

Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (Text with EEA relevance)

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee⁽¹⁾,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure⁽²⁾,

Whereas:

- (1) On 24 November 1986 the Council adopted Directive 86/609/EEC⁽³⁾ in order to eliminate disparities between laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes. Since the adoption of that Directive, further disparities between Member States have emerged. Certain Member States have adopted national implementing measures that ensure a high level of protection of animals used for scientific purposes, while others only apply the minimum requirements laid down in Directive 86/609/EEC. These disparities are liable to constitute barriers to trade in products and substances the development of which involves experiments on animals. Accordingly, this Directive should provide for more detailed rules in order to reduce such disparities by approximating the rules applicable in that area and to ensure a proper functioning of the internal market.
- (2) Animal welfare is a value of the Union that is enshrined in Article 13 of the Treaty on the Functioning of the European Union (TFEU).
- (3) On 23 March 1998 the Council adopted Decision 1999/575/EC concerning the conclusion by the Community of the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes⁽⁴⁾. By becoming party to that Convention, the Community acknowledged the importance of the protection and welfare of animals used for scientific purposes at international level.

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- (4) The European Parliament in its resolution of 5 December 2002 on Directive 86/609/EEC called for the Commission to come forward with a proposal for a revision of that Directive with more stringent and transparent measures in the area of animal experimentation.
- (5) On 15 June 2006, the Fourth Multilateral Consultation of Parties to the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes adopted a revised Appendix A to that Convention, which set out guidelines for the accommodation and care of experimental animals. Commission Recommendation 2007/526/EC of 18 June 2007 on guidelines for the accommodation and care of animals used for experimental and other scientific purposes⁽⁵⁾ incorporated those guidelines.
- (6) New scientific knowledge is available in respect of factors influencing animal welfare as well as the capacity of animals to sense and express pain, suffering, distress and lasting harm. It is therefore necessary to improve the welfare of animals used in scientific procedures by raising the minimum standards for their protection in line with the latest scientific developments.
- (7) Attitudes towards animals also depend on national perceptions, and there is a demand in certain Member States to maintain more extensive animal-welfare rules than those agreed upon at the level of the Union. In the interests of the animals, and provided it 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 TFEU.
- (8) In addition to vertebrate animals including cyclostomes, cephalopods should also be included in the scope of this Directive, as there is scientific evidence of their ability to experience pain, suffering, distress and lasting harm.
- (9) This Directive should also cover foetal forms of mammals, as there is scientific evidence showing that such forms in the last third of the period of their development are at an increased risk of experiencing pain, suffering and distress, which may also affect negatively their subsequent development. Scientific evidence also shows that procedures carried out on embryonic and foetal forms at an earlier stage of development could result in pain, suffering, distress or lasting harm, should the developmental forms be allowed to live beyond the first two thirds of their development.
- (10) While it is desirable to replace the use of live animals in procedures by other methods not entailing the use of live animals, the use of live animals continues to be necessary to protect human and animal health and the environment. However, this Directive represents an important step towards achieving the final goal of full replacement of procedures on live animals for scientific and educational purposes as soon as it is scientifically possible to do so. To that end, it seeks to facilitate and promote the advancement of alternative approaches. It also seeks to ensure a high level of protection for animals that still need to be used in procedures. This Directive should be reviewed regularly in light of evolving science and animal-protection measures.

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- (11) The care and use of live animals for scientific purposes is governed by internationally established principles of replacement, reduction and refinement. To ensure that the way in which animals are bred, cared for and used in procedures within the Union is in line with that of the other international and national standards applicable outside the Union, the principles of replacement, reduction and refinement should be considered systematically when implementing this Directive. When choosing methods, the principles of replacement, reduction and refinement should be implemented through a strict hierarchy of the requirement to use alternative methods. Where no alternative method is recognised by the legislation of the Union, the numbers of animals used may be reduced by resorting to other methods and by implementing testing strategies, such as the use of *in vitro* and other methods that would reduce and refine the use of animals.
- (12) Animals have an intrinsic value which must be respected. There are also the ethical concerns of the general public as regards the use of animals in procedures. Therefore, animals should always be treated as sentient creatures and their use in procedures should be restricted to areas which may ultimately benefit human or animal health, or the environment. The use of animals for scientific or educational purposes should therefore only be considered where a non-animal alternative is unavailable. Use of animals for scientific procedures in other areas under the competence of the Union should be prohibited.
- (13) The choice of methods and the species to be used have a direct impact on both the numbers of animals used and their welfare. The choice of methods should therefore ensure the selection of the method that is able to provide the most satisfactory results and is likely to cause the minimum pain, suffering or distress. The methods selected should use the minimum number of animals that would provide reliable results and require the use of species with the lowest capacity to experience pain, suffering, distress or lasting harm that are optimal for extrapolation into target species.
- (14) The methods selected should avoid, as far as possible, death as an end-point due to the severe suffering experienced during the period before death. Where possible, it should be substituted by more humane end-points using clinical signs that determine the impending death, thereby allowing the animal to be killed without any further suffering.
- (15) The use of inappropriate methods for killing an animal can cause significant pain, distress and suffering to the animal. The level of competence of the person carrying out this operation is equally important. Animals should therefore be killed only by a competent person using a method that is appropriate to the species.
- (16) It is necessary to ensure that the use of animals in procedures does not pose a threat to biodiversity. Therefore, the use of endangered species in procedures should be limited to a strict minimum.
- (17) Having regard to the present state of scientific knowledge, the use of non-human primates in scientific procedures is still necessary in biomedical research. Due to their genetic proximity to human beings and to their highly developed social skills, the use of non-human primates in scientific procedures raises specific ethical and practical problems in terms of meeting their behavioural, environmental and social needs in a

laboratory environment. Furthermore, the use of non-human primates is of the greatest concern to the public. Therefore the use of non-human primates should be permitted only in those biomedical areas essential for the benefit of human beings, for which no other alternative replacement methods are yet available. Their use should be permitted only for basic research, the preservation of the respective non-human primate species or when the work, including xenotransplantation, is carried out in relation to potentially life-threatening conditions in humans or in relation to cases having a substantial impact on a person's day-to-day functioning, i.e. debilitating conditions.

- (18) The use of great apes, as the closest species to human beings with the most advanced social and behavioural skills, should be permitted only for the purposes of research aimed at the preservation of those species and where action in relation to a life-threatening, debilitating condition endangering human beings is warranted, and no other species or alternative method would suffice in order to achieve the aims of the procedure. The Member State claiming such a need should provide information necessary for the Commission to take a decision.
- (19) The capture of non-human primates from the wild is highly stressful for the animals concerned and carries an elevated risk of injury and suffering during capture and transport. In order to end the capturing of animals from the wild for breeding purposes, only animals that are the offspring of an animal which has been bred in captivity, or that are sourced from self-sustaining colonies, should be used in procedures after an appropriate transition period. A feasibility study should be carried out to that effect and the transition period adopted if necessary. The feasibility of moving towards sourcing non-human primates only from self-sustaining colonies as an ultimate goal should also be examined.
- (20) There is a need for certain species of vertebrate animals used in procedures to be bred specifically for that purpose so that their genetic, biological and behavioural background is well-known to persons undertaking the procedures. Such knowledge both increases the scientific quality and reliability of the results and decreases the variability, ultimately resulting in fewer procedures and reduced animal use. Furthermore, for reasons of animal welfare and conservation, the use of animals taken from the wild in procedures should be limited to cases where the purpose of the procedures cannot be achieved using animals bred specifically for use in procedures.
- (21) Since the background of stray and feral animals of domestic species is not known, and since capture and placement into establishments increases distress for such animals, they should not, as a general rule, be used in procedures.
- (22) To enhance transparency, facilitate the project authorisation, and provide tools for monitoring compliance, a severity classification of procedures should be introduced on the basis of estimated levels of pain, suffering, distress and lasting harm that is inflicted on the animals.
- (23) From an ethical standpoint, there should be an upper limit of pain, suffering and distress above which animals should not be subjected in scientific procedures. To that end, the performance of procedures that result in severe pain, suffering or distress, which is likely to be long-lasting and cannot be ameliorated, should be prohibited.

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- (24) When developing a common format for reporting purposes, the actual severity of the pain, suffering, distress or lasting harm experienced by the animal should be taken into account rather than the predicted severity at the time of the project evaluation.
- (25) The number of animals used in procedures could be reduced by performing procedures on animals more than once, where this does not detract from the scientific objective or result in poor animal welfare. However, the benefit of reusing animals should be balanced against any adverse effects on their welfare, taking into account the lifetime experience of the individual animal. As a result of this potential conflict, the reuse of animals should be considered on a case-by-case basis.
- (26) At the end of the procedure, the most appropriate decision should be taken as regards the future of the animal on the basis of animal welfare and potential risks to the environment. The animals whose welfare would be compromised should be killed. In some cases, animals should be returned to a suitable habitat or husbandry system or animals such as dogs and cats should be allowed to be rehomed in families as there is a high level of public concern as to the fate of such animals. Should Member States allow rehoming, it is essential that the breeder, supplier or user has a scheme in place to provide appropriate socialisation to those animals in order to ensure successful rehoming as well as to avoid unnecessary distress to the animals and to guarantee public safety.
- (27) Animal tissue and organs are used for the development of *in vitro* methods. To promote the principle of reduction, Member States should, where appropriate, facilitate the establishment of programmes for sharing the organs and tissue of animals that are killed.
- (28) The welfare of the animals used in procedures is highly dependent on the quality and professional competence of the personnel supervising procedures, as well as of those performing procedures or supervising those taking care of the animals on a daily basis. Member States should ensure through authorisation or by other means that staff are adequately educated, trained and competent. Furthermore, it is important that staff are supervised until they have obtained and demonstrated the requisite competence. Non-binding guidelines at the level of the Union concerning educational requirements would, in the long run, promote the free movement of personnel.
- (29) The establishments of breeders, suppliers and users should have adequate installations and equipment in place to meet the accommodation requirements of the animal species concerned and to allow the procedures to be performed efficiently and with the least distress to the animals. The breeders, suppliers and users should operate only if they are authorised by the competent authorities.
- (30) To ensure the ongoing monitoring of animal-welfare needs, appropriate veterinary care should be available at all times and a staff member should be made responsible for the care and welfare of animals in each establishment.
- (31) Animal-welfare considerations should be given the highest priority in the context of animal keeping, breeding and use. Breeders, suppliers and users should therefore have an animal-welfare body in place with the primary task of focusing on giving advice on animal-welfare issues. The body should also follow the development and outcome of

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projects at establishment level, foster a climate of care and provide tools for the practical application and timely implementation of recent technical and scientific developments in relation to the principles of replacement, reduction and refinement, in order to enhance the life-time experience of the animals. The advice given by the animal-welfare body should be properly documented and open to scrutiny during inspections.

- (32) In order to enable competent authorities to monitor compliance with this Directive, each breeder, supplier and user should maintain accurate records of the numbers of animals, their origins and fate.
- (33) Non-human primates, dogs and cats should have a personal history file from birth covering their lifetimes in order to be able to receive the care, accommodation and treatment that meet their individual needs and characteristics.
- (34) The accommodation and care of animals should be based on the specific needs and characteristics of each species.
- (35) There are differences in the requirements for the accommodation and care of animals between Member States, which contribute to the distortion of the internal market. Furthermore, some of those requirements no longer reflect the most recent knowledge on the impacts of accommodation and care conditions on both the animal welfare and the scientific results of procedures. It is therefore necessary to establish in this Directive harmonised requirements for accommodation and care. These requirements should be updated on the basis of scientific and technical development.
- (36) To monitor compliance with this Directive, Member States should carry out regular inspections of breeders, suppliers and users on a risk basis. To ensure public confidence and promote transparency, an appropriate proportion of the inspections should be carried out without prior warning.
- (37) To assist the Member States in the enforcement of this Directive and on the basis of the findings in the reports on the operation of the national inspections, the Commission should, when there is reason for concern, carry out controls of the national inspection systems. Member States should address any weaknesses identified in the findings of these controls.
- (38) Comprehensive project evaluation, taking into account ethical considerations in the use of animals, forms the core of project authorisation and should ensure the implementation of principles of replacement, reduction and refinement in those projects.
- (39) It is also essential, both on moral and scientific grounds, to ensure that each use of an animal is carefully evaluated as to the scientific or educational validity, usefulness and relevance of the expected result of that use. The likely harm to the animal should be balanced against the expected benefits of the project. Therefore, an impartial project evaluation independent of those involved in the study should be carried out as part of the authorisation process of projects involving the use of live animals. Effective implementation of a project evaluation should also allow for an appropriate assessment of the use of any new scientific experimental techniques as they emerge.

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- (40) Due to the nature of the project, the type of species used and the likelihood of achieving the desired objectives of the project, it might be necessary to carry out a retrospective assessment. Since projects may vary significantly in terms of complexity, length, and the time period for obtaining the results, it is necessary that the decision on retrospective assessment should be made taking those aspects fully into account.
- (41) To ensure that the public is informed, it is important that objective information concerning projects using live animals is made publicly available. This should not violate proprietary rights or expose confidential information. Therefore, users should provide anonymous non-technical summaries of those projects, which Member States should publish. The published details should not breach the anonymity of the users.
- (42) To manage risks to human and animal health and the environment, the legislation of the Union provides that substances and products can be marketed only after appropriate safety and efficacy data have been submitted. Some of those requirements can be fulfilled only by resorting to animal testing, hereinafter referred to as 'regulatory testing'. It is necessary to introduce specific measures in order to increase the use of alternative approaches and to eliminate unnecessary duplication of regulatory testing. For that purpose Member States should recognise the validity of test data produced using test methods provided for under the legislation of the Union.
- (43) To reduce the administrative workload and enhance the competitiveness of research and industry in the Union, it should be possible to authorise multiple generic projects when carried out using established methods for testing, diagnostic or production purposes under one group authorisation, albeit without exempting any of these procedures from the project evaluation.
- (44) To ensure effective examination of authorisation applications and to enhance the competitiveness of research and industry in the Union, a time-limit should be set for the competent authorities to evaluate project proposals and take decisions on the authorisation of such projects. In order not to compromise the quality of the project evaluation, additional time might be required for more complex project proposals due to the number of disciplines involved, the novel characteristics and more complex techniques of the proposed project. However, the extension of deadlines for project evaluation should remain the exception.
- (45) Given the routine or repetitive nature of certain procedures, it is appropriate to provide for a regulatory option whereby the Member States could introduce a simplified administrative procedure for the evaluation of projects containing such procedures, provided certain requirements laid down in this Directive are complied with.
- (46) The availability of alternative methods is highly dependent on the progress of the research into the development of alternatives. The Community Framework Programmes for Research and Technological Development provided increasing funding for projects which aim to replace, reduce and refine the use of animals in procedures. In order to increase competitiveness of research and industry in the Union and to replace, reduce and refine the use of animals in procedures, the Commission and the Member

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States should contribute through research and by other means to the development and validation of alternative approaches.

- (47) The European Centre for the Validation of Alternative Methods, a policy action within the Joint Research Centre of the Commission, has coordinated the validation of alternative approaches in the Union since 1991. However, there is an increasing need for new methods to be developed and proposed for validation, which requires a reference laboratory of the Union for the validation of alternative methods to be established formally. This laboratory should be referred to as the European Centre for the Validation of Alternative Methods (ECVAM). It is necessary for the Commission to cooperate with the Member States when setting priorities for validation studies. The Member States should assist the Commission in identifying and nominating suitable laboratories to carry out such validation studies. For validation studies that are similar to previously validated methods and in respect of which a validation represents a significant competitive advantage, ECVAM should be able to collect charges from those who submit their methods for validation. Such charges should not be prohibitive of healthy competition in the testing industry.
- (48) There is a need to ensure a coherent approach to project evaluation and review strategies at national level. Member States should establish national committees for the protection of animals used for scientific purposes to give advice to the competent authorities and animal-welfare bodies in order to promote the principles of replacement, reduction and refinement. A network of national committees should play a role in the exchange of best practice at the level of the Union.
- (49) Technical and scientific advancements in biomedical research can be rapid, as can the increase in knowledge of factors influencing animal welfare. It is therefore necessary to provide for a review of this Directive. Such review should examine the possible replacement of the use of animals, and in particular non-human primates, as a matter of priority where it is possible, taking into account the advancement of science. The Commission should also conduct periodic thematic reviews concerning the replacement, reduction and refinement of the use of animals in procedures.
- (50) In order to ensure uniform conditions for implementation, implementing powers should be conferred on the Commission to adopt guidelines at the level of the Union on the requirements with regard to education, training and competence of breeders', suppliers' and users' staff, to adopt detailed rules regarding the Union Reference Laboratory, its duties and tasks and the charges it may collect, to establish a common format for submitting the information by Member States to the Commission on the implementation of this Directive, statistical information and other specific information, and for the application of safeguard clauses. According to Article 291 TFEU, rules and general principles concerning mechanisms for the control by Member States of the Commission's exercise of implementing powers shall be laid down in advance by a regulation adopted in accordance with the ordinary legislative procedure. Pending the adoption of that new regulation, Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the

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Commission⁽⁶⁾ continues to apply, with the exception of the regulatory procedure with scrutiny, which is not applicable.

- (51) The Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU in respect of the following: modifications of the list of species falling under the obligation of being specifically bred for use in procedures; modifications of the care and accommodation standards; modifications of methods of killing, including their specifications; modifications of the elements to be used for the establishment by Member States of requirements with regard to education, training and competence of breeders', suppliers' and users' personnel; modifications of certain obligatory elements of the application for authorisation; modifications regarding the Union Reference Laboratory, its duties and tasks; as well as modifications of examples of different types of procedures assigned to each of the severity categories on the basis of factors related to the type of procedure. It is of particular importance that the Commission carry out appropriate consultation during its preparatory work, including at expert level.
- (52) Member States should lay down rules on penalties applicable to infringements of the provisions of this Directive and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.
- (53) Directive 86/609/EEC should therefore be repealed. Certain modifications introduced by this Directive have a direct impact on the application of 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⁽⁷⁾. It is therefore appropriate to amend a provision of that Regulation accordingly.
- (54) Benefits to animal welfare from applying project authorisation retrospectively, and the related administrative costs, can only be justified for long term ongoing projects. Therefore, it is necessary to include transitional measures for ongoing short and medium term projects to avoid the need for retrospective authorisation with only limited benefits.
- (55) In accordance with paragraph 34 of the Interinstitutional Agreement on better law-making, Member States are encouraged to draw up, for themselves and in the interests of the Union, their own tables, which will, as far as possible, illustrate the correlation between this Directive and the transposition measures, and to make them public.
- (56) Since the objective of this Directive, namely the harmonisation of legislation concerning the use of animals for scientific purposes, cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS DIRECTIVE:

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- (1) [OJ C 277, 17.11.2009, p. 51.](#)
- (2) Position of the European Parliament of 5 May 2009 ([OJ C 212 E, 5.8.2010, p. 170](#)), position of the Council of 13 September 2010 (not yet published in the Official Journal) and position of the European Parliament of 8 September 2010 (not yet published in the Official Journal).
- (3) [OJ L 358, 18.12.1986, p. 1.](#)
- (4) [OJ L 222, 24.8.1999, p. 29.](#)
- (5) [OJ L 197, 30.7.2007, p. 1.](#)
- (6) [OJ L 184, 17.7.1999, p. 23.](#)
- (7) [OJ L 300, 14.11.2009, p. 1.](#)