Tab. 1: Comparison of the Directives from 2010 and 1986

DIRECTIVE 2010/…/EU of 8 August 2010 on the protection of animals used for scientific purposes	**COUNCIL DIRECTIVE of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (86/609/EEC)**	**Comments**
Article 1 **Subject matter and scope**		
1. This Directive establishes measures for the protection of animals used for scientific or educational purposes. To that end, it lays down rules on the following: (a) the replacement and reduction of the use of animals in procedures and the refinement of the breeding, accommodation, care and use of animals in procedures; (b) the origin, breeding, marking, care and accommodation and killing of animals; (c) the operations of breeders, suppliers and users; (d) the evaluation and authorisation of projects involving the use of animals in procedures.	Article 1 The aim of this Directive is to ensure that where animals are used for experimental or other scientific purposes the provisions laid down by law, regulation or administrative provisions in the Member States for their protection are approximated so as to avoid affecting the establishment and functioning of the common market, in particular by distorsions of competition or barriers to trade. Article 3 This Directive applies to the use of animals in experiments which are undertaken for one of the following purposes: (a) the development, manufacture, quality, effectiveness and safety testing of drugs, foodstuffs and other substances or products: (i) for the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality or their effects in man, animals or plants; (ii) for the assessment, detection, regulation or modification of physiological conditions in man, animals or plants; (b) the protection of the natural environment in the interests of the health or welfare of man or animal.	New: - educational purposes - reference to 3Rs - inclusion of breeding and supply - no positive list, to which type of procedures the Directive applies. This is a fundamental difference in comparison to the old Directive, which defined ‘the scope’ with the positive list. Thus anything outside the scope was merely just not regulated. The new Directive uses the positive list to state the areas for which purposes animals ***can be used.*** Thus any other use will be prohibited in the future (within the context of the area of competence of the Community e.g. excluding use of animals for the benefit of national for security).
2. This Directive shall apply where animals are used or intended to be used in procedures, or bred specifically so that their organs or		**New:** - inclusion of “intended to be used”

tissues may be used for scientific purposes. This Directive shall apply until the animals referred to in the first subparagraph have been killed, rehomed or returned to a suitable habitat or husbandry system. The elimination of pain, suffering, distress or lasting harm by the successful use of anaesthesia, analgesia or other methods shall not exclude the use of an animal in procedures from the scope of this Directive.		- inclusion of animals bred for their organs and tissue - redefinition of end of procedure
3. This Directive shall apply to the following animals: (a) live non-human vertebrate animals, including: i) independently feeding larval forms, and ii) foetal forms of mammals as from the last third of their normal development; (b) live cephalopods.	Article 2 For the purposes of this Directive the following definitions shall apply: (a) 'animal' unless otherwise qualified, means any live non-human vertebrate, including free-living larval and/or reproducing larval forms, but excluding foetal or embryonic forms;	New: - extension to foetal organisms and cephalopods
4. 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 3, if the animal is to be allowed to live beyond that stage of development and, as a result of the procedures performed, is likely to experience pain, suffering, distress or lasting harm after it has reached that stage of development.		Clarification for treatment of mothers or early life forms
5. This Directive shall not apply to the following: (a) non-experimental agricultural practices; (b) non-experimental clinical veterinary practices; (c) veterinary clinical trials required for the marketing authorisation of a veterinary medicinal product; (d) practices undertaken for the purposes of recognised animal husbandry;	Article 2 (d) …Non experimental, agricultural or clinical veterinary practices are excluded;	New: - Exclusion of veterinary clinical trials required for the marketing authorisation of a veterinary medicinal product

(e) practices undertaken for the primary purpose of identification of an animal; (f) practices not likely to cause pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice.		
6. This Directive shall apply without prejudice to Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products.		Referring to: Regulation (EC) No 1223/2009 of 30 November 2009 on cosmetic products, which applies as from 11 July 2013, which revised the 7th amendment of the cosmetics directive from 2003.
Article 2 **Stricter national measures**		
1. Member States may, while observing the general rules laid down in the Treaty, maintain provisions in force on [EiF], aimed at ensuring more extensive protection of animals falling within the scope of this Directive than those contained in this Directive. Before [1 January of the third year following the EiF] Member States shall inform the Commission about such national provisions. The Commission shall bring them to the attention of other Member States.	Article 24 This Directive shall not restrict the right of the Member States to apply or adopt stricter measures for the protection of animals used in experiments or for the control and restriction of the use of animals for experiments. In particular, Member States may require a prior authorization for experiments or programmes of work notified in accordance with the provisions of Article 12 (1).	Change in attitude, which led to strong concerns by animal welfare groups. Compare to recital (7): *"In the interests of the animals, and provided is does not affect the functioning of the internal market, it is appropriate to allow the Member States certain flexibility to maintain national rules aimed at more extensive protection of animals in so far as they are compatible with the treaty."*
2. When acting pursuant to paragraph 1, a Member State shall not prohibit or impede the supply or use of animals bred or kept in another Member State in accordance with this Directive, nor shall it prohibit or impede the placing on the market of products developed with the use of such animals in accordance with this Directive.		Consequence of Common Market
Article 3 **Definitions**		
(1) "procedure" means any use, invasive or non-invasive, of an animal for experimental or other scientific purposes, with known or unknown outcome, or educational purposes,	Article 2 (b) 'experimental animals' means animals used or to be used in	New: - broader definition of "procedure" and "project" instead of experiment, including education, organ donation,

which may cause the animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice. This includes any course of action intended, or liable, to result in the birth or hatching of an animal or the creation and maintenance of a genetically modified animal line in any such condition, but excludes the killing of animals solely for the use of their organs or tissues;	experiments; (d) 'experiment' means any use of an animal for experimental or other scientific purposes which may cause it 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, but excluding the least painful methods accepted in modern practice (i.e. 'humane' methods) of killing or marking an animal; an experiment starts when an animal is first prepared for use and ends when no further observations are to be made for that experiment; the elimination of pain, suffering, distress or lasting harm by the successful use of anaesthesia or analgesia or other methods does not place the use of an animal outside the scope of this definition. Non experimental, agricultural or clinical veterinary practices are excluded;	genetic modification and use of animals for routine production. - Often confused issues: Killing is not within the scope of a "procedure", however, it does not exclude those animals from the scope of this Directive i.e. animals bred for the purpose of their organs and their tissue are within the scope throughout their lifetime (cross ref. housing and care requirements) and the killing has to be carried out as per Article 6.
(2) "project" means a programme of work having a defined scientific objective and involving one or more procedures;		New definition.
(3) "establishment" means any installation, building, group of buildings or other premises and may include a place that is not wholly enclosed or covered and mobile facilities;	Article 2 (g) 'establishment' means any installation, building, group of buildings or other premises and may include a place which is not wholly enclosed or covered and mobile facilities;	
(4) "breeder" means any natural or legal person breeding animals referred to in Annex I with a view to their use in procedures or for the use of their tissue or organs for scientific purposes, or breeding other animals primarily for those purposes, whether for profit or not;	Article 2 (c) 'bred animals' means animals specially bred for use in experiments in facilities approved by, or registered with, the authority; (h) 'breeding establishment' means any establishment where animals are bred with a view to their use in experiments;	
(5) "supplier" means any natural or legal person, other than a breeder, supplying animals with a view to their use in procedures or for the use of their tissue or organs for scientific	Article 2 (i) 'supplying establishment' means any establishment, other than a breeding establishment, from which	

purposes, whether for profit or not;	animals are supplied with a view to their use in experiments;	
(6) "user" means any natural or legal person using animals in procedures, whether for profit or not;	Article 2 (j) 'user establishment' means any establishment where animals are used for experiments;	
(7) "competent authority" means an authority or authorities or bodies designated by a Member State to carry out the obligations arising from this Directive.	Article 2 (e) 'authority' means the authority or authorities designated by each Member State as being responsible for supervising the experiments within the meaning of this Directive;	
	Article 2 (f) 'competent person' means any person who is considered by a Member State to be competent to perform the relevant function described in this Directive; (k) 'properly anaesthetized' means deprived of sensation by methods of anaesthesia (whether local or general) as effective as those used in good veterinary practice; (l) 'humane method of killing' means the killing of an animal with a minimum of physical and mental suffering, depending on the species.	No longer defined
Article 4 **Principle of replacement, reduction and refinement**		
1. Member States shall ensure that, wherever possible, a scientifically satisfactory method or testing strategy, not entailing the use of live animals, shall be used instead of a procedure.	Article 7 2. An experiment shall not be performed if another scientifically satisfactory method of obtaining the result sought, not entailing the use of an animal, is reasonably and practicably available.	This has led to enormous discussions about the legal difference between “wherever possible” and “reasonably and practicably available”. Most probably they are minor, but interpretation might be influenced by Article 13, especially because of Article 4 (4).
2. Member States shall ensure that the number of animals used in projects is reduced to a minimum without compromising the objectives of the project.		

3. Member States shall ensure refinement of breeding, accommodation and care, and of methods used in procedures, eliminating or reducing to the minimum any possible pain, suffering, distress or lasting harm to the animals.	[see also new Article 22, old Article 19]	
4. This Article shall, in the choice of methods, be implemented in accordance with Article 13.		See above (1).
Article 5 **Purposes of procedures**		
Procedures may be carried out for the following purposes only: (a) basic research; (b) translational or applied research with any of the following aims: (i) the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality or their effects in human beings, animals or plants; (ii) the assessment, detection, regulation or modification of physiological conditions in human beings, animals or plants; or (iii) the welfare of animals and the improvement of the production conditions for animals reared for agricultural purposes. (c) for any of the aims in point (b) in the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs and other substances or products; (d) protection of the natural environment in the interests of the health or welfare of human beings or animals; (e) research aimed at preservation of the species; (f) higher education, or training for the acquisition, maintenance or	[see also new Article 1, old Article 3]	New: - extension to basic research, welfare of animals / production conditions, preservation of the species, higher education / vocational training and forensic inquiries - restriction of development, manufacture, quality, effectiveness and safety testing to aims under (b) See also Article 1

improvement of vocational skills; (g) forensic inquiries.		
Article 6 **Methods of killing**		
1. Member States shall ensure that animals are killed with minimum pain, suffering and distress.	[see also new Article 17, old Article 9 (4)]	
2. Member States shall ensure that animals are killed in the establishment of a breeder, supplier or user, by a competent person. However, in the case of a field study an animal may be killed by a competent person outside of an establishment.		
3. In relation to the animals covered by Annex IV, the appropriate method of killing as set out in that Annex shall be used.		
4. Competent authorities may grant exemptions from the requirement in paragraph 3: (a) to allow the use of another method provided that, on the basis of scientific evidence, the method is considered to be at least as humane; or (b) when, on the basis of scientific justification, the purpose of the procedure cannot be achieved by the use of a method of killing set out in Annex IV.		
5. Paragraphs 2 and 3 shall not apply where an animal has to be killed in emergency circumstances for animal-welfare, public-health, public-security, animal-health or environmental reasons.		
CHAPTER II **PROVISIONS ON THE USE** **OF CERTAIN ANIMALS** **IN PROCEDURES** **Article 7** **Endangered species**		

1. Specimens of those endangered species listed in Annex A to Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein, which do not fall within the scope of Article 7(1) of that Regulation, shall not be used in procedures, with the exception of those procedures meeting the following conditions: (a) the procedure has one of the purposes referred to in points (b)(i), (c) or (e) of Article 5 of this Directive; and (b) there is scientific justification to the effect that the purpose of the procedure cannot be achieved by the use of species other than those listed in that Annex.	Article 4 Each Member State shall ensure that experiments using animals considered as endangered under Appendix I of the Convention on International Trade in Endangered Species of Fauna and Flora and Annex C.I. of Regulation (EEC) N° 3626/82 (1) are prohibited unless they are in conformity with the above Regulation and the objects of the experiment are: - research aimed at preservation of the species in question, or - essential biomedical purposes where the species in question exceptionally proves to be the only one suitable for those purposes.	
2. Paragraph 1 shall not apply to any species of non-human primates.		
Article 8 **Non-human primates**		
1. Subject to paragraph 2, specimens of non-human primates shall not be used in procedures, with the exception of those procedures meeting the following conditions: (a) the procedure has one of the purposes referred to in (i) points (b)(i) or (c) of Article 5 of this Directive and is undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings; or (ii) points (a) or (e) of Article 5; and (b) there is scientific justification to the effect that the purpose of the procedure cannot be achieved by the use of species other than non-human primates. A debilitating clinical condition for the purposes of this Directive means a reduction in a person's normal physical or psychological ability to function.		New: - restriction of non-human primate use, though “A debilitating clinical condition for the purposes of this Directive means a reduction in a person's normal physical or psychological ability to function.”

2. Specimens of non-human primates listed in Annex A to Regulation (EC) No 338/97, which do not fall within the scope of Article 7(1) of that Regulation, shall not be used in procedures, with the exception of those procedures meeting the following conditions: (a) the procedure has one of the purposes referred to in (i) points (b)(i) or (c) of Article 5 of this Directive and is undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings; or (ii) point (e) of Article 5; and (b) there is scientific justification to the effect that the purpose of the procedure cannot be achieved by the use of species other than non-human primates and by the use of species not listed in that Annex.		
3. Notwithstanding paragraphs 1 and 2, great apes shall not be used in procedures, subject to the use of the safeguard clause in Article 55(2).		New: - ban of great ape use, though with a safeguard clause
Article 9 **Animals taken from the wild**		
1. Animals taken from the wild shall not be used in procedures.	Article 7 3. …Experiments on animals taken from the wild may not be carried out unless experiments on other animals would not suffice for the aims of the experiment.	New: - stricter wording against use of wild animals
2. Competent authorities may grant exemptions from paragraph 1 on the basis of scientific justification to the effect that the purpose of the procedure cannot be achieved by the use of an animal which has been bred for use in procedures.		
3. The capture of animals in the wild shall be carried out only by competent persons using methods which do not cause the animals avoidable pain, suffering, distress or lasting harm. Any animal found, at or after capture, to be injured or in poor health shall be		

examined by a veterinarian or another competent person and action shall be taken to minimise the suffering of the animal. Competent authorities may grant exemptions from the requirement of taking action to minimise the suffering of the animal if there is scientific justification.		
Article 10 **Animals bred for use in procedures**		
1. Member States shall ensure that animals belonging to the species listed in Annex I may only be used in procedures where those animals have been bred for use in procedures. However, from the dates set out in Annex II, Member States shall ensure that non-human primates listed therein may be used in procedures only where they are the offspring of non-human primates which have been bred in captivity or where they are sourced from self-sustaining colonies. For the purposes of this Article a "self-sustaining colony" means a colony in which animals are bred only within the colony or sourced from other colonies but not taken from the wild, and where the animals are kept in a way that ensures that they are accustomed to humans. The Commission shall, in consultation with the Member States and stakeholders, conduct a feasibility study, which shall include an animal health and welfare assessment, of the requirement laid down in the second subparagraph. The study shall be published no later than [7 years after the EiF]. It shall be accompanied, where appropriate, by proposals for amendments to Annex II.	Article 15 Breeding and supplying establishments shall be approved by or registered with, the authority and comply with the requirements of Articles 5 and 14 unless an exemption is granted under Article 19 (4) or Article 21. Article 19 … 4. In user establishments, only animals from breeding or supplying establishments shall be used unless a general or special exemption has been obtained under arrangements determined by the authority. Bred animals shall be used whenever possible. … Article 21 Animals belonging to the species listed in Annex I which are to be used in experiments shall be bred animals unless a general or special exemption has been obtained under arrangements determined by the authority.	Annex I 1. Mouse (Mus musculus) 2. Rat (Rattus norvegicus) 3. Guinea pig (Cavia porcellus) 4. Syrian (golden) hamster (Mesocricetus auratus) 5. Chinese hamster (Cricetulus griseus) 6. Mongolian gerbil (Meriones unguiculatus) 7. Rabbit (Oryctolagus cuniculus) 8. Dog (Canis familiaris) 9. Cat (Felis catus) 10. All species of non-human primates 11. Frog (Xenopus (laevis, tropicalis), Rana (temporaria, pipiens)) 12. Zebra fish (Danio rerio)
2. The Commission shall keep under review the use of sourcing non-human primates from self-sustaining colonies and, in consultation with the Member States and stakeholders, conduct a study to analyse the feasibility of sourcing animals only from self-sustaining colonies. The study shall be published no later		New: - requirement to move over to second or higher generation purpose-bred non-human primates subject to a feasibility study - explore self-sustaining colonies for non-human primate breeding

than [12 years after the EiF].		
3. Competent authorities may grant exemptions from paragraph 1 on the basis of scientific justification.		
Article 11 **Stray and feral animals of domestic species**		
1. Stray and feral animals of domestic species shall not be used in procedures.	Article 15 …A supplying establishment shall obtain animals only from a breeding or other supplying establishment unless the animal has been lawfully imported and is not a feral or stray animal. Article 19 … 4. …Stray animals of domestic species shall not be used in experiments. A general exemption made under the conditions of this paragraph may not extend to stray dogs and cats.	
2. The competent authorities may only grant exemptions from paragraph 1 subject to the following conditions: (a) there is an essential need for studies concerning the health and welfare of the animals or serious threats to the environment or to human or animal health, and (b) there is scientific justification to the effect that the purpose of the procedure can be achieved only by the use of a stray or a feral animal.	Article 15 …General or special exemption from this last provision may be granted to a supplying establishment under arrangements determined by the authority.	New: - stricter wording for exemptions for use of stray and feral animals
CHAPTER III **PROCEDURES** **Article 12** **Procedures**		
1. Member States shall ensure that procedures are carried out in a user's establishment. The competent authority may grant an exemption from the first subparagraph	Article 19 1. User establishments shall be registered with, or approved by, the authority. …	

on the basis of scientific justification.	3. Experiments may, where authorized by the authority, be conducted outside user establishments.	
2. Procedures may be carried out only within the framework of a project.		New: - no isolated experiments that are not part of a larger project shall be authorised
Article 13 **Choice of methods**		
1. Without prejudice to national legislation prohibiting certain types of methods, Member States shall ensure that a procedure is not carried out if another method or testing strategy for obtaining the result sought, not entailing the use of a live animal, is recognized under the legislation of the Union.	[see also new Article 4, old Article 7]	New: - accepted alternative methods have to be used This led to enormous discussion, whether this weakens the “alternative clause” of Article 4, since the requirement is only for methods accepted in legislation (validated or not). Common interpretation is that this only stresses in addition to Article 4 the need to use accepted alternative methods for regulatory testing.
2. In choosing between procedures, those which to the greatest extent meet the following requirements shall be selected, that is to say those which: (a) use the minimum number of animals, (b) involve animals with the lowest capacity to experience pain, suffering, distress or lasting harm, (c) cause the least pain, suffering, distress or lasting harm, and are most likely to provide satisfactory results.	Article 7 3. When an experiment has to be performed, the choice of species shall be carefully considered and, where necessary, explained to the authority. In a choice between experiments, those which use the minimum number of animals, involve animals with the lowest degree of neurophysiological sensitivity, cause the least pain, suffering, distress or lasting harm and which are most likely to provide satisfactory results shall be selected.	- reduce, refine and use of lower species, i.e. with lowest capacity to experience pain, suffering, distress or lasting harm
3. Death as the end-point of a procedure shall be avoided as far as possible and replaced by early and humane end-points. Where death as the end-point is unavoidable, the procedure shall be designed so as to: (a) result in the deaths of as few animals as possible; and (b) reduce the duration and intensity of suffering to the animal to the minimum possible and, as far as		New: - avoidance of death as endpoint

possible, ensure a painless death.		
Article 14 **Anaesthesia**		
1. Member States shall ensure that, unless it is inappropriate, procedures are carried out under general or local anaesthesia, and that analgesia or another appropriate method is used to ensure that pain, suffering and distress are kept to a minimum. Procedures that involve serious injuries that may cause severe pain shall not be carried out without anaesthesia.	Article 7 4. All experiments shall be designed to avoid distress and unnecessary pain and suffering to the experimental animals. They shall be subject to the provisions laid down in Article 8. The measures set out in Article 9 shall be taken in all cases. Article 8 1. All experiments shall be carried out under general or local anaesthesia.	
2. When deciding on the appropriateness of using anaesthesia, the following shall be taken into account: (a) whether anaesthesia is judged to be more traumatic to the animal than the procedure itself; and (b) whether anaesthesia is incompatible with the purpose of the procedure.	Article 8 2. Paragraph 1 above does not apply when: (a) anaesthesia is judged to be more traumatic to the animal than the experiment itself; (b) anaesthesia is incompatible with the object of the experiment. In such cases appropriate legislative and/or administrative measures shall be taken to ensure that no such experiment is carried out unnecessarily. Anaesthesia should be used in the case of serious injuries which may cause severe pain. 3. If anaesthesia is not possible, analgesics or other appropriate methods should be used in order to ensure as far as possible that pain, suffering, distress or harm are limited and that in any event the animal is not subject to severe pain, distress or suffering.	
3. Member States shall ensure that animals are not given any drug to stop or restrict their showing pain without an adequate level of anaesthesia or analgesia. In these cases, a scientific justification shall be provided, accompanied by the		**New**: Neuromuscular blocking agents cannot be used without anaesthesia or analgesia. In addition, their use requires a scientific justification.

details of the anaesthetic or analgesic regimen.		
4. An animal, which may suffer pain once anaesthesia has worn off, shall be treated with pre-emptive and post-operative analgesics or other appropriate pain-relieving methods provided that it is compatible with the purpose of the procedure.	Article 8 4. Provided such action is compatible with the object of the experiment, an anaesthetized animal, which suffers considerable pain once anaesthesia has worn off, shall be treated in good time with pain-relieving means or, if this is not possible, shall be immediately killed by a humane method.	
5. As soon as the purpose of the procedure has been achieved appropriate action shall be taken to minimise the suffering of the animal.		
Article 15 **Classification of severity of procedures**		
1. Member States shall ensure that all procedures are classified as "non-recovery", "mild", "moderate", or "severe" on a case-by-case basis using the assignment criteria set out in Annex VIII.	Article 12 … 2. Where it is planned to subject an animal to an experiment in which it will, or may, experience severe pain which is likely to be prolonged, that experiment must be specifically declared and justified to, or specifically authorized by, the authority. …	New: - concept of severity
2. Subject to the use of the safeguard clause in Article 55(3), Member States shall ensure that a procedure is not performed if it involves severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.	Article 12 2. … The authority shall take appropriate judicial or administrative action if it is not satisfied that the experiment is of sufficient importance for meeting the essential needs of man or animal.	New: - ban of very severe procedures which are long lasting and cannot be ameliorated
Article 16 **Reuse**		
1. Member States shall ensure that an animal already used in one or more procedures, when a different animal on which no procedure has previously been carried out could also be used, may only be reused in a new procedure provided that the following conditions are met:	Article 10 Member States shall ensure that any re-use of animals in experiments shall be compatible with the provisions of this Directive. In particular, an animal shall not be used more than once in experiments	

(a) the actual severity of the previous procedures was "mild" or "moderate"; (b) it is demonstrated that the animal's general state of health and well-being has been fully restored; (c) the further procedure is classified as "mild", "moderate" or "non-recovery"; and (d) it is in accordance with veterinary advice, taking into account the lifetime experience of the animal.	entailing severe pain, distress or equivalent suffering.	
2. In exceptional circumstances, by way of derogation from point (a) of paragraph 1 and after a veterinary examination of the animal, the competent authority may allow reuse of an animal, provided the animal has not been used more than once in a procedure entailing severe pain, distress or equivalent suffering.		
Article 17 **End of the procedure**		
1. A procedure shall be deemed to end when no further observations are to be made for that procedure or, as regards new genetically modified animal lines, when the progeny are no longer observed or expected to experience pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle.		- New definition on until when the creation of a GM-line continues to be considered a "procedure"
2. At the end of a procedure, a decision to keep an animal alive shall be taken by a veterinarian or by another competent person. An animal shall be killed when it is likely to remain in moderate or severe pain, suffering, distress or lasting harm.	Article 9 1. At the end of any experiment, it shall be decided whether the animal shall be kept alive or killed by a humane method, subject to the condition that it shall not be kept alive if, even though it has been restored to normal health in all other respects, it is likely to remain in lasting pain or distress. 2. The decisions referred to in paragraph 1 shall be taken by a competent person, preferably a veterinarian. 3. … (b) an animal is not to be kept alive or cannot benefit from the provisions of	

	Article 5 concerning its well-being, it shall be killed by a humane method as soon as possible.	
3. Where an animal is to be kept alive, it shall receive care and accommodation appropriate to its state of health.	Article 9 3. Where, at the end of an experiment: (a) an animal is to be kept alive, it shall receive the care appropriate to its state of health, be placed under the supervision of a veterinarian or other competent person and shall be kept under conditions conforming to the requirements of Article 5. The conditions laid down in this subparagraph may, however, be waived where, in the opinion of a veterinarian, the animal would not suffer as a consequence of such exemption; …	
Article 18 **Sharing organs and tissues**		
Member States shall facilitate, where appropriate, the establishment of programmes for the sharing of organs and tissues of animals killed.		New: - facilitate sharing of organs and tissues
Article 19 **Setting free of animals and rehoming**		
Member States may allow animals used or intended to be used in procedures to be rehomed, or returned to a suitable habitat or husbandry system appropriate to the species, provided that the following conditions are met: (a) the state of health of the animal allows it; (b) there is no danger to public health, animal health or the environment; and (c) appropriate measures have been taken to safeguard the well-being of the animal.	Article 11 Notwithstanding the other provisions of this Directive, where it is necessary for the legitimate purposes of the experiment, the authority may allow the animal concerned to be set free, provided that it is satisfied that the maximum possible care has been taken to safeguard the animal's well-being, as long as its state of health allows this to be done and there is no danger for public health and the environment.	New: - rehoming explicitly allowed
CHAPTER IV **AUTHORISATION** **SECTION 1** **REQUIREMENTS FOR BREEDERS,**		

SUPPLIERS AND USERS **Article 20** **Authorisation of breeders, suppliers and users**		
1. Member States shall ensure that all breeders, suppliers and users are authorised by, and registered with, the competent authority. Such authorisation may be granted for a limited period. Authorisation shall be granted only if the breeder, supplier or user and its establishment is in compliance with the requirements of this Directive.	Article 7 1. Experiments shall be performed solely by competent authorized persons, or under the direct responsibility of such a person, or if the experimental or other scientific project concerned is authorized in accordance with the provisions of national legislation. (see also article 15 old, article 10 new) Article 12 1. Member States shall establish procedures whereby experiments themselves or the details of persons conducting such experiments shall be notified in advance to the authority. …	
2. The authorisation shall specify the person responsible for ensuring compliance with the provisions of this Directive and the person or persons referred to in Article 24(1) and in Article 25.		
3. Renewal of the authorisation shall be required for any significant change to the structure or the function of an establishment of a breeder, supplier or user that could negatively affect animal welfare.		
4. Member States shall ensure that the competent authority is notified of any changes of the person or persons referred to in paragraph 2.		
Article 21 **Suspension and withdrawal of authorisation**		
1. Where a breeder, supplier or user no longer complies with the requirements set out in this Directive, the competent authority shall take appropriate remedial action, or require such action to be taken, or suspend or withdraw its authorisation.		

2. Member States shall ensure that, where the authorisation is suspended or withdrawn, the welfare of the animals housed in the establishment is not adversely affected.		
Article 22 **Requirements for installations and equipment**		
1. Member States shall ensure that all establishments of a breeder, supplier or user have installations and equipment suited to the species of animals housed and, where procedures are carried out, to the performance of the procedures.	[see Article 33 new, Article 5 old]	
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, and aim at obtaining reliable results using the minimum number of animals and causing the minimum degree of pain, suffering, distress or lasting harm.	Article 19 1. …Arrangements shall be made for user establishments to have installations and equipment suited to the species of animals used and the performance of the experiments conducted there; their design, construction and method of functioning shall be such as to ensure that the experiments are performed as effectively as possible, with the object of obtaining consistent results with the minimum number of animals and the minimum degree of pain, suffering, distress or lasting harm.	
3. For the purposes of implementation of paragraphs 1 and 2, Member States shall ensure that the relevant requirements as set out in Annex III are complied with.	Article 5 …For the implementation of the provisions of paragraphs (a) and (b), Member States shall pay regard to the guidelines set out in Annex II.	New: - From housing and care guidance (legally not binding) to standards (legally binding), a key element to achieve good animal welfare.
Article 23 **Competence of personnel**		
1. Member States shall ensure that each breeder, supplier and user has sufficient staff on site.		
2. The staff shall be adequately educated and trained before they perform any of the following functions: (a) carrying out procedures on animals;	Article 14 Persons who carry out experiments or take part in them and persons who take care of animals used for experiments, including duties of a supervisory nature, shall have appropriate education and training. In particular, persons carrying out or	New: - requirement to work under supervision until competence has been demonstrated.

(b) designing procedures and projects; (c) taking care of animals; or (d) killing animals. Persons carrying out the functions referred to in point (b) shall have received instruction in a scientific discipline relevant to the work being undertaken and shall have species-specific knowledge. Staff carrying out functions referred to in points (a), (c) or (d) shall be supervised in the performance of their tasks until they have demonstrated the requisite competence. Member States shall ensure, through authorisation or by other means, that the requirements laid down in this paragraph are fulfilled.	supervising the conduct of experiments shall have received instruction in a scientific discipline relevant to the experimental work being undertaken and be capable of handling and taking care of laboratory animals; they shall also have satisfied the authority that they have attained a level of training sufficient for carrying out their tasks.	
3. Member States shall publish, on the basis of the elements set out in Annex V, minimum requirements with regard to education and training and the requirements for obtaining, maintaining and demonstrating requisite competence for the functions set out in paragraph 2.		New: - minimum requirements for curriculum Annex V 1. National legislation in force relevant to the acquisition, husbandry, care and use of animals for scientific purposes. 2. Ethics in relation to human-animal relationship, intrinsic value of life and arguments for and against the use of animals for scientific purposes. 3. Basic and appropriate species-specific biology in relation to anatomy, physiological features, breeding, genetics and genetic alteration. 4. Animal behaviour, husbandry and enrichment. 5. Species-specific methods of handling and procedures, where appropriate. 6. Animal health management and hygiene. 7. Recognition of species-specific distress, pain and suffering of most common laboratory species.

		8. Anaesthesia, pain relieving methods and killing. 9. Use of humane end-points. 10. Requirement of replacement, reduction and refinement. 11. Design of procedures and projects, where appropriate.
4. Non-binding guidelines at the level of the Union on the requirements laid down in paragraph 2 may be adopted in accordance with the advisory procedure referred to in Article 56(2).		
Article 24 **Specific requirements for personnel**		
1. Member States shall ensure that each breeder, supplier and user has one or several persons on site who shall: (a) be responsible for overseeing the welfare and care of the animals in the establishment; (b) ensure that the staff dealing with animals have access to information specific to the species housed in the establishment; (c) be responsible for ensuring that the staff are adequately educated, competent and continuously trained and that they are supervised until they have demonstrated the requisite competence.	Article 19 … 2. In each user establishment: (a) the person or persons who are administratively responsible for the care of the animals and the functioning of the equipment shall be identified; (b) sufficient trained staff shall be provided; (c) adequate arrangements shall be made for the provision of veterinary advice and treatment; (d) a veterinarian or other competent person should be charged with advisory duties in relation to the well-being of the animals.	New: - requirement for a named person responsible for the competence of staff
2. Member States shall ensure that persons specified in Article 40(2)(b) shall: (a) ensure that any unnecessary pain, suffering, distress or lasting harm that is being inflicted on an animal in the course of a procedure is stopped; and (b) ensure that the projects are carried out in accordance with the project authorization or, in the cases referred		New: - explicit animal welfare obligations for person named responsible

to in Article 42, in accordance with the application sent to the competent authority or any decision taken by the competent authority, and ensure that in the event of non-compliance, the appropriate measures to rectify it are taken and recorded.		
Article 25 **Designated veterinarian**		
Member States shall ensure that each breeder, supplier and user has a designated veterinarian with expertise in laboratory animal medicine, or a suitably qualified expert where more appropriate, charged with advisory duties in relation to the well-being and treatment of the animals.	Article 16 The approval or the registration provided for in Article 15 shall specify the competent person responsible for the establishment entrusted with the task of administering, or arranging for the administration of, appropriate care to the animals bred or kept in the establishment and of ensuring compliance with the requirements of Articles 5 and 14.	
Article 26 **Animal-welfare body**		
1. Member States shall ensure that each breeder, supplier and user sets up an animalwelfare body.		New: - institutional animal welfare body
2. The animal-welfare body shall include at least the person or persons responsible for the welfare and care of the animals and, in the case of a user, a scientific member. The animalwelfare body shall also receive input from the designated veterinarian or the expert referred to in Article 25.		
3. Member States may allow small breeders, suppliers and users to fulfil the tasks laid down in Article 27(1) by other means.		
Article 27 **Tasks of the animal-welfare body**		
1. The animal-welfare body shall, as a minimum, carry out the following tasks: (a) advise the staff dealing with animals on matters related to the welfare of animals, in relation to their acquisition, accommodation, care and use;		

(b) advise the staff on the application of the requirement of replacement, reduction and refinement, and keep it informed of technical and scientific developments concerning the application of that requirement; (c) establish and review internal operational processes as regards monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the establishment; (d) follow the development and outcome of projects, taking into account the effect on the animals used, and identify and advise as regards elements that further contribute to replacement, reduction and refinement; and (e) advise on rehoming schemes, including the appropriate socialisation of the animals to be rehomed.		
2. Member States shall ensure that the records of any advice given by the animal-welfare body and decisions taken regarding that advice are kept for at least three years. The records shall be made available to the competent authority upon request.		
Article 28 **Breeding strategy for non-human primates**		
Member States shall ensure that breeders 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.		New: - requirement to decrease captured non-human primate use in experiments and as breeders
Article 29 **Scheme for rehoming or setting free of animals**		
Where Member States allow rehoming, the breeders, suppliers and users from which animals are intended to be rehomed shall have a rehoming scheme in place that ensures socialisation of the animals that are rehomed. In the case of wild animals, where appropriate, a programme of rehabilitation shall be in		

place before they are returned to their habitat.		
Article 30 **Animal records**		
1. Member States shall ensure that all breeders, suppliers and users keep records of at least the following: (a) the number and the species of animals bred, acquired, supplied, used in procedures, set-free or rehomed; (b) the origin of the animals, including whether they are bred for use in procedures; (c) the dates on which the animals are acquired, supplied, released or rehomed; (d) from whom the animals are acquired; (e) the name and address of the recipient of animals; (f) the number and species of animals which died or were killed in each establishment. For animals that have died, the cause of death shall, when known, be noted; and (g) in the case of users, the projects in which animals are used.	Article 17 1. Breeding and supplying establishments shall record the number and the species of animals sold or supplied, the dates on which they are sold or supplied, the name and address of the recipient and the number and species of animals dying while in the breeding or supplying establishment in question. 2. Each authority shall prescribe the records which are to be kept and made available to it by the person responsible for the establishments mentioned in paragraph 1;… Article 19 … 5. User establishments shall keep records of all animals used and produce them whenever required to do so by the authority. In particular, these records shall show the number and species of all animals acquired, from whom they were acquired and the date of their arrival. Such records shall be kept for a minimum of three years and shall be submitted to the authority which asks for them.	New: - more explicit definition of animal records to be kept
2. The records referred to in paragraph 1 shall be kept for a minimum of five years and made available to the competent authority upon request.	Article 17 **…** such records shall be kept for a minimum of three years from the date of the last entry and shall undergo periodic inspection by officers of the authority.	New: - longer keeping of animal records
Article 31 **Information on dogs, cats and non-human primates**		

1. Member States shall ensure that all breeders, suppliers and users keep the following information on each dog, cat and non-human primate: (a) identity; (b) place and date of birth, when available; (c) whether it is bred for use in procedures; and (d) in the case of a non-human primate, whether it is the offspring of non-human primates that have been bred in captivity.	Article 18 … 4. Particulars of the identity and origin of each dog, cat or non-human primate shall be entered in the records of each establishment.	New: - more explicit definition of animal records to be kept for dogs, cats and non-human primates
2. Each dog, cat and non-human primate shall have an individual history file, which follows the animal as long as it is kept for the purposes of this Directive. The file shall be established at birth or as soon as possible thereafter and shall cover any relevant reproductive, veterinary and social information on the individual animal and the projects in which it has been used.		New: - individual history file also covering social information is introduced, not only for non-human primates but also for dogs and cats
3. The information referred to in this Article shall be kept for a minimum of three years after the death or rehoming of the animal and shall be made available to the competent authority upon request. In the case of rehoming, relevant veterinary care and social information from the individual history file referred to in paragraph 2 shall accompany the animal.		
Article 32 **Marking and identification of dogs, cats and non-human primates**		
1. Each dog, cat or non-human primate shall be provided, at the latest at the time of weaning, with a permanent individual identification mark in the least painful manner possible.	Article 18 1. Each dog, cat or non-human primate in any breeding, supplying or user establishment shall, before it is weaned, be provided with an individual identification mark in the least painful manner possible except in the cases referred to in paragraph 3. …	

2. Where a dog, cat or non-human primate is transferred from one breeder, supplier or user to another before it is weaned, and it is not practicable to mark it beforehand, a record, specifying in particular its mother, must be maintained by the receiver until it is marked.	Article 18 3. Where a dog, cat or non-human primate is transferred from one establishment as referred to in paragraph 1 to another before it is weaned, and it is not practicable to mark it beforehand, a full documentary record, specifying in particular its mother, must be maintained by the receiving establishment until it can be so marked.	
3. Where an unmarked dog, cat or non-human primate, which is weaned, is received by a breeder, supplier or user it shall be permanently marked as soon as possible and in the least painful manner possible.	Article 18 … 2. Where an unmarked dog, cat or non-human primate is taken into an establishment for the first time after it has been weaned it shall be marked as soon as possible. …	
4. The breeder, supplier and user shall provide, at the request of the competent authority, reasons for which the animal is unmarked.		
Article 33 **Care and accommodation**		
1. Member States shall, as far as the care and accommodation of animals is concerned, ensure that: (a) all animals are provided with accommodation, an environment, food, water and care which are appropriate to their health and well-being; (b) any restrictions on the extent to which an animal can satisfy its physiological and ethological needs are kept to a minimum; (c) the environmental conditions in which animals are bred, kept or used are checked daily; (d) arrangements are made to ensure that any defect or avoidable pain, suffering, distress or lasting harm discovered is eliminated as quickly as possible; and (e) animals are transported under	Article 5 Member States shall ensure that, as far as the general care and accommodation of animals is concerned: (a) all experimental animals shall be provided with housing, an environment, at least some freedom of movement, food, water and care which are appropriate to their health and well-being; (b) any restriction on the extent to which an experimental animal can satisfy its physiological and ethological needs shall be limited to the absolute minimum; (c) the environmental conditions in which experimental animals are bred, kept or used must be checked daily; (d) the well-being and state of health of experimental animals shall be	

appropriate conditions.	observed by a competent person to prevent pain or avoidable suffering, distress or lasting harm; (e) arrangements are made to ensure that any defect or suffering discovered is eliminated as quickly as possible….	
2. For the purposes of paragraph 1, Member States shall ensure that the care and accommodation standards set out in Annex III are applied from the dates provided for therein.		New: - detailed definition of standards of care in Annex III, which can be amended without revision of the entire legislation
3. Member States may allow exemptions from the requirements of paragraph 1(a) or paragraph 2 for scientific, animal-welfare or animal-health reasons.		
SECTION 2 **INSPECTIONS** **Article 34** **Inspections by the Member States**		
1. Member States shall ensure that the competent authorities carry out regular inspections of all breeders, suppliers and users, including their establishments, to verify compliance with the requirements of this Directive.	Article 19 … 5. … User establishments shall be subject to periodic inspection by representatives of the authority.	
2. The competent authority shall adapt the frequency of inspections on the basis of a risk analysis for each establishment, taking account of: (a) the number and species of animals housed; (b) the record of the breeder, supplier or user in complying with the requirements of this Directive; (c) the number and types of projects carried out by the user in question; and (d) any information that might indicate non-compliance.		New: - improved frequency of inspections
3. Inspections shall be carried out on at least one third of the users each year in accordance with the risk analysis referred to in paragraph 2. However, breeders, suppliers and		New: - unannounced inspections and use of a risk based approach

users of non-human primates shall be inspected at least once a year.		
4. An appropriate proportion of the inspections shall be carried out without prior warning.		
5. Records of all inspections shall be kept for at least five years.		
Article 35 **Controls of Member State inspections**		
1. The Commission shall, when there is due reason for concern, taking into account inter alia the proportion of inspections carried out without prior warning, undertake controls of the infrastructure and operation of national inspections in Member States.		New: - Commission to inspect Member State inspection systems
2. The Member State in the territory of which the control referred to in paragraph 1 is being carried out shall give all necessary assistance to the experts of the Commission in carrying out their duties. The Commission shall inform the competent authority of the Member State concerned of the results of the control.		
3. The competent authority of the Member State concerned shall take measures to take account of the results of the control referred to in paragraph 1.		
SECTION 3 **REQUIREMENTS FOR PROJECTS** **Article 36** **Project authorisation**		
1. Member States shall ensure, without prejudice to Article 42, that projects are not carried out without prior authorisation from the competent authority, and that projects are carried out in accordance with the authorisation or, in the cases referred to in Article 42, in accordance with the application sent to the competent authority or any decision taken by the competent authority.	Article 7 1. Experiments shall be performed solely by competent authorized persons, ….	

2. Member States shall ensure that no project is carried out unless a favourable project evaluation by the competent authority has been received in accordance with Article 38.		
Article 37 **Application for project authorisation**		
1. Member States shall ensure that an application for project authorisation is submitted by the user or the person responsible for the project. The application shall include at least the following: (a) the project proposal; (b) a non-technical project summary; and (c) information on the elements set out in Annex VI.		New: - detailed list of elements for applications for authorisation Annex VI 1. Relevance and justification of the following: (a) use of animals including their origin, estimated numbers, species and life stages; (b) procedures. 2. Application of methods to replace, reduce and refine the use of animals in procedures. 3. The planned use of anaesthesia, analgesia and other pain relieving methods. 4. Reduction, avoidance and alleviation of any form of animal suffering, from birth to death where appropriate. 5. Use of humane end-points. 6. Experimental or observational strategy and statistical design to minimise animal numbers, pain, suffering, distress and environmental impact where appropriate. 7. Reuse of animals and the accumulative effect thereof on the animals. 8. The proposed severity classification of procedures. 9. Avoidance of unjustified duplication of procedures where appropriate. 10. Housing, husbandry and care

		conditions for the animals. 11. Methods of killing. 12. Competence of persons involved in the project.
2. Member States may waive the requirement in paragraph 1(b) for projects referred to in Article 42(1).		
Article 38 **Project evaluation**		
1. The project evaluation shall be performed with a degree of detail appropriate for the type of project and shall verify that the project meets the following criteria: (a) the project is justified from a scientific or educational point of view or required by law; (b) the purposes of the project justify the use of animals; and (c) the project is designed so as to enable procedures to be carried out in the most humane and environmentally sensitive manner possible.		New: - strict minimum requirements for a systematic and comprehensive project evaluation covering o criteria o the steps (including a detailed list of minimum elements to cover the application of the Three Rs as specified in Annex VI) o expertise that needs to inform the process o impartiality and transparency
2. The project evaluation shall consist in particular of the following: (a) an evaluation of the objectives of the project, the predicted scientific benefits or educational value; (b) an assessment of the compliance of the project with the requirement of replacement, reduction and refinement; (c) an assessment and assignment of the classification of the severity of procedures; (d) a harm-benefit analysis of the project, to assess whether the harm to the animals in terms of suffering, pain and distress is justified by the expected outcome taking into account ethical considerations, and may ultimately benefit human beings, animals or the environment; (e) an assessment of any justification		

referred to in Articles 6 to 12, 14, 16, and 33; and (f) a determination as to whether and when the project should be assessed retrospectively.		
3. The competent authority carrying out the project evaluation shall consider expertise in particular in the following areas: (a) the areas of scientific use for which animals will be used including replacement, reduction and refinement in the respective areas; (b) experimental design, including statistics where appropriate; (c) veterinary practice in laboratory animal science or wildlife veterinary practice where appropriate; (d) animal husbandry and care, in relation to the species that are intended to be used.		
4. The project evaluation process shall be transparent. Subject to safeguarding intellectual property and confidential information, the project evaluation shall be performed in an impartial manner and may integrate the opinion of independent parties.		
Article 39 **Retrospective assessment**		
1. Member States shall ensure that when determined in accordance with Article 38(2)(f), the retrospective assessment shall be carried out by the competent authority which shall, on the basis of the necessary documentation submitted by the user, evaluate the following: (a) whether the objectives of the project were achieved; (b) the harm inflicted on animals, including the numbers and species of animals used, and the severity of the procedures; and (c) any elements that may contribute to the further implementation of the		New: - tailor-made retrospective evaluation of projects involving procedures with severe harm, projects involving non-human primates as well as those selected within the evaluation of applications

requirement of replacement, reduction and refinement.		
2. All projects using non-human primates and projects involving procedures classified as "severe", including those referred to in Article 15(2), shall undergo a retrospective assessment.		
3. Without prejudice to paragraph 2 and by way of derogation from Article 38(2)(f), Member States may exempt projects involving only procedures classified as "mild" or "non-recovery" from the requirement for a retrospective assessment.		
Article 40 **Granting of project authorisation**		
1. The project authorisation shall be limited to procedures which have been subject to: (a) a project evaluation; and (b) the severity classifications assigned to those procedures.		New: - detailed requirements for authorisations
2. The project authorisation shall specify the following: (a) the user who undertakes the project; (b) the persons responsible for the overall implementation of the project and its compliance with the project authorisation; (c) the establishments in which the project will be undertaken, where applicable; and (d) any specific conditions following the project evaluation, including whether and when the project shall be assessed retrospectively.		
3. Project authorisations shall be granted for a period not exceeding five years.		
4. Member States may allow the authorisation of multiple generic projects carried out by the		

same user if such projects are to satisfy regulatory requirements or if such projects use animals for production or diagnostic purposes with established methods.		
Article 41 **Authorisation decisions**		
1. Member States shall ensure that the decision regarding authorisation is taken and communicated to the applicant 40 working days at the latest from the receipt of the complete and correct application. This period shall include the project evaluation.		New: - detailed requirements for authorisation process
2. When justified by the complexity or the multi-disciplinary nature of the project, the competent authority may extend the period referred to in paragraph 1 once, by an additional period not exceeding 15 working days. The extension and its duration shall be duly motivated and shall be notified to the applicant before the expiry of the period referred to in paragraph 1.		
3. Competent authorities shall acknowledge to the applicant all applications for authorizations as quickly as possible, and shall indicate the period referred to in paragraph 1 within which the decision is to be taken.		
4. In the case of an incomplete or incorrect application, the competent authority shall, as quickly as possible, inform the applicant of the need to supply any additional documentation and of any possible effects on the running of the applicable time period.		
Article 42 **Simplified administrative procedure**		
1. Member States may decide to introduce a simplified administrative procedure for projects containing procedures classified as "non-recovery", "mild" or "moderate" and not using non-human primates, that are necessary to satisfy regulatory requirements, or which use animals for production or diagnostic purposes with established methods.		New: - option for simplified authorisation process

2. When introducing a simplified administrative procedure, Member States shall ensure that the following provisions are met: (a) the application specifies elements referred to in Article 40(2)(a), (b) and (c); (b) a project evaluation is performed in accordance with Article 38; and (c) that the period referred to in Article 41(1) is not exceeded.		
3. If a project is changed in a way that may have a negative impact on animal welfare, Member States shall require an additional project evaluation with a favourable outcome.		
4. Article 40(3) and (4), Article 41(3) and Article 44(3), (4) and (5) shall apply mutatis mutandis to projects that are allowed to be carried out in accordance with this Article.		
Article 43 **Non-technical project summaries**		
1. Subject to safeguarding intellectual property and confidential information, the non-technical project summary shall provide the following: (a) information on the objectives of the project, including the predicted harm and benefits and the number and types of animals to be used; (b) a demonstration of compliance with the requirement of replacement, reduction and refinement. The non-technical project summary shall be anonymous and shall not contain the names and addresses of the user and its personnel.		New: - publication of anonymous non-technical project summaries
2. Member States may require the non-technical project summary to specify whether a project is to undergo a retrospective assessment and by what deadline. In such a case, Member States shall ensure that the non-technical project summary is updated with the results of any retrospective assessment.		

3. Member States shall publish the non-technical project summaries of authorised projects and any updates thereto.		
Article 44 **Amendment, renewal and withdrawal of a project authorisation**		
1. Member States shall ensure that amendment or renewal of the project authorisation is required for any change of the project that may have a negative impact on animal welfare.		New: - further detailed requirements for authorisation process
2. Any amendment or renewal of a project authorisation shall be subject to a further favourable outcome of the project evaluation.		
3. The competent authority may withdraw the project authorisation where the project is not carried out in accordance with the project authorisation.		
4. Where a project authorisation is withdrawn, the welfare of the animals used or intended to be used in the project must not be adversely affected.		
5. Member States shall establish and publish conditions for amendment and renewal of project authorisations.		
Article 45 **Documentation**		
1. Member States shall ensure that all relevant documentation, including project authorisations and the result of the project evaluation is kept for at least three years from the expiry date of the authorisation of the project or from the expiry of the period referred to in Article 41(1) and shall be available to the competent authority.		New: - further detailed requirements for authorisation process
2. Without prejudice to paragraph 1, the documentation for projects which have to undergo retrospective assessment shall be kept until the retrospective assessment has been completed.		

	Article 20 When user establishments breed animals for use in experiments on their own premises, only one registration or approval is needed for the purposes of Article 15 and 19. However, the establishments shall comply with the relevant provisions of this Directive concerning breeding and user establishments.	Omitted simplification
CHAPTER V **AVOIDANCE OF DUPLICATION** **AND ALTERNATIVE APPROACHES** **Article 46** **Avoidance of duplication of procedures**		
Each Member State shall accept data from other Member States that are generated by procedures recognised by the legislation of the Union, unless further procedures need to be carried out regarding that data for the protection of public health, safety or the environment.	Article 22 1. In order to avoid unnecessary duplication of experiments for the purposes of satisfying national or Community health and safety legislation, Member States shall as far as possible recognize the validity of data generated by experiments carried out in the territory of another Member State unless further testing is necessary in order to protect public health and safety.	Mutual acceptance of data
Article 47 **Alternative approaches**		
1. The Commission and the Member States shall contribute to the development and validation of alternative approaches which could provide the same or higher levels of information as those obtained in procedures using animals, but which do not involve the use of animals or use fewer animals or which entail less painful procedures, and they shall take such other steps as they consider appropriate to encourage research in this field.	Article 23 1. The Commission and Member States should encourage research into the development and validation of alternative techniques which could provide the same level of information as that obtained in experiments using animals but which involve fewer animals or which 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 monitor trends in experimental methods. …	The basis for funding of the development and validation of alternative methods
2. Member States shall assist the Commission in identifying and nominating suitable specialised and		New:

qualified laboratories to carry out such validation studies.		- nomination of national laboratories
3. After consulting the Member States, the Commission shall set the priorities for those validation studies and allocate the tasks between the laboratories for carrying out those studies.		New: - consultation of Member States as to priorities for validation and sharing of work
4. Member States shall, at national level, ensure the promotion of alternative approaches and the dissemination of information thereon.		New: - Member State obligation to disseminate information on alternatives
5. Member States shall nominate a single point of contact to provide advice on the regulatory relevance and suitability of alternative approaches proposed for validation.		New: - Member State obligation to create single point of contact for advice on regulatory relevance of alternatives
6. The Commission shall take appropriate action with a view to obtaining international acceptance of alternative approaches validated in the Union.		New: - Commission obligation to foster international acceptance of validated methods
Article 48 **Union Reference Laboratory**		
1. The Union Reference Laboratory and its duties and tasks shall be those referred to in Annex VII.		New: - anchoring of an EU reference laboratory (ECVAM) ANNEX VII Duties and Tasks of the Union Reference Laboratory 1. The Union Reference Laboratory referred to in Article 48 is the Commission's Joint Research Centre. 2. The Union Reference Laboratory shall be responsible, in particular, for: (a) coordinating and promoting the development and use of alternatives to procedures including in the areas of basic and applied research and regulatory testing; (b) coordinating the validation of

		alternative approaches at Union level; (c) acting as a focal point for the exchange of information on the development of alternative approaches; (d) setting up, maintaining and managing public databases and information systems on alternative approaches and their state of development; (e) promoting dialogue between legislators, regulators, and all relevant stakeholders, in particular, industry, biomedical scientists, consumer organisations and animal welfare groups, with a view to the development, validation, regulatory acceptance, international recognition, and application of alternative approaches. 3. The Union Reference Laboratory shall participate in the validation of alternative approaches.
2. The Union Reference Laboratory may collect charges for the services it provides that do not directly contribute to the further advancement of replacement, reduction and refinement.		New: - ECVAM can ask for fees
3. Detailed rules necessary for the implementation of paragraph 2 of this Article and Annex VII may be adopted in accordance with the regulatory procedure referred to in Article 56(3).		
Article 49 **National committees for the protection of animals used for scientific purposes**		
1. Each Member State shall establish a national committee for the protection of animals used for scientific purposes. It shall advise the competent authorities and animal-welfare bodies on matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practice.		New: - Member State obligation to create national committees
2. The national committees referred to in paragraph 1 shall exchange information on the operation of		New: - network of Member State

animal-welfare bodies and project evaluation and share best practice within the Union.		committees
CHAPTER VI **FINAL PROVISIONS** **Article 50** **Adaptation of annexes to technical progress**		
In order to ensure that the provisions of Annexes I and III to VIII reflect the state of technical or scientific progress, taking into account the experience gained in the implementation of this Directive, in particular through the reporting referred to in Article 54(1), the Commission may adopt, by means of delegated acts in accordance with Article 51 and subject to the conditions laid down in Articles 52 and 53, modifications of those Annexes, with the exception of provisions of Sections I and II of Annex VIII. The dates referred to in Section B of Annex III shall not be brought forward. When adopting such delegated acts, the Commission shall act in accordance with the relevant provisions of this Directive.		
Article 51 **Exercise of the delegation**		
1. The power to adopt delegated acts referred to in Article 50 shall be conferred on the Commission for a period of eight years beginning on [EiF]. The Commission shall make a report in respect of the delegated power at the latest 12 months before the end of the eight year period. The delegation of power shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 52.		
2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the		

European Parliament and to the Council.		
3. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in Articles 52 and 53.		
Article 52 **Revocation of the delegation**		
1. The delegation of power referred to in Article 50 may be revoked at any time by the European Parliament or by the Council.		
2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of power shall endeavour to inform the other institution and the Commission within a reasonable time before the final decision is taken, indicating the delegated power which could be subject to revocation and possible reasons for a revocation.		
3. The decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the Official Journal of the European Union.		
Article 53 **Objections to delegated acts**		
1. The European Parliament or the Council may object to a delegated act within a period of two months from the date of notification. At the initiative of the European Parliament or the Council this period shall be extended by two months.		
2. If, on expiry of that period, neither the European Parliament nor the Council has objected to the delegated act, it shall be published in the Official Journal of the European Union and shall enter into force at the date stated therein. The delegated act may be published in the Official Journal of the European Union and enter into force		

before the expiry of that period if the European Parliament and the Council have both informed the Commission of their intention not to raise objections.		
3. If the European Parliament or the Council objects to a delegated act, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.		
Article 54 **Reporting**		
1. Member States shall by [8 years from the EiF], and every five years thereafter, send the information on the implementation of this Directive and in particular Articles 10(1), 26, 28, 34, 38, 39, 43 and 46 to the Commission.		New: - reporting requirement for European Commission on implementation of Directive every 5 years
2. Member States shall collect and make publicly available, on an annual basis, statistical information on the use of animals in procedures, including information on the actual severity of the procedures and on the origin and species of non-human primates used in procedures. Member States shall submit that statistical information to the Commission by [5 years from the EiF] and every year thereafter.	Article 13 1. On the basis of requests for authorization and notifications received, and on the basis of the reports made, the authority in each Member State shall collect, and as far as possible periodically make publicly available, the statistical information on the use of animals in experiments…	Continuation of statistical reports. New: - Member State obligation to provide annual statistical reports - reporting on actual severity
3. Member States shall submit to the Commission, on annual basis, detailed information on exemptions granted under Article 6(4)(a).		
4. The Commission shall by [18 months from the EiF] establish a common format for submitting the information referred to in paragraphs 1, 2, and 3 of this Article in accordance with the regulatory procedure referred to in Article 56(3).	Article 13 1. …the statistical information on the use of animals in experiments in respect of: (a) the number and kinds of animals used in experiments; (b) the number of animals, in selected categories, used in the experiments referred to in Article 3; (c) the number of animals, in selected categories, used in experiments required by legislation.	Content of statistical reports to be defined as part of the implementation

	Article 13 2. Member States shall take all necessary steps to ensure that the confidentiality of commercially sensitive information communicated pursuant to this Directive is protected.	
Article 55 **Safeguard clauses**		
1. Where a Member State has scientifically justifiable grounds for believing it is essential to use non-human primates for the purposes referred to in Article 8(1)(a)(i) with regard to human beings, but where the use is not undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions, it may adopt a provisional measure allowing such use, provided the purpose cannot be achieved by the use of species other than non-human primates.		New: - an extremely cumbersome opportunity to overcome otherwise banned use of non-human primates, especially great apes and very severe procedures
2. Where a Member State has justifiable grounds for believing that action is essential for the preservation of the species or in relation to an unexpected outbreak of a life-threatening or debilitating clinical condition in human beings, it may adopt a provisional measure allowing the use of great apes in procedures having one of the purposes referred to in points (b)(i), (c) or (e) of Article 5; provided that the purpose of the procedure cannot be achieved by the use of species other than great apes or by the use of alternative methods. However, the reference to Article 5(b)(i) shall not be taken to include the reference to animals and plants.		
3. Where, for exceptional and scientifically justifiable reasons, a Member State deems it necessary to allow the use of a procedure involving severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated, as referred to in Article 15(2), it may adopt a provisional measure to allow such procedure. Member States may decide not to allow the use of non-human primates in such procedures.		

4. A Member State which has adopted a provisional measure in accordance with paragraph 1, 2 or 3 shall immediately inform the Commission and the other Member States thereof, giving reasons for its decision and submitting evidence of the situation as described in paragraphs 1, 2 and 3 on which the provisional measure is based. The Commission shall put the matter before the Committee referred to in Article 56(1) within 30 days of receipt of the information from the Member State and shall, in accordance with the regulatory procedure referred to in Article 56(3), either: (a) authorise the provisional measure for a time period defined in the decision; or (b) require the Member State to revoke the provisional measure.		
Article 56 **Committee**		
1. The Commission shall be assisted by a committee.	Article 22 … 3. The Commission shall establish a permanent consultative committee within which the Member States would be represented, which will assist the Commission in organizing the exchange of appropriate information, while respecting the requirements of confidentiality, and which will also assist the Commission in the other questions raised by the application of this Directive.	Comitology committee required to adopt measures under adaptation to technical process
2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.		
3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of		

Article 8 thereof. The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.		
Article 57 **Commission report**		
1. By [9 years after the EiF] and every five years thereafter, the Commission shall, based on the information received from the Member States under Article 54(1), submit to the European Parliament and the Council a report on the implementation of this Directive.	Article 26 At regular intervals not exceeding three years, and for the first time five years following notification of this Directive, Member States shall inform the Commission of the measures taken in this area and provide a suitable summary of the information collected under the provisions of Article 13. The Commission shall prepare a report for the Council and the European Parliament.	New: - European Commission has to compile within one year the Member State reports received every five years on implementation and provide this to the European Parliament
2. By [9 years after the EiF] and every three years thereafter, the Commission shall, based on the statistical information submitted by Member States under Article 54(2), submit to the European Parliament and the Council a summary report on that information.		
Article 58 **Review**		
The Commission shall review this Directive by [7 years after the date of EiF], taking into account advancements in the development of alternative methods not entailing the use of animals, in particular of non-human primates, and shall propose amendments, where appropriate. The Commission shall, where appropriate, and in consultation with the Member States and stakeholders, conduct periodic thematic reviews of the replacement, reduction and refinement of the use of animals in procedures, paying specific attention to non-human primates, technological developments, and new scientific and animal-welfare knowledge.	Article 23 … 2. The Commission shall report before the end of 1987 on the possibility of modifying tests and guidelines laid down in existing Community legislation taking into account the objectives referred to in paragraph 1.	New: - after 7 years the European Commission shall provide a review with suggested changes, if appropriate, to the Directive, especially with regard to alternative methods
Article 59 **Competent authorities**		

1. Each Member State shall designate one or more competent authorities responsible for the implementation of this Directive. Member States may designate bodies other than public authorities for the implementation of specific tasks laid down in this Directive only if there is proof that the body: (a) has the expertise and infrastructure required to carry out the tasks; and (b) is free of any conflict of interests as regards the performance of the tasks. Bodies thus designated shall be considered competent authorities for the purposes of this Directive.	Article 6 1. Each Member State shall designate the authority or authorities responsible for verifying that the provisions of this Directive are properly carried out. 2. In the framework of the implementation of this Directive, Member States shall adopt the necessary measures in order that the designated authority mentioned in paragraph 1 above may have the advice of experts competent for the matters in question.	Obligation to nominate national competent authorities
2. Each Member State shall communicate details of a national authority serving as contact point for the purposes of this Directive to the Commission by [three months after the EiF], as well as any update to such data. The Commission shall make publicly available the list of those contact points.		
Article 60 **Penalties**		
Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by [27 months following the EiF], and shall notify the Commission without delay of any subsequent amendment affecting them.		New: - obligation to Member States to enforce the Directive with penalties

Article 61 **Transposition**		
1. Member States shall adopt and publish, by [24 months from the EiF], the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions. They shall apply those provisions from [1 January of the third year following EiF]. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. The method of making such reference shall be laid down by Member States.	Article 25 1. Member States shall take the measures necessary to comply with this Directive by 24 November 1989. They shall forthwith inform the Commission thereof. 2. Member States shall communicate to the Commission the provisions of national law which they adopt in the field covered by this Directive.	Obligation to convert the Directive into national law in two years.
2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.	Article 22 … 2. To that end, Member States shall, where practicable and without prejudice to the requirements of existing Community Directives, furnish information to the Commission on their legislation and administrative practice relating to animal experiments, including requirements to be satisfied prior to the marketing of products; they shall also supply factual information on experiments carried out in their territory and on authorizations or any other administrative particulars pertaining to these experiments.	
Article 62 **Repeal**		
1. Directive 86/609/EEC is repealed with effect from [1 January of the third year following EiF] with the exception of Article 13, which shall be repealed with the effect from [30 months from the EiF].		Repeal of the old Directive from 1 Jan 2014 onward

2. References to the repealed Directive shall be construed as references to this Directive.		
Article 63 **Amendment of Regulation (EC) No 1069/2009**		
Point (a)(iv) of Article 8 of Regulation (EC) No 1069/2009 is replaced by the following: "(iv) animals used in a procedure or procedures defined in Article 3 of Directive …/…/EU of … on the protection of animals used for scientific purposes, in cases where the competent authority decides that such animals or any of their body parts have the potential to pose serious health risks to humans or to other animals, as a result of that procedure or those procedures without prejudice to Article 3(2) of Regulation (EC) No 1831/2003;		Referring to: REGULATION (EC) No 1069/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption
Article 64 **Transitional provisions**		
1. Member States shall not apply laws, regulations and administrative provisions adopted in accordance with Articles 36 to 45 to projects which have been approved before [1 January of the third year following EiF] and the duration of which does not extend beyond [1 January of the eighth year following EiF].		Projects authorised before 2013 and not extending 2018 do not fall under the new authorisation process until 1 January 2019
2. Projects which have been approved before [1 January of the third year following EiF] and the duration of which extends beyond [1 January of the eighth year following EiF] shall obtain project authorisation by [1 January of the eighth year following EiF].		
Article 65 **Entry into force**		
This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.		

Article 66 **Addressees**		
This Directive is addressed to the Member States.	Article 27 This Directive is addressed to the Member States.	
ANNEX I List of animals referred to in Article 10		
ANNEX II List of non-human primates and dates referred to in the second subparagraph of Article 10(1)		
ANNEX III Requirements for establishments and for the care and accommodation of animals		**New:** **-** Status changed from guidelines into minimum standards.
ANNEX IV Methods of killing animals		
ANNEX V List of elements referred to in Article 23(3)		minimum requirements with regard to education and training and the requirements for obtaining, maintaining and demonstrating requisite competence
ANNEX VI List of elements referred to in Article 37 (1)(c)		minimum elements to be included in an application for project authorisation
ANNEX VII Duties and Tasks of the Union Reference Laboratory		
ANNEX VIII Severity classification of procedures		

EiF = Entry into Force, i.e. 20 days after publication in the Official Journal in fall 2010.