economic weight to support the proposal in Article 27 to ensure that non EU suppliers of NHPs have a strategy in place to increase the proportion of animals that are the offspring of non-human primates that have been bred in captivity.

In article 35, requiring prior authorisation for all projects, including humane killing and the use of invertebrates would severely hamper research and put the EU at a significant competitive disadvantage.

The care and accommodation standards referred to in Article 32 should only be guidelines as it is in the Annex A of the European Convention of the Council of Europe (ETS 123). However it is a concern that the annex proposed by the Commission is only an abridged version of the CoE text ?

In order to facilitate the development of alternative testing methods, the scope of the European Centre for the Validation of Alternative Methods (ECVAM) should be extended to include the co-ordination and promotion of alternatives to animal procedures. A greater focus should be placed on both the development of and the promotion of alternative methods. The key to reducing and eventually eliminating experiments on animals is by ensuring that alternative methods are encouraged and supported at an EU level. Each member state should designate national reference labs to ensure that research into this area is co-ordinated, supported and encouraged at EU level in order to foster better sharing and co-ordination of alternative methods.

19.2.2009

OPINION OF THE COMMITTEE ON THE ENVIRONMENT, PUBLIC HEALTH AND FOOD SAFETY

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: Marios Matsakis

SHORT JUSTIFICATION

Not just new knowledge on ethological aspects of housing laboratory animals, but also new applications of animal use, in particular in the area of genetic engineering, made the revision of the Directive 86/609/EEC an urgent matter, although it was at that time a historic achievement and good progress has been made since then, particularly with regard to the introduction of 3Rs (replacement, reduction, refinement) principles.

On behalf of the ENVI Committee, I very much welcome the Commission's proposal to revise the Directive. It contains valuable measures that will improve animal welfare, while introducing more stringent regulations along the lines of the internationally accepted principles of humane experimental techniques and good science. It covers many concerns regarding the protection of animals used for experimental and scientific purposes. There are, however, areas where the Commission's proposal needs strengthening.

From an animal welfare angle, I welcome the extension of the scope of the Directive to include sentient foetal animals and invertebrate species as well as basic biological research. I also welcome the introduction of humane methods of killing in the context of the Directive.

The use of non-human hominids should be phased out with an immediate ban on the use of great apes and wild-caught primates. The phasing out of the use of "F1" primates, meaning the end of the use of the offspring of primates caught in the wild is of outmost importance both from an ethical and an animal welfare and conservation point of view. The measure would reduce pressure on wild populations and prevent the cruelty associated with the trade in wild primates.

In contrast to the Commission's proposal, we believe that exemptions to the rule would leave the door open to laboratory experimentation on these highly endangered species. The so-called "safeguard clause" in regard of Great Apes (Article 50) should be therefore deleted.

This move is in line with the commitments originally expressed in Directive 86/609, over twenty years ago. Prohibitions or partial prohibitions on the use of Great Apes and wild-caught primates in procedures are already in place in several Member States, and Great Apes use is no more in practice in the EU territory. Rapid harmonization throughout Europe is therefore possible.

Mandatory use of reasonably and practically available '3Rs' methods in Article 13 is a substantial step forward, compared with less stringent regulation in the Directive 86/609. Essential is also the establishment of an EU-wide upper limit of permissible pain and suffering (Article 15). Procedures causing severe suffering of animals should not be permitted.

However, the absence of criteria for classification of procedures is of concern as many measures contained in the proposal depend on severity classifications. We are proposing a possible solution to this, adding an extra annex to give provisional definitions on severity grades.

In regard of methods used in procedures, toxicological studies requiring death as an end-point should be refined (some progress has been achieved in this area) to prevent animals suffering beyond the time at which death is inevitable. Recording, reporting and analyzing the levels of suffering due to experiments should be mandatory in order to inform the ethical review and authorization process.

The principles of ethical review and authorization (Chapter IV) are among central features. Ethical reviews which are already used in 21 Member States need to be an integral part of the authorization process aiming at comparing the use of animals in scientific research with ethical concerns. Harm/benefit assessment, balancing the use of animals with the expected benefits for human health or medical research or regulatory need, is an important part of it. Further on, the retrospective assessment will encourage good science as well as animal welfare and the '3Rs'.

I welcome national inspections (Article 33), which stipulate at least one unannounced inspection per year. I also believe that an EU inspectorate should be established to perform unannounced inspections of establishments in order to ensure that severity classifications are applied uniformly and correctly in the Member States. Reports and findings (particularly breaches of this Directive) of EU and national inspections should be published.

Increased transparency, as proposed in Article 40 is welcomed too, taking into account the need for safeguarding confidential information, as well as an obligation of the Commission and Member States to contribute to the development of alternatives to animal methods (Article 45). This goes also for the establishment of national laboratories to assist the validation of alternative methods.

AMENDMENTS

The Committee on the Environment, Public Health and Food Safety 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 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 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.	(7) This Directive should also cover, ***only when it is scientifically proven that the nervous system is able to integrate pain signals,*** embryonic and foetal forms of vertebrate animals ***for which a birth is envisaged***, 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.

Amendment 2

Proposal for a directive
Recital 11 a (new)

Text proposed by the Commission	*Amendment*
	(11a) In accordance with the objectives of the Community Action Plan on the Protection and Welfare of Animals (2006 – 2010) the Commission should endeavour to promote the welfare of animals used for scientific purposes internationally, and in particular to seek promotion of the replacement, reduction and refinement of animal procedures

through the World Organisation for Animal Health (OIE), and by seeking to add animal welfare standards to the criteria assessed in order to establish compliance with Good Laboratory Practice (GLP).

Justification

The Communication from the Commission on a Community Action Plan on the Protection and Welfare of Animals 2006-2010 lists promotion of high animal welfare standards in the EU and at the international level as one of its primary objectives. Promotion of the replacement, reduction and refinement of animal procedures through the World Organisation for Animal Health would not only further this objective, but would protect EU industry by raising animal welfare standards in third countries.

Amendment 3

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 to only those procedures where ***the cumulative*** pain, distress and suffering ***have been justified at ethical review.***

Justification

The justification for reuse of animals in procedures is clearly related to the severity of the procedure and the duration of any effects of treatment. An expert judgement is required and is best provided via the ethical review process.

Amendment 4

Proposal for a directive
Article 2 – paragraph 2

Text proposed by the Commission	*Amendment*
2. This Directive shall apply to the following animals:	***deleted***
(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

The directive should also include independently feeding larval forms and embryonic or foetal forms as from the last third of their normal development, only when science has been scientifically established.

Amendment 5

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.	***deleted***

Justification

This would have a major impact on the potential production of GM transgenic animals without having an impact on animal welfare.

Amendment 6

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

Text proposed by the Commission	*Amendment*
	(6a) 'confidential information' means information the non-consensual release of which would cause detriment to the legitimate commercial or research interests of its owner or a third party.

Justification

The new definition of 'confidential information' is needed because the concept is relevant in several places in the proposal.

Amendment 7

Proposal for a directive
Article 7 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) it is guaranteed that the animals used in the procedure are those whose survival is not endangered or threatened and are purpose-bred only.

Justification

The exclusion of fundamental research harbours the risk that useful knowledge, which can be important for the survival of a species in danger of extinction cannot be gained anymore. Therefore, this article would be contradictory to the goal of the international convention on biodiversity of Washington. Only by expanding the exceptions to the area of fundamental research can it be guaranteed that specific adaptation, which can often only be found in rare, frequently endangered species who are specifically adopted, can be tested adequately.

Amendment 8

Proposal for a directive
Article 8 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the procedure has one of the purposes	(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;	referred to in points (1), (2)(a), (3) or the purpose referred to in point (5) of Article 5;

Justification

To decide to use primates solely for the conditions set out in the proposal for a directive would result in the abandonment of a large amount of research and a reduction in the European Union's capacity in this sector. Some fundamental research experiments, or research on infectious diseases, for example, could then be banned in Europe.

Amendment 9

Proposal for a directive
Article 8 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(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 ***and ethical justification*** that the purpose of the procedure cannot be achieved by the use of other species than non-human primates.

Justification

The specific ethical importance of experiments with inhuman primates should be highlighted.

Amendment 10

Proposal for a directive
Article 9 – title

Text proposed by the Commission	*Amendment*
Animals ***taken from the wild***	Animals ***that are not purpose-bred***

Justification

More reasonable and appropriate wording.

Amendment 11

Proposal for a directive
Article 9 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Animals ***taken from the wild*** shall not be used in procedures.	1. Animals ***that are not purpose-bred*** shall not be used in procedures.

Justification

More reasonable and appropriate wording.

Amendment 12

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. 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.
	The Commission will publish, 18 months after the entry into force of this Directive, a feasibility study on the timetable mentioned in Annex III.
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.	***In the light of the results of that study,*** 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 reasons of animal welfare***.

Justification

The Commission's agenda is not realistic and does not take into consideration all the ethical, technical, economic and animal health aspects raised by Annex III. The proposed dates should therefore be postponed and a short-term study carried out after the publication of this directive in order to incorporate all the necessary data with a view to applying Annex III.

Amendment 13

Proposal for a directive
Article 10 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. The Commission, 5 years after the entry into force of this Directive, shall carry out an animal welfare assessment and a feasibility evaluation of the implementation of the requirements set out in paragraph 1. .

Amendment 14

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 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.	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 ***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 practically available.

Justification

Alternative methods to an animal experiment must be internationally accepted or it will have the consequence of both the animal and the alternative experiment being conducted with the animal experiment being done outside of the EU.

To have to conduct both animal and non animal studies is counter to animal welfare, especially when the alternative model is an ex-vivo test requiring animal tissues.

Amendment 15

Proposal for a directive
Article 14 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	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***, so long as the purpose is compatible with the procedure***.

Justification

The use of analgesics should not affect the outcome of the operation.

Amendment 16

Proposal for a directive
Article 15 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. By ...*, the Commission shall bring forward a proposal on definitions of severity which contains at least definitions of "up to mild", "moderate" and "severe". Up to that date, the transitional explanatory definitions shall be applicable as guidance in the Member States.
	**** 18 months from the date of entry into force of this Directive.***

Justification

Severity definitions should be harmonised all over the European Union, and provisional definitions are necessary until the final definitions are accepted by the Commission.

Amendment 17

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.	***deleted***

Justification

The concept of prolonged suffering is too vague. Suffering is a product of intensity and duration and this needs to be recognised.

Amendment 18

Proposal for a directive
Article 15 – paragraph 4 – subparagraph 1

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 ***in line with good practice developed in Europe***.

Justification

The review of the Directive cannot be completed and finalised before severity classification is defined and exemplified by relevant guidance. This is because severity classification is used as a basis of other provision in this directive with possible consequences on ability to conduct research in the EU. The lack of definition of severity bands within the current draft makes it impossible to assess the full impact of the Directive. The current text could result in the ban of severity class 3 in general. That would mean that substances for certain diseases cannot be tested and developed anymore. Example: Rheumatoid Arthritis, transplantation.

Amendment 19

Proposal for a directive
Article 15 – paragraph 4 – subparagraph 2

Text proposed by the Commission	*Amendment*
Those measures, designed to amend non-essential elements of this Directive by	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).	supplementing it, shall be adopted by...* in accordance with the regulatory procedure with scrutiny referred to in Article 51(3) ***after consultation of stakeholders. Until such classification is in place, the transitional classification shall apply***. **** 18 months from the entry into force of this Directive***

Justification

Severity definitions should be harmonised in the European Union, and provisional definitions are necessary until he final definitions are accepted by the European Commission.

Amendment 20

Proposal for a directive
Article 16 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the previous procedure was classified as ***'up to mild'***;	(a) the previous procedure was classified as ***'moderate' or less***;

Justification

Current restriction of reuse to "up-to mild" will result in dramatic increase in numbers of animals used for experimental purposes. In pharmacokinetic studies which consist in checking the effect of a new compound, the number of dogs would increase 20 times under the current proposed wording, since studies with an unknown compound, would be classified as "moderate" even if the genuine effect is "up to mild".

This increase of animals is ethically questionable and is harmful in terms of animal welfare aspects.

Amendment 21

Proposal for a directive
Article 16 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(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 restored;

Justification

Current restriction of reuse to up-to mild will result in dramatic increase in numbers of animals used for experimental purposes. In pharmacokinetic studies which consist on checking the effect of a new compound, the number of dogs would increase 20 times under the current proposed wording, since studies with an unknown compound, would be classified as "moderate" even if the genuine effect is "up to mild".

This increase of animals is ethically questionable and is harmful in terms of animal welfare aspects.

Amendment 22

Proposal for a directive
Article 16 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) the further ***procedure is*** classified as ***'up to mild'*** or 'non-recovery'.	(c) the further ***procedures are*** classified as ***'moderate' or less*** or 'non-recovery'.

Justification

Current restriction of reuse to up-to mild will result in dramatic increase in numbers of animals used for experimental purposes. In pharmacokinetic studies which consist on checking the effect of a new compound, the number of dogs would increase 20 times under the current proposed wording, since studies with an unknown compound, would be classified as "moderate" even if the genuine effect is "up to mild".

This increase of animals is ethically questionable and is harmful in terms of animal welfare aspects.

Amendment 23

Proposal for a directive
Article 16 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) the repeated re-use of the animal is supported by veterinary examination.

Justification

Current restriction of reuse to up-to mild will result in dramatic increase in numbers of animals used for experimental purposes. In pharmacokinetic studies which consist on checking the effect of a new compound, the number of dogs would increase 20 times under the

current proposed wording, since studies with an unknown compound, would be classified as "moderate" even if the genuine effect is "up to mild".

This increase of animals is ethically questionable and is harmful in terms of animal welfare aspects.

Amendment 24

Proposal for a directive
Article 16 – paragraph 2

Text proposed by the Commission	*Amendment*
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'.	2. By way of derogation from paragraph 1, the competent authority, on the basis of scientific justification ***or reasons of animal welfare***, 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 ***or repeated*** procedure is classified as 'up to mild' or as 'non-recovery'.

Justification

Animals already used once in an experiment should only be used in a further experiment, when the second intervention is terminal or can be classified as "up to mild" in the future. This could on one hand dramatically increase the number of animals used in experiments, which is paradox, given the effort to reduce the number of experimental animals.

Amendment 25

Proposal for a directive
Article 16 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The repeated use of animals, which have been implanted with telemetric instruments for the transmission of measured data or other instruments for the repeated sampling or analysis of vital functions, shall be excluded from the conditions set out in this Article.

Justification

The Commission text means that animals already used once in an experiment could only be used in a further experiment, when the second intervention is terminal or can be classified as "up to mild" in the future. This could on the one hand dramatically increase the number of animals used in experiments, which is a paradox, given the effort to reduce the number of experimental animals. The repeated use by the AM would be beneficial to animal welfare.

Amendment 26

Proposal for a directive
Article 18

Text proposed by the Commission	*Amendment*
Article 18	***deleted***
Sharing organs and tissues	
Member States shall establish programmes for the sharing of organs and tissues of animals killed by a humane method.	

Justification

It is very difficult to implement such a demand at a national or at EU level. In particular the aspects of quality, the continuous standardisation of a sampling, the storing, respectively the conditions of storage and transport have to be implemented and controlled.

Amendment 27

Proposal for a directive
Article 19 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) and the animals concerned are not genetically modified experimental animals or non-human primates.

Justification

The release of experimental animals in the wild or domestic population as a general request is not appropriate. On the one hand, such an approach is contradictory to any kind of sense of responsibility to the experimental animal. Furthermore, this request would not be compatible with the guidelines in the German law on animals and nature conservation.

Amendment 28

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.	***deleted***

Justification

The accreditation of people who work with experimental animals is limited to 5 years and will only be extended after another check of the professional qualifications. This contradicts the basic principle of equal treatment regarding different professional categories. The request for further and advanced training in Art.20 part 2 and 4 covers the assurance of qualification.

Amendment 29

Proposal for a directive
Article 24 – point 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) technicians, who are sufficiently qualified for handling the animal species covered by this Directive.

Justification

In the catalogue the indispensable person of a qualified technician was missing.

Amendment 30

Proposal for a directive
Article 26 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) assess and approve each individual project based on the cost to the animal

and the benefits to research;

Amendment 31

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. ***The use of F1 colonies (captive bred animals not caught wild) is permitted, unless and until the use of F2 colonies (***the offspring of ***non-primates which have*** been bred in captivity***) for experimental purposes has been established in accordance with the third subparagraph of Article 10(1).***

Justification

Third-world countries hardly will be able to develop these strategies to move to F2 animals within a short period of time. The consequences will be counterproductive: Surplus F1 will be euthanised, released in the wild, or trapped.

Amendment 32

Proposal for a directive
Article 30 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
2. Each non-human primate shall have an individual history file, which *follows* the animal throughout its life.	2. Each non-human primate***, cat and dog*** shall have an individual history file which *shall follow* the animal throughout its life. ***The Member States must ensure the adequacy and consistency of this Directive.***

Justification

While the European Commission seems to understand the importance of keeping information on non-human primates, cats and dogs (and therefore recognises the controversy on the use of those particular species), it is not clear why the obligation to keep individual history files only applies to non-human primates. This is surely essential for the purposes of the research, quite apart from welfare considerations. This should be at least extended to cats and dogs (assuming that such procedures are allowed to continue for the time being).

For the promotion of a standardised and adequate rule of files management, the Member States should be involved.

Amendment 33

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.

Justification

Confidential information must be protected. This idea is contrary to all functions of the market and would lead to a movement of industry to non-European countries.

Amendment 34

Proposal for a directive
Article 40 – paragraph 1 – introductory paragraph

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, ***company and personnel details,*** the non-technical project summary shall provide the following:

Justification

It is necessary to secure adequate anonymity and that information is collected at national level to avoid projects being tracked back to companies at regional level.

Amendment 35

Proposal for a directive
Article 40 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) a demonstration ***of compliance with the requirement*** of replacement, reduction and	(b) a demonstration ***that the principles*** of replacement, reduction and refinement

refinement.	***have been considered***.

Justification

One cannot demonstrate compliance with 3Rs at a time the project is submitted – the principles of 3Rs should be built into experimental design and evidence that it has been considered presented.

Amendment 36

Proposal for a directive
Article 41 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Project authorisations shall be granted for a period not exceeding ***four years***.	3. Project authorisations shall be granted for a period not exceeding ***five years***.

Justification

Bureaucracy dismantling.

Amendment 37

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 ***regulatory testing*** projects when those projects are required by law.

Justification

For regulatory testing generic protocols are used and are usually determined under ICH guidelines. These together with regional guidelines determine the studies required and there is little scope to modify them. They should only require approval once.

Amendment 38

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. ***Renewal*** of a project authorisation shall be subject to a further favourable ethical evaluation.

Justification

There is the risk that minor amendments that have no welfare impact will become the majority of the approvals required. Amendments that do not change the severity classification should be handled under a notification, not approval procedure.

Amendment 39

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 otherwise*** to the development and***, where appropriate, the scientific*** validation of alternative approaches ***intended to*** provide ***a comparable*** level of information as that obtained in procedures using animals but that do not involve the use of animals or use fewer animals or that entail less painful procedures and shall take such other steps as they consider appropriate to encourage research in this field.

Amendment 40

Proposal for a directive
Article 45 a (new)

Text proposed by the Commission	*Amendment*
	Article 45a
	European Centre of Excellence for Alternative Methods

1. The Commission shall, by [one year after entry into force of this Directive], establish a European Centre of Excellence for Alternative Methods to facilitate the development and use of alternatives to animal procedures.

2. The European Centre of Excellence for Alternative Methods shall co-ordinate and promote the development and use of alternatives to animal procedures including applied and basic biomedical research and veterinary research and regulatory testing by performing the following functions:

(a) coordinate research undertaken to facilitate the development of alternatives to animal procedures by the National reference laboratories for alternative methods described in Article 46;

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

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

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

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

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

3. The European Centre of Excellence for Alternative Methods shall, by increasing the capacity and competencies of the existing European Centre for the Validation of Alternative Methods (ECVAM) work towards the goal of full replacement of animal tests used for regulatory purposes and shall fulfill the following functions:

(a) coordinate pre-validation and validation studies undertaken by the National reference laboratories for alternative methods in accordance with Article 46 of this Directive;

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

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

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

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

Justification

Various pieces of Community legislation require animal testing. To effectively implement the 3R principles across the board, both EU and national centres for alternative methods should be established to provide coordinated and strategically focused efforts.

Amendment 41

Proposal for a directive
Article 48 – paragraph 1

Text proposed by the Commission	*Amendment*
The Commission may adapt ***Annexes II to VII*** to technical and scientific progress.	The Commission may adapt ***Annexes I to VII*** to technical and scientific progress.

Justification

The list of invertebrate animals, including independently feeding larval forms should be equally revised according to technical and scientific progress.

Severity definitions should be harmonised all over the European Union, and provisional definitions are necessary until the final definitions are accepted by the Commission.

Amendment 42

Proposal for a directive
Article 52 – paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. By [***three years*** after the transposition date] and every ***three 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.

Justification

More frequent progress reports to the Parliament and Council will allow for better implementation of this directive in the Member States.

Amendment 43

Proposal for a directive
Article 52 – paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. By [***one year*** after transposition date] and ***annually*** 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.

Justification

More frequent progress reports to the Parliament and Council will allow for better implementation of this directive in the Member States.

Amendment 44

Proposal for a directive
Annex III - table

Text proposed by the Commission

Species	Dates
Marmoset (Callithrix jacchus)	[date of application referred to in the second subparagraph of the first paragraph of the 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]***

Amendment

Species	Dates
Marmoset (Callithrix jacchus)	[date of application referred to in the second subparagraph of the first paragraph of the Article on transposition]
Cynomolgus monkey (Macaca fascicularis)	***[date to be determined depending on the results of the feasibility study requested in Article 10]***
Rhesus monkey (Macace mulatta)	***[date to be determined depending on the results of the feasibility study requested in***

	Article 10]
Other species of non-human primates	***[date to be determined depending on the results of the feasibility study requested in Article 10]***

Justification

The Commission's agenda is not realistic and does not take into consideration all the ethical, technical, economic and animal health aspects raised by Annex III. The proposed dates should therefore be postponed and a short-term study carried out after the publication of this directive in order to incorporate all the necessary data with a view to applying Annex III.

Amendment 45

Proposal for a directive
Annex V

Text proposed by the Commission	*Amendment*
	Annex deleted

Justification

Annex V could lead to the appliance of out-dated methods for the killing of experimental animals in the future. It should be replaced by guidelines which can be easily updated.

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	ENVI 4.12.2008
Drafts(wo)man Date appointed	Mojca Drčar Murko 21.1.2009
Discussed in committee	9.2.2009
Date adopted	17.2.2009
Result of final vote	+: 23 –: 18 0: 0
Members present for the final vote	Adamos Adamou, Johannes Blokland, John Bowis, Hiltrud Breyer, Martin Callanan, Avril Doyle, Mojca Drčar Murko, Edite Estrela, Jill Evans, Karl-Heinz Florenz, Elisabetta Gardini, Cristina Gutiérrez-Cortines, Satu Hassi, Jens Holm, Caroline Jackson, Christa Klaß, Urszula Krupa, Peter Liese, Jules Maaten, Linda McAvan, Riitta Myller, Péter Olajos, Miroslav Ouzký, Vittorio Prodi, Guido Sacconi, Daciana Octavia Sârbu, Amalia Sartori, Carl Schlyter, Horst Schnellhardt, Richard Seeber, Kathy Sinnott, Thomas Ulmer, Anja Weisgerber, Anders Wijkman
Substitute(s) present for the final vote	Karsten Friedrich Hoppenstedt, Johannes Lebech, Caroline Lucas
Substitute(s) under Rule 178(2) present for the final vote	Albert Deß, Fiona Hall, Elisabeth Jeggle, Juan Andrés Naranjo Escobar

11.3.2009

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

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 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.	(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 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 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-***	(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 ***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.***

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***.

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 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.***	(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 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	(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***.	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 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.	(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 ***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 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.	(40) To ensure that the public is informed, it is important that objective information 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	(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.	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	1. Where a method of testing not involving the use of animals exists***, provides equally relevant information*** and may be used in

shall ensure that the alternative method is used.	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***	(a) the procedure has one of the purposes referred to in points (1), (2)(a), (3) and (5) of Article 5;

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.	(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	***1a. In the light of the results of the study referred to in paragraph 1, and if justified***

may only be used in procedures where they are the offspring of non-human primates which have been bred in captivity.	***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 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.	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 ***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 practically 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***	1. Member States shall ensure that all procedures are classified as 'up to mild', 'moderate' ***or*** 'severe' ***in accordance with Annex VIIa.***

ethological needs and the use of anaesthesia or analgesia or both.

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 and accommodation of animals is concerned, ensure the following:	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;	(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 in Annex IV as from the dates provided for in that Annex.	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.

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	3. Member States may allow exemptions to paragraph 2 for ***justified scientific reasons,***

paragraph 2 for animal welfare 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 the competent authority.	2. Granting of authorisation shall be subject to favourable ethical evaluation by 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 for a period not exceeding ***four*** years.	3. Project authorisations shall be granted 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	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.	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	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,

animals.	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

PROCEDURE

Title	Protection of animals used for scientific purposes
References	COM(2008)0543 – C6-0391/2008 – 2008/0211(COD)
Date submitted to Parliament	5.11.2008
Committee responsible Date announced in plenary	AGRI 4.12.2008
Committee(s) asked for opinion(s) Date announced in plenary	ENVI ITRE 4.12.2008 4.12.2008
Associated committee(s) Date announced in plenary	ITRE 19.2.2009
Rapporteur(s) Date appointed	Neil Parish 1.12.2008
Discussed in committee	19.1.2009 16.2.2009 9.3.2009 31.3.2009
Date adopted	31.3.2009
Result of final vote	+: 18 –: 7 0: 0
Members present for the final vote	Vincenzo Aita, Luis Manuel Capoulas Santos, Giovanna Corda, Albert Deß, Konstantinos Droutsas, Constantin Dumitriu, Michl Ebner, Lutz Goepel, Friedrich-Wilhelm Graefe zu Baringdorf, Lily Jacobs, Elisabeth Jeggle, Véronique Mathieu, Mairead McGuinness, Rosa Miguélez Ramos, James Nicholson, Neil Parish, Agnes Schierhuber, Willem Schuth, Czesław Adam Siekierski, Alyn Smith, Petya Stavreva, Jeffrey Titford, László Tőkés, Witold Tomczak, Donato Tommaso Veraldi, Janusz Wojciechowski, Andrzej Tomasz Zapałowski
Substitute(s) under Rule 178(2) present for the final vote	Katerina Batzeli, Jorgo Chatzimarkakis, Béla Glattfelder, Roselyne Lefrançois, Catherine Neris, Markus Pieper