

EUROPEAN PARLIAMENT

2004



2009

Committee on Agriculture and Rural Development

2008/0211(COD)

18.2.2009

*****I**

DRAFT 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 Industry, Research and Energy and the Committee on the Environment, Public Health and Food Safety (A6-0000/2009),
1. Approves the Commission proposal as amended;
 2. Instructs its President to forward its position to the Council and Commission.

Amendment 1

Proposal for a directive

Recital 6

Text proposed by the Commission

(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.

Amendment

(6) It is necessary 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.

Or. en

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

(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.

Amendment

deleted

Or. en

Amendment 3

Proposal for a directive Recital 8

Text proposed by the Commission

(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.

Amendment

(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.

Or. en

Amendment 4

Proposal for a directive Recital 9

Text proposed by the Commission

(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.

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 implementing this Directive. ***The 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.***

Or. en

Amendment 5

Proposal for a directive Recital 10

Text proposed by the Commission

(10) Animals have an intrinsic value in themselves which must be respected. There are also ethical concerns of the general

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.

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. Use of animals for scientific procedures in other areas under Community competence should be prohibited.

Or. en

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 6

Proposal for a directive

Recital 12

Text proposed by the Commission

(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.

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 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.

Or. en

Justification

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

Amendment 7

Proposal for a directive

Recital 14

Text proposed by the Commission

(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.

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 **a trained and** authorised person with a humane method that is considered appropriate to the species.

Or. en

Amendment 8

Proposal for a directive

Recital 16

Text proposed by the Commission

(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

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-to-day 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.***

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.

Or. en

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 9

Proposal for a directive Recital 18

Text proposed by the Commission

(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

Amendment

(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 the feasibility of limiting the animals used to those from self-sustaining colonies.***

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.

Establishments breeding and supplying non-human primates should therefore have a strategy in place to support and facilitate the progressive move towards that goal.

Or. en

Justification

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

Amendment 10

Proposal for a directive Recital 21

Text proposed by the Commission

(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.***

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.

Or. en

Amendment 11

Proposal for a directive Recital 22

Text proposed by the Commission

(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.

Amendment

(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.

Or. en

Amendment 12

Proposal for a directive Recital 23

Text proposed by the Commission

(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***.

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

Amendment 13**Proposal for a directive****Recital 24***Text proposed by the Commission*

(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.

Amendment

(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 14**Proposal for a directive****Recital 26***Text proposed by the Commission*

(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

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.

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.

Authorisation by a competent authority and proof of the successful completion of relevant training courses should be mutually recognised by all Member States.

Or. en

Amendment 15

Proposal for a directive Recital 29

Text proposed by the Commission

(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.

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 ***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.

Or. en

Amendment 16

Proposal for a directive Recital 30

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 17

Proposal for a directive Recital 31

Text proposed by the Commission

(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.

Amendment

(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.

Or. en

Amendment 18

Proposal for a directive Recital 32

Text proposed by the Commission

(32) The accommodation and care of the animals should be based on the specific

Amendment

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

needs and characteristics of each species.

based on the best and most up-to-date scientific evidence.

Or. en

Amendment 19

Proposal for a directive

Recital 34

Text proposed by the Commission

(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.

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 ***subject always to developments based on new scientific evidence.***

Or. en

Amendment 20

Proposal for a directive

Recital 38

Text proposed by the Commission

(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

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 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

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.

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.

Or. en

Amendment 21

Proposal for a directive Recital 39

Text proposed by the Commission

(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.

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 *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.

Or. en

Amendment 22

Proposal for a directive Recital 45

Text proposed by the Commission

(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

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.

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 is extended to include the co-ordination and promotion of the development and use of alternatives to animal experiments.***

Or. en

Amendment 23

Proposal for a directive Recital 49

Text proposed by the Commission

(49) In particular, power should be conferred on the Commission to establish the criteria for classification of procedures and to adapt ***Annexes II to VII*** to scientific and technical progress. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, inter alia by supplementing it with new non-essential elements, they must be adopted in

Amendment

(49) In particular, power should be conferred on the Commission to establish the criteria for classification of procedures and to adapt ***Annexes I to VII*** to scientific and technical progress. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, inter alia by supplementing it with new non-essential elements, they must be adopted in

accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

Or. en

Amendment 24

Proposal for a directive

Article 2 – paragraph 1 - subparagraph 1

Text proposed by the Commission

1. This Directive shall apply *where* animals are used or intended to be used in procedures, or where they are bred specifically so that their organs or tissues may be used for scientific purposes.

Amendment

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

Or. en

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 25

Proposal for a directive

Article 2 – paragraph 1 - subparagraph 2

Text proposed by the Commission

The elimination of pain, suffering, distress or lasting harm by the successful use of anaesthesia, analgesia or other methods

Amendment

Where there is any pain, suffering, distress or lasting harm, *its elimination* by the successful use of anaesthesia, analgesia or

shall not exclude the use of an animal in procedures from the scope of this Directive.

other methods shall not exclude the use of an animal in procedures from the scope of this Directive

Or. en

Amendment 26

Proposal for a directive

Article 2 – paragraph 2 – point a

Text proposed by the Commission

(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;

Amendment

(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;

Or. en

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 27

Proposal for a directive

Article 2 – paragraph 2 – point b

Text proposed by the Commission

(b) live invertebrate animals, **including independently feeding larval forms**, of those species listed in Annex I.

Amendment

(b) live invertebrate animals of those species **of orders** listed in Annex I.

Or. en

Amendment 28

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**

Or. en

Justification

This would have a major impact on statistics e.g. production, of GM animals without impact on animal welfare.

Amendment 29

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 :

Or. en

Amendment 30

Proposal for a directive

Article 2 – paragraph 4 – point d

Text proposed by the Commission

(d) practices that **are not invasive**

Amendment

(d) practices that **involve only the observation of an animal**

Or. en

Justification

The current wording is unclear and could lead to confusion. Some studies which are not invasive are still stressful

Amendment 31

Proposal for a directive

Article 3 – paragraph 1

Text proposed by the Commission

(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;

Amendment

(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 **(including death), and**, 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;

Or. en

Justification

The amendment on the definition of 'procedure' is simply to make it clear that death is a 'lasting harm' which would seem obvious to the public (but a court in the UK has decided to the contrary).

Amendment 32

Proposal for a directive Article 3 – paragraph 6a (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 procedures within the meaning of this Directive.

Or. en

Amendment 33

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

Text proposed by the Commission

Amendment

(6b) 'Competent Person' means any person who is considered by a Member State to be competent to perform the relevant function described in this Directive.

Or. en

Amendment 34

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

Text proposed by the Commission

Amendment

(6c) '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.

Or. en

Amendment 35

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

Text proposed by the Commission

Amendment

(6d) 'Practice' means any non-experimental activity or any scientific activity which does not constitute an experiment.

Or. en

Amendment 36

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

Text proposed by the Commission

Amendment

(6e) '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.

Or. en

Amendment 37

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.

Or. en

Amendment 38

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.

Or. en

Amendment 39

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

Text proposed by the Commission

Amendment

(6j) '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.

Or. en

Amendment 40

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

Text proposed by the Commission

Amendment

(6k) '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

Or. en

Amendment 41

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, ***experimentation or other scientific activity*** not involving the use of living animals

shall ensure that the alternative method is used.

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 ***instead***.

Or. en

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.

Amendment 42

Proposal for a directive

Article 5 – paragraph 2 – point bb (new)

Text proposed by the Commission

Amendment

(bb) Agricultural science when it does not relate to usual practices described in Article 1

Or. en

Justification

The list is very restrictive and does not include: sustainable agriculture, ageing studies, nutrition of healthy human, farm animal welfare

Amendment 43

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 ***and health and welfare*** of the species;

Amendment 44

Proposal for a directive

Article 6 – paragraph 1 – subparagraph 1

Text proposed by the Commission

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.

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 *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 45

Proposal for a directive

Article 6 – paragraph 2

Text proposed by the Commission

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.

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.
Notwithstanding any exemption, animals shall be killed with a minimum of pain,

suffering and distress.

Or. en

Amendment 46

Proposal for a directive

Article 8 – paragraph 1 – point a

Text proposed by the Commission

(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;

Amendment

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

Or. en

Justification

The current wording could significantly affect the ability to carry out basic research.

Amendment 47

Proposal for a directive

Article 8 – paragraph 1 – point b

Text proposed by the Commission

(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.

Amendment

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

Or. en

Amendment 48

Proposal for a directive

Article 10 – paragraph 1 – subparagraph -1 (new)

Text proposed by the Commission

Amendment

(-1) The Commission will 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 the Directive.

Or. en

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 49

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.***

Or. en

Amendment 50

Proposal for a directive Article 12 – subparagraph 1

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 51

Proposal for a directive Article 14 – paragraph 1

Text proposed by the Commission

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

Amendment

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

Or. en

Justification

Anaesthesia is appropriate for only a small minority of procedures and so it is unwise to have anaesthesia as the default requirement.

Amendment 52

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.

Or. en

Justification

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

Amendment 53

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.

Or. en

Amendment 54

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

5. An animal, which may suffer pain once anaesthesia has worn off, shall be treated

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

with pre-emptive and post-operative analgesics or other appropriate pain-relieving methods, provided that it is compatible with the purpose of the procedure. Where the treatment with analgesics is not possible, the animal shall be immediately killed by a humane method.

Or. en

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 55

Proposal for a directive Article 15 – paragraph 1

Text proposed by the Commission

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.**

Amendment

1. Member States shall ensure that all procedures are classified as 'up to mild', 'moderate' **or 'severe' in conformity with Annex VIIa.**

Or. en

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 56

Proposal for a directive Article 15 – paragraph 2

Text proposed by the Commission

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.

Amendment

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.***

Or. en

Justification

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

Amendment 57

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

Text proposed by the Commission

4. The Commission shall establish the criteria for classification of procedures.

Amendment

4. The Commission shall, ***within 12 months from the entry into force of this Directive***, establish the criteria for classification of procedures

Or. en

Amendment 58

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 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).

Deleted

Or. en

Amendment 59

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:

Or. en

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 60

Proposal for a directive Article 16 – point a

Text proposed by the Commission

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

Amendment

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

Or. en

Justification

If re-use is not possible, every experiment requires another animal to be used and put through the stress of the preparatory work.

Amendment 61

Proposal for a directive Article 16 – point c

Text proposed by the Commission

(c) the further procedure is classified as 'up to mild' or 'non-recovery'.

Amendment

(c) the further procedure is classified as '**moderate**', 'up to mild' or 'non-recovery'.

Or. en

Amendment 62

Proposal for a directive Article 16 – point ca (new)

Text proposed by the Commission

Amendment

(ca) The repeated re-use of the animal is supported by veterinary examination.

Or. en

Amendment 63

Proposal for a directive Article 16 – paragraphe 2

Text proposed by the Commission

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'.

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

Or. en

Justification

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

Amendment 64

Proposal for a directive Article 17 – paragraph 3

Text proposed by the Commission

3. An animal shall be killed by a humane method when it is likely to remain in lasting pain or distress.

Amendment

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.

Or. en

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 65

Proposal for a directive

Article 19 – title

Text proposed by the Commission

Amendment

Setting free of animals and re-homing

Re-homing

Or. en

Justification

It is not in the interest of animals to be set free.

Amendment 66

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 return to a standard breeding system appropriate to the species*** or re-homed provided that the following conditions are met:

Or. en

Justification

In the case of domestic species, rehoming cannot be understood as freedom. These species have long been selected by humans for their use as farm animals (such as dairy cows, pigs, etc.) or pets (cats and dogs).

Amendment 67

Proposal for a directive Article 19 – point c

Text proposed by the Commission

(c) the maximum possible care has been taken to safeguard the well-being of the animal.

Amendment

(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.***

Or. en

Amendment 68

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

Text proposed by the Commission

Amendment

ca) no rodents, especially those who are genetically modified, shall be set free or re-homed

Or. en

Justification

Setting free of rodents, especially GM mouse strains, would cause serious concerns on both welfare and environmental considerations.

Amendment 69

Proposal for a directive Article 20 – paragraph 1a (new)

Text proposed by the Commission

Amendment

1a. Member States shall ensure that persons are trained and authorised by an institution before they carry out any

killing by a humane method;

Or. en

Amendment 70

Proposal for a directive

Article 20 – paragraph 2 – subparagraph 1

Text proposed by the Commission

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.

Amendment

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 demonstrated the requisite competence.

Or. en

Amendment 71

Proposal for a directive

Article 20 – paragraph 2 – subparagraph 2

Text proposed by the Commission

Persons carrying out the functions referred to in point (b) of paragraph 1 shall have received instruction in a scientific discipline relevant to the work being undertaken and shall be capable of handling and taking care of the species concerned.

Amendment

Persons carrying out the functions referred to in point (b) of paragraph 1 shall have received instruction in a scientific ***or animal care*** discipline relevant to the work being undertaken and shall be capable of handling and taking care of the species concerned.

Or. en

Amendment 72

Proposal for a directive Article 20 – paragraph 3

Text proposed by the Commission

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.

Amendment

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 education and training qualifications and authorisation to conduct designated procedures.**

Or. en

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 73

Proposal for a directive Article 23 – paragraph 2

Text proposed by the Commission

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.

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

Or. en

Amendment 74

Proposal for a directive Article 24 – paragraph 2a (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 (and more if necessary) trained person on site (at all times) to care for the animals' welfare.

Or. en

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 75

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, ***as a minimum***, include the designated veterinarian, the ***senior*** 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 or persons with expertise in the 3Rs (replacement, reduction and refinement)***.

Or. en

Justification

It would not be appropriate for all animal care employees to participate in the permanent ethical review body.

Amendment 76

Proposal for a directive

Article 26 – paragraph 1 – point d – introductory part

Text proposed by the Commission

(d) review annually all projects which are of more than 12 months duration, focusing in particular on:

Amendment

(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:

Or. en

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 77

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

Or. en

Amendment 78

Proposal for a directive

Article 26 – paragraph 1 – point ea (new)

Text proposed by the Commission

Amendment

(ea) review and authorise amendments to procedures that are "moderate" or below that do not increase the severity of the procedure to "severe".

Or. en

Justification

The decision for retrospective review for other than severe or NHP's should be left with the ethical review.

Amendment 79

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 3Rs.***

Or. en

Amendment 80

Proposal for a directive Article 27 – paragraph 1

Text proposed by the Commission

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.

Amendment

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. ***As long the use of non-human primates is authorised, the European Commission and the Member States shall take all necessary provisions to support the appropriate conditions of transport.***

Or. en

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 81

Proposal for a directive Article 27 – paragraph 2

Text proposed by the Commission

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.

Amendment

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.

Or. en

Amendment 82

Proposal for a directive

Article 29 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

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

Or. en

Justification

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

Amendment 83

Proposal for a directive

Article 29 – paragraph 1 – point a

Text proposed by the Commission

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

Amendment

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

Or. en

Justification

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

Amendment 84

Proposal for a directive

Article 29 – paragraph 1 – point e

Text proposed by the Commission

(e) the name and address of the **recipient of**

Amendment

(e) the name and address of the **the**

animals;

establishment receiving the animals;

Or. en

Amendment 85

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

Text proposed by the Commission

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

Amendment

(f) the number and species of ***dogs, cats and non-human primates*** which have died or have been killed using a humane method in the establishment.

Or. en

Amendment 86

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

Text proposed by the Commission

2. Each non-human primate shall have an individual history file, which follows the animal throughout its life.

Amendment

2. Each non-human primate, ***dog and cat*** shall have an individual history file, which follows the animal throughout its life.

Or. en

Amendment 87

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

Text proposed by the Commission

The file shall be established at birth and shall cover ***detailed*** reproductive, medical

Amendment

The file shall be established at birth and

and social information on the individual animal.

shall cover **any relevant** reproductive, medical and social information on the individual animal.

Or. en

Amendment 88

Proposal for a directive Article 31 – paragraph 1

Text proposed by the Commission

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

Amendment

1. Each dog, cat or non-human primate in any breeding, supplying or user establishment shall, except in the cases referred to in paragraph 2, be provided, before it is weaned, with an individual identification mark ***accepted by the Member States***.

Or. en

Amendment 89

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

Text proposed by the Commission

(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;

Amendment

(d) the well-being and state of health of animals are observed ***on a daily basis*** by a competent person to prevent pain or avoidable suffering, distress or lasting harm;

Or. en

Amendment 90

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

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 91

Proposal for a directive Article 32 – paragraph 2

Text proposed by the Commission

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.

Amendment

2. For the purposes of points (a) and (b) of paragraph 1, Member States shall apply **appropriate** care and accommodation standards, **either those** set out in Annex IV as from the dates provided for in that Annex, **or standards aimed at achieving similar or improved welfare standards as determined by subsequent scientific study.**

Or. en

Amendment 92

Proposal for a directive Article 32 – paragraph 3

Text proposed by the Commission

3. Member States may allow exemptions to paragraph 2 for animal welfare reasons.

Amendment

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

Or. en

Amendment 93

Proposal for a directive Article 33 – paragraph 4

Text proposed by the Commission

4. Records of all inspections shall be kept for at least five years.

Amendment

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.***

Or. en

Amendment 94

Proposal for a directive Article 34 – paragraph 1

Text proposed by the Commission

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

Amendment

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.***

Or. en

Justification

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

Amendment 95

Proposal for a directive Article 35 – paragraph 1

Text proposed by the Commission

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

Amendment

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.**

Or. en

Justification

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

Amendment 96

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

Text proposed by the Commission

1. The user establishment shall submit an application for the project authorisation, which shall include the following:

Amendment

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:

Or. en

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 97

Proposal for a directive

Article 37 – paragraph 1 – point b

Text proposed by the Commission

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

Amendment

b) the purposes of the project ***are justified by the possible pain, suffering, distress or lasting harm which will be involved for the*** animals.

Or. en

Amendment 98

Proposal for a directive

Article 37 – paragraph 2 – point d

Text proposed by the Commission

(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;

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 ***may*** ultimately ***benefit*** human beings, animals or the environment;

Or. en

Amendment 99

Proposal for a directive

Article 37 – paragraph 3 – introductory part

Text proposed by the Commission

3. The competent authority carrying out the ethical evaluation shall consider experts in

Amendment

3. For projects classified as "severe" or for those using non-human primates, the

particular in the following areas:

competent authority carrying out the ethical evaluation shall consider experts in particular in the following areas:

Or. en

Amendment 100

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 the opinion of independent parties. ***For intellectual property and security reasons, confidential information should be kept.***

Or. en

Amendment 101

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. All projects shall undergo a retrospective review by the permanent ethical review body which will submit the results of such review to the competent authority.

Or. en

Justification

It is necessary to avoid duplication between annual review and retrospective review.

Amendment 102

Proposal for a directive

Article 38 – paragraph 1 – subparagraph 2

Text proposed by the Commission

Amendment

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

deleted

Or. en

Amendment 103

Proposal for a directive

Article 38 – paragraph 1a (new)

Text proposed by the Commission

Amendment

1a. The competent authority shall, in addition, perform a retrospective assessment of all projects classified as "severe" and all projects using non-human primates classified as "moderate" or "severe".

Or. en

Amendment 104

Proposal for a directive

Article 38 – paragraph 2 - introductory part

Text proposed by the Commission

Amendment

2. Retrospective assessment shall evaluate the following:

2. Retrospective assessment ***as referred to in paragraphs 1 and 1a*** shall evaluate the

following:

Or. en

Amendment 105

Proposal for a directive Article 38 – paragraph 3

Text proposed by the Commission

Amendment

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

Or. en

Amendment 106

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. *deleted*

Or. en

Amendment 107

Proposal for a directive

Article 40 – paragraph 1 - introductory part

Text proposed by the Commission

1. Subject to safeguarding confidential information, the non-technical project summary shall provide the following:

Amendment

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

Or. en

Amendment 108

Proposal for a directive

Article 40 – paragraph 1 - point a

Text proposed by the Commission

(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;

Amendment

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

Or. en

Amendment 109

Proposal for a directive

Article 40 – paragraph 4

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 110

Proposal for a directive Article 42 – paragraph 1

Text proposed by the Commission

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

Amendment

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.***

Or. en

Amendment 111

Proposal for a directive Article 42 – paragraph 2

Text proposed by the Commission

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

Amendment

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

Or. en

Justification

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

Amendment 112

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.

Or. en

Amendment 113

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.***

Or. en

Amendment 114

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***

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.

protection of public health, safety or the environment.

Or. en

Amendment 115

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

Or. en

Amendment 116

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

Text proposed by the Commission

Amendment

2a. Subject to safeguarding 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.

Or. en

Amendment 117

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 his proposed project already exists and, if so, to access it (including contributing towards the cost thereof), and Member States shall similarly verify whether such data exists before granting an authorisation.

Or. en

Amendment 118

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 the reasonable steps required by paragraph 3

Or. en

Amendment 119

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

Or. en

Amendment 120

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 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. ***It is appropriate to establish large scale veterinary biobanks to support the 3Rs initiative using surplus tissue taken as part of clinical procedures.***

Or. en

Amendment 121

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.

Or. en

Amendment 122

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

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 123

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

Text proposed by the Commission

(e) provide training on the use of alternative methods to persons referred to in Article 20(1).

Amendment

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

Or. en

Amendment 124

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

Or. en

Amendment 125

Proposal for a directive Article 48 - paragraph 1

Text proposed by the Commission

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

Amendment

The Commission may adapt **Annexes I to VII** to technical and scientific progress.

Or. en

Justification

Those annexes should be subject to comitology review as they rely on evolving science.

Amendment 126

**Proposal for a directive
Article 53**

Text proposed by the Commission

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.

Amendment

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.

Or. en

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 127

**Proposal for a directive
Annex I - Title**

Text proposed by the Commission

Invertebrate **Species** referred to in Article 2 (2)

Amendment

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

Or. en

Amendment 128

**Proposal for a directive
Annex I – line 1**

Text proposed by the Commission

Amendment

Cyclostomes

deleted

Or. en

Justification

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

Amendment 129

**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

Or. en

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 130

**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

Or. en

Amendment 131

Proposal for a directive Annex IV – Title

Text proposed by the Commission

Amendment

Care and accomodation **standards** referred to in Article 32

Care and accomodation **guidelines** referred to in Article 32

Or. en

Justification

The Council of Europe prososed guidelines, it has to be like that also in the proposition of the Commission.

Amendment 132

Proposal for a directive Annex V – title

Text proposed by the Commission

Amendment

Humane Methods of Killing of animals

Recommended guidelines for Humane Methods of Killing of animals

Or. en

Justification

There will be restricted opportunities to refine methods if it is necessary to conform to a prescriptive list.

Amendment 133

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***
- 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 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 eg 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 (eg. kidney,
pancreas)*

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

Or. en

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.