Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Directive	2008/0211(COD)
Protection of animals used for scientific purposes See also 2001/0277(COD) Amended by 2018/0205(COD) Subject 3.10.04.02 Animal protection 4.20.02.06 Clinical practice and experiments	Procedure completed

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	AGRI Agriculture and Rural Development		21/07/2009
		PPE JEGGLE Elisabeth	
	Former committee responsible		
	AGRI Agriculture and Rural Development		01/12/2008
		PPE-DE PARISH Neil	
	Former committee for opinion		
	ITRE Industry, Research and Energy (Associated committee)		
	ENVI Environment, Public Health and Food Safety		02/03/2009
		ALDE MATSAKIS Marios	
Council of the European Union	Council configuration	Meeting	Date
	Justice and Home Affairs (JHA)	3018	03/06/2010
	Agriculture and Fisheries	2986	14/12/2009
	Agriculture and Fisheries	2952	22/06/2009
European Commission	Commission DG	Commissioner	
	Environment	POTOČNIK Janez	

Key events

04/11/2008	Legislative proposal published	COM(2008)0543	Summary
04/12/2008	Committee referral announced in Parliament, 1st reading		
19/02/2009	Referral to associated committees announced in Parliament		
31/03/2009	Vote in committee, 1st reading		Summary

03/04/2009	Committee report tabled for plenary, 1st reading	A6-0240/2009	
04/05/2009	Debate in Parliament		
05/05/2009	Results of vote in Parliament		
05/05/2009	Decision by Parliament, 1st reading	T6-0343/2009	Summary
22/06/2009	Debate in Council	2952	Summary
14/12/2009	Debate in Council	2986	Summary
02/06/2010	Council position published	06106/1/2010	Summary
17/06/2010	Committee referral announced in Parliament, 2nd reading		
12/07/2010	Vote in committee, 2nd reading		Summary
13/07/2010	Committee recommendation tabled for plenary, 2nd reading	A7-0230/2010	
08/09/2010	Debate in Parliament		
08/09/2010	Decision by Parliament, 2nd reading	T7-0308/2010	Summary
22/09/2010	Final act signed		
22/09/2010	End of procedure in Parliament		
20/10/2010	Final act published in Official Journal		

Technical information

Procedure reference	2008/0211(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
	See also 2001/0277(COD) Amended by 2018/0205(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 114-p1
Stage reached in procedure	Procedure completed
Committee dossier	AGRI/7/02658

Documentation gateway

Legislative proposal		COM(2008)0543	05/11/2008	EC	Summary
Document attached to the procedure		SEC(2008)2410	05/11/2008	EC	
Document attached to the procedure		SEC(2008)2411	05/11/2008	EC	
Committee draft report		PE418.310	18/02/2009	EP	
Committee opinion	ENVI	PE420.060	19/02/2009	EP	
Committee opinion	ITRE	PE418.345	11/03/2009	EP	

Amendments tabled in committee		PE421.337	16/03/2009	EP	
Amendments tabled in committee		PE421.385	16/03/2009	EP	
Committee report tabled for plenary, 1st reading/single reading		A6-0240/2009	03/04/2009	EP	
Text adopted by Parliament, 1st reading/single reading		T6-0343/2009	05/05/2009	EP	Summary
Economic and Social Committee: opinion, report		CES0874/2009	13/05/2009	ESC	
Commission response to text adopted in plenary		SP(2009)3616	07/07/2009	EC	
Council statement on its position		09968/2010	31/05/2010	CSL	
Council position		06106/1/2010	03/06/2010	CSL	Summary
Commission communication on Council's position		COM(2010)0324	15/06/2010	EC	Summary
Committee draft report		PE443.087	30/06/2010	EP	
Amendments tabled in committee		PE445.661	30/06/2010	EP	
Committee recommendation tabled for plenary, 2nd reading		A7-0230/2010	13/07/2010	EP	
Text adopted by Parliament, 2nd reading		T7-0308/2010	08/09/2010	EP	Summary
Draft final act		00037/2010/LEX	22/09/2010	CSL	
Follow-up document		COM(2013)0859	05/12/2013	EC	Summary
Follow-up document		SWD(2013)0497	05/12/2013	EC	
For information		C(2015)3773	03/06/2015	EC	Summary
Follow-up document		COM(2017)0631	08/11/2017	EC	Summary
Follow-up document		SWD(2017)0353	08/11/2017	EC	
Follow-up document		COM(2017)0680	23/11/2017	EC	Summary
Follow-up document		COM(2020)0015	05/02/2020	EC	Summary
Follow-up document		COM(2020)0016	05/02/2020	EC	
Follow-up document		SWD(2020)0015	05/02/2020	EC	
Follow-up document		SWD(2020)0010	05/02/2020	EC	
Follow-up document		SWD(2021)0204	14/07/2021	EC	
Follow-up document		SWD(2022)0199	15/07/2022	EC	
Follow-up document		SWD(2023)0084	31/03/2023	EC	

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

Directive 2010/63
OJ L 276 20.10.2010, p. 0033 Summary

Corrigendum to final act 32010L0063R(01)
OJ L 163 22.06.2012, p. 0019

Final legislative act with provisions for delegated acts

Protection of animals used for scientific purposes

PURPOSE: to strengthen the protection of animals still used in scientific procedures in line with the European Union's Protocol on Animal Welfare.

PROPOSED ACT: Directive of the European Parliament and of the Council.

CONTENT: Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes was adopted to harmonise practices in the area of animal experimentation in the EU. However, due to a variety of weaknesses in that Directive, a number of Member States have established considerably more far-reaching measures in their national implementation whereas others apply only minimum rules. This uneven situation needs to be rectified to ensure that the objectives of the internal market are re-established. The proposal aims at ensuring a level playing field, throughout the EU, for industry and the research community, at the same time strengthening the protection of animals still used in scientific procedures in line with the EC Treaty's Protocol on Animal Welfare.

Many provisions of the current directive are open to interpretation. The latter does not include ethical reviews or requirements to obtain authorisations for experiments. The directive does not explicitly address the internationally recognised Three R concept of Replacement, Reduction and Refinement to minimise the use of experimental animals. Replacement refers to replacing procedures which involve live animals with alternatives not using sentient animals. Reduction refers to reducing to a minimum the use of animals in procedures without compromising the quality of results. Refinement refers to using methods that avoid pain, suffering or distress or lasting harm to a bare minimum. This last 'R' also includes improving the care, treatment and living conditions of animals. Revising the directive will strengthen legislation in the area of animal experiments in the EU, reduce the use of experimental animals and ensure that those that are still used in experiments receive appropriate care and humane treatment.

The main points of the proposal are as follows :

- the new directive will make it compulsory to carry out ethical reviews and require that experiments where animals are used be subject to authorisation;
- it will widen the scope of the directive to include specific invertebrate species and foetuses in their last trimester of development and also larvae and other animals used in basic research, education and training;
- it will also set minimum housing and care requirements;
- only animals of second or older generations should be used, subject to transitional periods, to avoid taking animals from the wild and exhausting wild populations;
- alternatives to testing on animals must be used when available and the number of animals used in projects be reduced to a minimum. Member States will be required to improve the breeding, accommodation and care measures and methods used in procedures so as to eliminate or reduce to a minimum any possible pain, suffering, distress or lasting harm caused to animals. These measures are based on the three R principle of replacing, reducing and refining the use of animals in experiments;
- the proposal provides for tightening of national inspections, not only to ensure compliance, but as a means to promote the exchange of best practices and implementation of the principles of the Three Rs.

Scope: the proposed directive covers all live non-human vertebrate animals intended for experiments plus certain other species likely to experience pain. It also includes animals specifically bred so that their organs or tissue can be used in scientific procedures. It does not cover behavioural studies carried out on animals kept in zoos or those used in military experiments, or non-experimental, agricultural or clinical veterinary practices and trials. It also does not cover animals used in husbandry or practices for marking an animal.

Non-human primates: specific provisions have been incorporated to reduce the use of non-human primates to an absolute minimum. A strict case-by-case scrutiny is imposed in cases where non-human primates are still the only suitable species. The proposal limits the use of non-human primates by prohibiting the use of Great Apes and restricting the use of other species of nonhuman primate to only specific fields of application. Furthermore, there are ambitious requirements on the origins of the animals and specific monitoring mechanisms are foreseen to ensure the effectiveness of the proposed measures, ultimately facilitating the move towards abolishing the use of non-human primates in scientific procedures. It is recognised, however, that current scientific knowledge will not allow us to achieve this goal in the near future.

Protection of animals used for scientific purposes

The Committee on Agriculture and Rural Development adopted the report drawn up by Neil PARISH (EPP-ED, UK) amending, under the first reading of the codecision procedure, the proposal for a directive of the European Parliament and of the Council on the protection of animals used for scientific purposes.

The main amendments were as follows:

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

Scope: the Directive should apply to live non-human vertebrate animals, including independently feeding larval forms and embryonic or foetal forms of species of mammals as from the last third of their normal development.

Alternative methods: pursuant to this Directive, testing methods which involve the use of human embryonic and foetal cells shall not be regarded as alternatives.

MEPs request that Member States should ensure that funding is provided for training and research on, and development and implementation of, scientifically satisfactory methods or testing strategies that do not entail the use of animals.

Humane method of killing: a new measure has been introduced stipulating thatwhen more humane methods of killing are developed, this will allow them to be used immediately instead of waiting several years for Annex V to be updated.

National measures: this Directive shall not prevent Member States from applying or adopting stricter national measures seeking to improve the well-being and protection of animals used for scientific purposes.

Non-human primates (NHP): the proposal bans the use of NHPs except in certain circumstances. There is no scientific justification for the special status granted to NHPs, so that basic research should be allowed, without being restricted to experiments designed to achieve specific medical research objectives. A new paragraph is inserted to introduce a review of the use of non-human primates in procedures which is to be conducted by the Commission every two years.

Animals bred for use in procedures: MEPs consider that the recommendation made in the proposal only to source non-human primates from self sustaining colonies of F2 primates (the second generation bred in captivity) is a noble aim and one which in the long term will ensure that fewer animals are taken from the wild. However, the proposal is not practical within the timescale that the Commission has envisioned. Moreover, five years after the entry into force of this Directive, the Commission shall carry out A feasibility study should therefore be conducted ahead of any mandated move towards establishing a policy of only sourcing from F2 self sustaining colonies.

Severity classifications: the Commission identifies a number of severity clauses, "up to mild"

"moderate" and "severe" governing how experiments can be undertaken, however it does not define what the classifications are. MEPs wish to clarify this situation by including a new Annex VIIa called ?General Definitions of Degrees of Severity?.

MEPs note that the ban on ?prolonged? ?severe? procedures appears to preclude any "severe" category procedures, and could be highly restrictive. This is why they propose that Member States should ensure that the procedures classified as "severe" are scientifically justified, and ethically monitored if the pain, suffering or distressis likely to be prolonged. Such procedures

must be exceptional and shall be subject to particular harm/benefit analysis and scrutiny by the competent authority.

Reuse: MEPs support the principle of re-use however they believe that current restriction will result in dramatic increase in numbers of animals used for experimental purposes. They propose that an animal already used in the procedure may be re-used where the previous procedure performed on the animal is classified as ?up to moderate? as opposed to ?up to mild?. An animal that has undergone a "severe" procedure should not be re-used.

In contrast those previously subjected to a "moderate" procedure should be permitted to undergo a further "moderate" procedure. The repeated re-use of the animal is supported by veterinary examination.

Authorised persons: Member States shall ensure the mutual recognition of education and training qualifications and authorisation to conduct designated procedures.

Tasks of the permanent ethical review body: MEPs consider it judicious to provide a yearly review of all projects classified as "severe" or those on non-human primates, and every 3 years for all other projects.

Breeding strategy of non-human primates: EU establishments acquiring non-human primates shall supply proof to the competent authority, on request, that the establishment from which animals have been acquired have a breeding strategy in place. The Commission and the Member States should also take the necessary measures to support appropriate transport conditions for nonhuman primates on the territory of the European Union.

Project authorisation: the Commission may undertake controls of the infrastructure and operation of national inspections in Member States and to ensure that severity classifications are applied correctly and uniformly within the territory of the EU. Member States shall ensure that projects classified as ?severe? or any projects involving non-human primates are not carried out without a prior authorisation by the competent authority. All other projects shall be notified in advance to the competent authority following ethical review by the institution's permanent ethical review body.

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

Granting project authorisations: project authorisations shall be granted for a period not exceeding five years.

European Centre for the Validation of Alternative Methods: MEPs suggest that the remit of the European Centre for the Validation of Alternative Methods shall be extended so that it includes the co-ordination and promotion of the development and use of alternatives to animal procedures including applied and basic biomedical research and veterinary research and regulatory testing by, for instance, coordinating research undertaken to facilitate the development of alternatives to animal procedures by the National Centres or providing databases to facilitate the exchange of relevant information.

Each Member State shall nominate a centre responsible for supporting the development, validation and promotion of alternatives to animal tests used for regulatory purposes, and facilities to develop and promote the use of alternatives to animal procedures undertaken for other purposes, such as basic and applied biomedical and veterinary research.

Protection of animals used for scientific purposes

The European Parliament adopted by 540 votes to 66, with 34 abstentions, a legislative resolution amending, under the first reading of the codecision procedure, the proposal for a directive of the European Parliament and of the Council on the protection of animals used for scientific purposes.

The main amendments are as follows:

Purpose: according to MEPs, this Directive shall apply to the accommodation and husbandry of animals used for scientific purposes, and shall cover all uses of animals in procedures that are likely to cause them pain, suffering, distress or lasting harm.

Scope: the Directive shall apply to live non-human vertebrate animals, including embryonic or foetal forms of species of mammals as from the last third of their normal development. However, independently feeding larval forms shall be excluded from the scope.

Alternative methods: where a method of testing or experimentation exists which, from a scientific point of view, is a satisfactory method or testing strategy for obtaining the result sought, Member States shall ensure that the alternative method is used, provided it is not prohibited in the Member State concerned.

Pursuant to this Directive, testing methods which involve the use of human embryonic and foetal cells shall not be regarded as alternatives, in other words the Member States may take their own ethical decisions concerning the use of these methods of testing.

MEPs request that Member States should ensure that funding is provided for training and research on, and development and implementation of, scientifically satisfactory methods or testing strategies that do not entail the use of animals.

Humane method of killing: a new measure has been introduced stipulating that, when more humane methods of killing are developed, this will allow them to be used immediately instead of waiting several years for Annex V to be updated.

National measures: this Directive shall not prevent Member States from applying or adopting stricter national measures seeking to improve the well-being and protection of animals used for scientific purposes.

Non-human primates (NHP): the proposal bans the use of NHPs except in certain circumstances. There is no scientific justification for the special status granted to NHPs, so that basic research should be allowed, without being restricted to experiments designed to achieve specific medical research objectives. A new paragraph is inserted to introduce a review of the use of non-human primates in procedures which is to be conducted by the Commission every two years.

Use of cadavers, tissue and organs of animals for training purposes: MEPs consider that, for higher education and training purposes, the cadavers, tissue and organs of animals may be used only if they come from animals slaughtered in accordance with the provisions of Council Regulation (EC) No .../2009 [on the protection of animals at the time of killing].

Animals bred for use in procedures: MEPs consider that the recommendation made in the proposal only to source non-human primates from self sustaining colonies of F2 primates (the second generation bred in captivity) is a noble aim and one which in the long term will ensure that fewer animals are taken from the wild. However, the proposal is not practical within the timescale that the Commission has envisioned. Moreover, five years after the entry into force of this Directive, the Commission shall carry out a feasibility study ahead of any mandated move towards establishing a policy of only sourcing from F2 self sustaining colonies.

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

Severity classifications: in its proposal, the Commission identifies a number of severity clauses - "up to mild", "moderate" and "severe" or "non-recovery" - governing how experiments can be undertaken. However it does not define what the classifications are. MEPs wish to clarify this situation by including a new Annex VIIa called ?General Definitions of Degrees of Severity?.

MEPs note that the ban on "prolonged" "severe" procedures appears to preclude any "severe" category procedures, and could be highly restrictive. This is why they propose that Member States should ensure that the procedures classified as "severe" are scientifically justified, and ethically monitored if the pain, suffering or distress is likely to be more than transient. Such procedures must be exceptional and shall be subject to particular harm/benefit analysis and scrutiny by the competent authority.

Reuse: the Parliament supports the principle of re-use but believes that current restriction will result in dramatic increase in numbers of animals used for experimental purposes. MEPs propose that an animal already used in the procedure may be re-used where the previous procedure performed on the animal is classified as ?up to moderate? as opposed to ?up to mild?.

In any event, an animal that has undergone a "severe" procedure should not be re-used. In contrast, those previously subjected to a "moderate" procedure should be permitted to undergo a further "moderate" procedure. The repeated re-use of the animal is supported by veterinary examination.

Authorised persons: Member States shall ensure the mutual recognition of education and training qualifications and authorisation to conduct designated procedures. Where an establishment no longer complies with requirements set out in the Directive, the competent authority shall have the power to suspend or withdraw its authorisation, or take appropriate remedial action or require such action to be taken. There shall be appropriate procedures for the license-holders to appeal against any such decision.

Each breeding, supplying and user establishment shall ensure that there is at least one trained person available at all times to look after the animals? welfare.

Tasks of the permanent ethical review body: MEPs consider it judicious to provide a yearly review of all projects classified as "severe" or those on non-human primates, and every 3 years for all other projects. Member States shall pay particular attention to the collection, collation and publication of records relating to projects classified as "severe" or those on non-human primates.

Breeding strategy of non-human primates: the obligations shall only concern EU breeding and supplying establishments of non-human primates. Where the use of non-human primates is authorised, the Commission and the Member States shall take all necessary measures to ensure appropriate transport conditions.

Monitoring inspections: the Commission shall undertake controls of the infrastructure and operation of national inspections as well as of the correct application of severity classifications in Member States. To that end, the Commission shall set up a system to monitor each Member State 's inspections and enforcement of this Directive on average once every three years, ensuring harmonised practices for the use and the care of animals used or intended to be used in scientific procedures.

Project authorisation: MEPs consider that projects classified as "moderate" or "severe" or any projects involving non-human primates should not be carried out without a prior authorisation by the competent authority. All other projects shall be notified in advance to the competent authority following ethical review by the institution?s permanent ethical review body.

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

Granting project authorisations: project authorisations shall be granted for a period not exceeding five years (instead of three years).

Sharing of data: Member States shall ensure the sharing of data generated by procedures, including those which have taken place in the European Union prior to the coming into force of this Directive. Anyone seeking to rely on data owned by another shall, where appropriate, contribute towards the cost of producing such data.

European Centre for the Validation of Alternative Methods: MEPs suggest that the remit of the European Centre for the Validation of Alternative Methods shall be extended so that it includes the co-ordination and promotion of the development and use of alternatives to animal procedures including applied and basic biomedical research and veterinary research and regulatory testing by, for instance, coordinating research undertaken to facilitate the development of alternatives to animal procedures by the National Centres or providing databases to facilitate the exchange of relevant information.

Each Member State shall nominate a centre responsible for supporting the development, validation and promotion of alternatives to animal tests used for regulatory purposes, and facilities to develop and promote the use of alternatives to animal procedures undertaken for other purposes, such as basic and applied biomedical and veterinary research.

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

In the periodic reviews, the Commission shall give priority to the reduction and elimination of procedures causing the greatest permissible pain, suffering, distress or lasting harm and those which are not designed to alleviate life-threatening or debilitating clinical conditions in human beings, with a view to the elimination of all procedures.

The Commission shall take into account evolving public opinion about the use of animals in procedures in the periodic reviews.

Protection of animals used for scientific purposes

The Council took note of the Presidency progress report on the Commission proposal for a Directive of the European Parliament and of the Council on the protection of animals used for scientific purposes.

Protection of animals used for scientific purposes

The Council took note of the state of play of negotiations with the European Parliament, under the codecision procedure, on the proposal for a Directive on the protection of animals used for scientific purposes.

The Parliament delivered its opinion at first reading on 5 May 2009.

Protection of animals used for scientific purposes

The Council states that its position confirms the objectives proposed by the Commission and incorporates the majority of the European Parliament's first-reading amendments, either verbatim, in part or in spirit. The Council's position also includes a number of changes other than those envisaged in the European Parliament's first-reading opinion. These changes have been thoroughly negotiated with the European Parliament, which has confirmed its provisional agreement on the full text by a letter.

The main amendments to the Commission proposal are as follows:

Authorisation of persons: with the aim of reducing administrative burden and in order to cater more efficiently for different types of operators, the Council removed the proposed mandatory authorisation of persons carrying out or supervising procedures. Instead it put the emphasis on the requirements on competence of staff. These requirements include the obligation to specify in the authorisation of each breeder, supplier and user a person responsible for ensuring the adequate education, competence and continuous training of the staff.

Union Reference Laboratory: in line with an amendment of the Parliament, the Council strengthened the promotion of alternative methods at Union level by the introduction of a centralised Union Reference Laboratory, assigning it a set of responsibilities, including coordination and validation of alternative approaches and acting as a focal point for the exchange of information on their development.

Safeguard clauses: the Council introduced two additional safeguard clauses to take into account possible future situations where, for scientifically justifiable grounds, Member States deem it is necessary to authorise the use of nonhuman primates in areas not linked with debilitating and life-threatening conditions in humans or to surpass the upper limit for severity of procedures. This authorisation could only be provisional and would be subject to a Union control procedure.

Classification of the severity of procedures: sharing Parliament?s approach, the Council introduced into the Directive a system for a uniform classification of severity of procedures.

Protection of animals used for scientific purposes

The Commission notes that out of 167 amendments adopted by the Parliament, 76 were acceptable to the Commission either fully, in part or in principle.

41 amendments were accepted by the Commission and incorporated to varying degrees in the Council's position. These include the introduction of a new Annex providing detailed criteria for the four severity classes of procedures, criteria which were originally envisaged as part of implementing acts. However, the Commission welcomed this amendment and convened an expert meeting to agree on the detailed criteria. This allowed the annex to be updated by the Presidency with the latest expert understanding of the severity classes.

44 amendments were rejected by the Commission but have been incorporated in full, in part or in principle in the Council's position. These are all considered acceptable by the Commission as they do not endanger the original objectives or, if altering these objectives marginally, could still be acceptable in the spirit of compromise to reach an early second reading political agreement:

- in addition to vertebrate species including their larval forms, the scope now covers foetal forms only of mammals from the last third of their development and cephalopods as the only group of invertebrate animals. The Commission can accept this in the spirit of overall compromise;
- the final agreement allows for the maintenance of stricter measures, but not the adoption of new ones;
- Parliament asked for a feasibility study to be carried out on the sole use of second or higher generation purpose-bred non-human primates, and a modification of the deadline set out by the Commission for sole use of these animals. The Commission will conduct a further study to analyse the feasibility of sourcing animals only from self-sustaining colonies;
- the text now allows for a systematic re-use of animals already subject to 'moderate' procedures where the subsequent procedure can also be of 'moderate' severity. However, all Three Rs (the principle of replacement, reduction and refinement of the use of animals in procedures) have to be balanced when projects are evaluated, including decisions on re-use, and thus this amendment can be acceptable to the Commission;
- the text text puts the emphasis on risk analysis, however, requiring a minimum of one third of user establishments to be inspected annually, with the exceptions of breeders, suppliers and users of non-human primates which require annual inspections. An appropriate proportion of inspections shall be carried out without prior notice;
- Member States may now allow the authorisation of multiple generic projects which are also carried out for production or diagnostic purposes with established methods, in addition to those carried out to satisfy regulatory requirements.

18 amendments were accepted in full, in part or in principle by the Commission but not incorporated in the Council's position. However, it is important to note that a number of these were considered to be already covered in other articles or an Annex and thus considered superfluous. In light of the political agreement, these amendments are unlikely to be re-tabled.

37 amendments were rejected by both institutions. As a result of the political agreement on the text, these amendments are unlikely to be re-tabled.

The Council?s position also included a number of amendments over and above those set out in the European Parliament?s first reading. These amendments concern: (i) the authorisation of persons; (ii) EU reference laboratory; (iii) safeguard clauses; (iv) the classification of procedures according to their degree of severity.

The Commission concludes that the final text retains all key objectives that the Commission had set for the revision; namely to address the current problems of the uneven playing field, to fully incorporate the principle of the "Three Rs", including the promotion of the alternatives to animal testing, and to improve significantly the welfare of the animals still needed for scientific purposes. Parliament?s first reading placed a lot of emphasis on the reduction of administrative burden and the continuity and viability of European research and industry relying still on the use of animals.

The Council has addressed Parliament?s concerns by providing for more flexible rules for the implementation of project authorisation as well as for re-use of animals and by agreeing on a risk management based inspection scheme to ensure appropriate enforcement and compliance with the revised Directive. The concerns of administrative burden have inter alia been taken into account in more generous transposition times of the housing and care standards as well as in the way in which animal welfare bodies are to be implemented.

Lastly, both institutions voiced the need for further promotion of alternatives to animal testing. In response an EU reference laboratory for the validation of alternative methods, supported by Member States' efforts to bring in further resources in terms of suitable specialised laboratories, is envisaged.

The Commission supports the common position which strikes the right balance between the needs of the industry and research community whilst upgrading and harmonising the animal welfare standards for animals used or intended to be used for scientific purposes.

Protection of animals used for scientific purposes

The Committee on Agriculture and Rural Development adopted the recommendation drawn up by Elisabeth JEGGLE (EPP, DE) at second reading on the Council position at first reading with a view to the adoption of a directive of the European Parliament and of the Council on the protection of animals used for scientific purposes.

The committee recommended that the European Parliament adopts the Council position as it stands.

Protection of animals used for scientific purposes

The European Parliament adopted a legislative resolution on the Council position at first reading with a view to the adoption of a directive of the European Parliament and of the Council on the protection of animals used for scientific purposes.

The European Parliament adopted the Council position as it stands.

Protection of animals used for scientific purposes

PURPOSE: to strengthen the protection of animals used for scientific purposes and contribute to the reduction of animal use and ensure that

the animals used in experiments receive appropriate care and humane treatment.

LEGISLATIVE ACT: Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes.

CONTENT: the Council adopted a draft directive for the protection of animals used for scientific purposes, aimed at strengthening the protection of animals whilst allowing research to continue playing a key role in the fight against diseases.

To recall, Council Directive 86/609/EEC was adopted 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.

This new Directive provides 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.

Subject matter and scope: 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.

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

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 (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); (b) live cephalopods (as there is scientific evidence of their ability to experience pain, suffering, distress and lasting harm).

Methods of killing: 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.

Principle of the three Rs (replacement, reduction and refinement): 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. Member States shall ensure that the number of animals used in projects is reduced to a minimum without compromising the objectives of the project. They shall also 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.

Project evaluation: 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.

Non-human primates: the keeping and use of non-human primates for scientific purposes will be subject to tight restrictions. Experiments with great apes such as chimpanzees, gorillas and orangutans will be prohibited; a Member State may however allow exceptionally the use of great apes if it has justifiable reasons for believing that it is essential for the survival of the species itself or because of an unexpected outbreak of a life-threatening or debilitating disease in human beings. As a general rule, animals taken from the wild will not be allowed to be used in experiments, with some exceptions. The directive will also progressively require that non-human primates may only be used if they are the offspring of animals which have been bred in captivity or if they are sourced from self-sustaining colonies.

Inspections by the Member States: 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.

Alternative approaches: 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. The Commission shall take appropriate action with a view to obtaining international acceptance of alternative approaches validated in the Union.

Union Reference Laboratory: it shall be responsible, inter alia, for: (i) coordinating and promoting the development and use of alternatives to procedures including in the areas of basic and applied research and regulatory testing; (ii) promoting dialogue between legislators, regulators, and all relevant stakeholders. 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 (three Rs).

Safeguard clauses: two safeguard clauses are included in the Directive to take into account of possible future situations where, for scientifically justifiable grounds, Member States deem it is necessary to authorise the use of nonhuman primates in areas not linked with debilitating and life-threatening conditions in humans or to surpass the upper limit for severity of procedures. This authorisation could only be provisional and would be subject to a Union control procedure.

Classification of the severity of procedures: 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. The severity of a procedure shall be

determined by the degree of pain, suffering, distress or lasting harm expected to be experienced by an individual animal during the course of the procedure. Subject to the use of the safeguard clause, 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.

Reporting: Member States shall by 10 November 2018, and every 5 years thereafter, send the information on the implementation of this Directive to the Commission. They 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. The Commission shall by 10 May 2012 establish a common format for submitting the information.

Commission report: by 10 November 2019 and every 5 years thereafter, the Commission shall report on the implementation of this Directive. By 10 November 2019 and every 3 years thereafter, it shall present a summary report on that information.

Review: the Commission shall review this Directive by 10 November 2017, 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.

Transitional provisions: Member States shall not apply laws, regulations and administrative provisions adopted in accordance with Articles 36 to 45 (Requirements for projects) to projects which have been approved before 1 January 2013 and the duration of which does not extend beyond 1 January 2018. Projects which have been approved before 1 January 2013 and the duration of which extends beyond 1 January 2018 shall obtain project authorisation by 1 January 2018.

ENTRY INTO FORCE: 10/11/2010.

TRANSPOSITION: 10/11/2012.

Protection of animals used for scientific purposes

In accordance with the requirements of Directive 86/609/EEC, the Commission presents its seventh report on the statistics on the number of animals used for experimental and other scientific purposes in the Member States of the European Union.

The objective of the report is to present statistical data on the number of animals used for scientific purposes in the Member States of the European Union during the year 2011. The report contains the results of the data collected by all 27 Member States in 2011 with the exception of one (France) which provided data from 2010.

Due to differences in the reporting year and an increase in the number of Member States over the years, the Commission states that it is not possible to draw accurate quantitative conclusions on the evolution of the use of animals for experimental purposes in the EU.

Results: in the EU, the total number of animals used for experimental and other scientific purposes from the data collected in 2011 is just under 11.5 million (with data from France from 2010). This is a reduction of over half a million animals used in the EU from the number reported in 2008 :

- as found in previous reports, rodents and rabbits account for 80% of the total number of animals used in the EU. Mice are the most commonly used species with 61% of the total use, followed by rats with 14% ;
- the second most used group of animals was, as in previous years, cold-blooded animals which represent almost 12,5%. The third largest group of animals used was birds with 5.9% of the total use ;
- as stated in the previous three statistical reports no Great Apes were used in experiments in the EU in 2011.

Comparison with previous reports: the report notes that the effect of the inclusion of the data from new Member States since 2005 i.e. Bulgaria and Romania, did not lead to an increase in the total number of animals. On the contrary, a decrease was reported in 2008 and this downwards trend continued in 2011 (by more than 500 000 animals). However, the use of some individual species has increased.

There is a clear increase in the total numbers of five species out of the 25 species reported. For other species a net decrease is observed :

- the highest increase is noted for fish (310 307) in comparison to 2008 and for rabbits (25 000). For species used in lower numbers (i.e. in the thousands range) there is an increase in the number of animals in the category other carnivores (2 129), horses, donkeys and cross-breds (710) and other mammals (2 184) ;
- the largest decrease observed in 2011 for the more commonly used species is for rats with a reduction of more than 500 000 animals. In the same range there is also a reduction in the use of mice (122 876). There is also a significant reduction in the use of 'other birds' (more than 85 000) and guinea-pigs (49 401) ;
- there is a clear decrease in the use of prosimians and non-human primates (-94%).
- no use of great apes has been reported in EU since in 1999.

The Commission notes that this is the last time that animal use data will be collected in accordance with the requirements of Directive 86/609/EEC. This Directive has been replaced by Directive 2010/63/EU on the protection of animals used for scientific purposes, and the presentation of data has been completely revised with effect from 10 May 2013.

Protection of animals used for scientific purposes

This Communication sets out the Commission's legal and political conclusions, the actions it intends to take and the reasons for taking these in line with Regulation (EU) No 211/2011 on the Citizens' Initiative (Stop Vivisection).

"Stop Vivisection" is the third European Citizens' Initiative submitted to the European Commission on 3 March 2015. It was signed by 1.17 million citizens.

The Initiative asks the Commission:

- to abrogate Directive 2010/63/EU on the protection of animals used for scientific purposes and put forward a new proposal aimed at phasing out the practice of animal experimentation, making compulsory the use - in biomedical and toxicological research - of data directly relevant for the human species.

The organisers underline that (i) there are clear ethical objections of EU citizens to animal experiments; (ii) the animal model is not suitable to predict human responses and that animal testing hinders the development of new and more efficient methods in research.

Assessment of the citizens initiative: the Commission shares the Citizens' Initiative's conviction that animal testing should be phased out. This is the ultimate goal of EU legislation. However, the Commission:

- does not share the view that scientific principles invalidate the 'animal model'. Indeed, despite differences with humans, animal models have been the key scientific drivers to develop almost all existing effective and safe medical treatments and prevention measures for human and animal diseases;
- is of the opinion that animal experimentation does not pose an obstacle to developing alternative research tools. The use of animals in research actually provides a mechanistic understanding of the biology of animals and humans, which enables the development of more ethical, cost-effective, predictive and faster alternative methods. The Commission recognises the limitations of both animal models and alternatives, and constantly follows up and supports new developments for improved predictive methods.

Continued need for Directive 2010/63/EU: the Directive states that the final goal is a full phasing out of animal testing, but acknowledges that animal use is still necessary on the way to reaching this goal. Directive 2010/63/EU modernised and further harmonised rules on animal use across the EU in line with the most ambitious global standards and hence greatly increased the welfare of animals in scientific research and testing.

The Directive implements the Three Rs - to replace, reduce and refine animal use in Europe - and the Commission underlines the importance of continued efforts by all players, from Member States to the research community, to reach these goals.

At the same time, Directive 2010/63/EU is the catalyst for the development and uptake of alternative approaches, which is in line with the request of this Initiative.

Abrogating the Directive would not prevent the use of animals in experiments. It would instead deregulate the way in which such experiments are carried out, make the animals concerned more vulnerable and hinder the perspectives of developing alternatives. The Commission underlines that, for the time being, animal experimentation remains important for protecting human and animal health, and for maintaining an intact environment. It therefore does not intend to submit a proposal to repeal Directive 2010/63/EU and is not intending to propose the adoption of a new legislative framework.

Actions to be taken: the Commission will take the following actions to accelerate the development and uptake of non-animal approaches in research and testing:

1. Accelerating progress in the Three Rs through knowledge sharing: translating knowledge across disciplines and sectors accelerates progress in the Three Rs. Relevant knowledge is wide-ranging and can include scientific understanding of fundamental biological processes, how to refine animal experiments to minimise potential pain and suffering, how to optimally design non-animal approaches to tackle research questions or assess the safety of a substance, or how to characterise and standardise novel models to ensure that they are fit-for-purpose. A number of platforms and networks exist that contribute greatly to the advancement of the Three Rs, some of which are facilitated by the Commission. However, the systematic sharing of information and knowledge could likely be further enhanced.

Building on existing activities of the Commission, relevant EU agencies and OECD, the Commission:

- will analyse technologies, information sources and networks from all relevant sectors with potential impact on the advancement of the Three Rs,
- will present by end 2016 an assessment of options to enhance knowledge sharing among all relevant parties. The assessment will consider how to systematically accelerate knowledge exchange through communication, dissemination, education and training.

2. Development, validation and implementation of new alternative approaches: the Commission will continue to support the development, validation and implementation of alternative approaches for regulatory and research use. This will include close cooperation between the Commission, Member States and international organisations and be supported, as appropriate, by EU programmes.

3. Enforcement of compliance with the Three Rs principle and alignment of relevant sector legislation: the Commission will actively monitor compliance with Directive 2010/63/EU, in particular the Three Rs principle. By end 2016, the Commission will examine regulatory requirements in the relevant sector legislation mandating animal testing to assess if the legislative text enables an efficient up-take of available alternative approaches.

4. Engaging in a dialogue with the scientific community: the Commission will stay in close dialogue with the scientific community at EU and international level to identify alternative test methods, and will organise a conference by end 2016 on how to advance towards the goal of phasing out animal testing. The Commission urges the Member States, acting within their competences, to take account of the concerns raised in this initiative and to step up their efforts to fully implement and enforce Directive 2010/63/EU, and to actively participate in the development of alternative approaches.

Protection of animals used for scientific purposes

This Commission report responds to the provisions of Article 58 of Directive 2010/63 / EU on the protection of animals used for scientific purposes which requires a review of the Directive by 10 November 2017 at the latest. The purpose of the review is to determine whether the objectives of the Directive are achieved fulfilled, whether it is fit for its purpose or needs updating given the latest scientific and ethical developments.

Although it is still too early to assess many aspects of its performance against the policy objectives, the Directives framework is generally considered to be a sound basis for the regulation of animals used for scientific purposes. Therefore, no changes to the Directive are proposed at this stage.

Positive effects and problems noted: early indications are that the implementation of the Directive will deliver some of the changes and expected results. For example, stakeholders consider that the creation of animal welfare bodies is an effective requirement as it already contributes positively to the improvement of use practices.

Other positive effects were reported, including: (i) raised standards in care, accommodation and research practices; (ii) increased awareness of the three Rs (replacing and reducing the use of animals for scientific purposes and refining the care provided to them); (iii) the promotion of the culture of care; (iv) the growing recognition in the research community of the link between animal welfare and good science; and (v) greater transparency.

Areas identified by stakeholders as needing further attention and progress include the efficiency and consistency of project evaluation and authorisation processes as well as access to, and quality and transparency of information on the use of animals.

In addition, four key issues hindering a more rapid uptake of alternatives were identified: lack of knowledge; insufficient communication/spreading of information; acceptability, and cost.

Use of non-human primates: with the aim of ending capture of non-human primates from the wild for both scientific and breeding purposes, the Directive allows, after an appropriate transition period, the use only of non-human primates that are the offspring of animals which have been bred in captivity or that are sourced from self-sustaining colonies.

On the basis of the Article 10 feasibility study, there is no justification to prolong the transitional period set out in Annex II (November 2022) for the use of second and/or higher generation purpose-bred non-human primates. However, the reporting categories in Commission Implementing Decision 2012/707/EU will be amended to require inter alia systematic reporting of the generation of non-human primates used, including when acquired from self-sustaining colonies.

Lastly, once sufficient scientific evidence is available, Annex III on care and accommodation will need to be amended to incorporate standards for cephalopods and to provide more details for some groups of species.

Annex IV should be amended to provide appropriate killing methods in for cephalopods, and to align existing methods with latest the scientific knowledge on the basis of annual reports by Member States, where appropriate

Factual information on practical implementation of the Directive by Member States is not due until 2018. National statistical data were published for the first time in 2015, but trends of animal use at EU level will not be known before 2019. Information on retrospective assessments of projects will become available from 2019.

Therefore, a full REFIT evaluation of the Directive will be undertaken after 2019 when better information is available.

Protection of animals used for scientific purposes

The Commission presented a report on the exercise of the power to adopt delegated acts conferred on the Commission pursuant to 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.

Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes regulates the care and use of animals for scientific purposes. It empowers the Commission to adopt delegated acts to adapt the Annexes I and III to VIII (with the exception of provisions of Sections I and II of Annex VIII) to scientific and technical progress:

- list of animals requiring these specifically bred for use in procedures;
- requirements for establishments and for the care and accommodation of animals;
- methods of killing animals;
- minimum requirements for education and training of staff;
- obligatory information to be included in a project application;
- duties and tasks of the Union Reference Laboratory established for the coordination of validation of alternative methods at Union level;
- severity classification of procedures [examples of different types of procedures assigned to each of the severity categories.

The power to adopt delegated acts was conferred on the Commission for a period of 8 years beginning on 9 November 2010 and the Commission is required to prepare a report in respect of the delegation of 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.

The Commission has, over the past seven years, not exercised the delegated powers conferred to it under Directive 2010/63/EU. Until now, however, no sufficient scientific information has become available to warrant such an update of the relevant Annexes. In addition, the Directive took longer than was foreseen until its transposition in all Member State legislation was completed. There is only limited experience on the provisions contained in the Annexes of the Directive.

However, the Commission considers that as research continues to deliver new knowledge on the welfare needs of the species used, and as new investigation techniques and tools become available, the Commission will be required to use its delegated powers to ensure the Directive is adapted to scientific and technical progress.

Protection of animals used for scientific purposes

The Commission presented a report on the implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes in the Member States of the European Union. The report is based on the reports submitted by the Member States. Its main conclusions are as follows:

Implementation of the legislation

All Member States made changes to their national legislation to transpose the Directive, but the extent of these varied significantly, dependent also on how the previous Directive (86/609/EEC) had been implemented.

Experience with the new legislative requirements is still limited, particularly for those Member States whose transposition has been slow. However, it is clear that most Member States are committed to meeting the requirements of the Directive. For example, most Member States have indicated that they have made major changes due to: (i) the extended scope; (ii) the new requirements on accommodation and care for animals and on killing methods; (iii) the risk-based approach and the frequency of inspections.

In addition, the focus on alternative approaches caused many Member States to consider how to best meet the provisions in the Directive. Some set up three Rs (replacement, reduction and refinement) centres voluntarily to promote alternatives.

Structures and framework of competent authorities

In 21 Member States, one ministry is responsible for the implementation of the Directive. The structures for project evaluation and authorisation vary considerably - from single committees (competent authorities) responsible for the evaluation and authorisation of all projects in the Member State to regional structures, to local ethics committees which assess only local projects, or within a single establishment.

The implementation of animal welfare structures and national committees for the protection of animals used for scientific purposes has been successful, although it depends on the resources available.

Animal welfare bodies are recognised as a very positive step towards improving animal welfare and science. Their inputs have highlighted the importance of applying the Three Rs to all animals, whether used, bred or held in stock. Animal welfare bodies have improved communication between those conducting procedures and those caring for the animals.

Education and training requirements continue to differ between Member States even if some simplified processes have been installed to facilitate movement of scientists. Several Member States reported that they are currently carrying out activities to improve the provision of training. Despite the diversity of training, no observations suggested that lack of skills was a problem.

Differences in project application and evaluation processes and authorisation times continue to impact negatively on the objective of achieving a level playing field for scientists across the EU

Sourcing of non-human primates

The Directive promotes second or higher generation purpose-bred non-human primates in the EU. The implementation reports show that authorised breeding establishments in the EU already offer non-human primates today.

Inspections

The report notes that 18 Member States performed more inspections (covering users, breeders and suppliers) than one third of the number of authorised users in their Member State per year. Nine Member States appear not to have achieved one third in some years. One Member States has performed fewer inspections in all five years.

Five Member States reported no unannounced inspections. Despite this, the total proportion of unannounced inspections in the EU since the Directive took effect seems to be relatively high, around 40%.

Animals bred for use in procedures

For the first time in the EU, the number of animals bred and killed without being used in procedures was reported for the year 2017 (12 597 816 animals in total). Together, the annual statistical report and the implementation report give a comprehensive picture of all animals needed to support research, testing and education/training in the EU in a given year.

Non-technical project summaries

The Directive requires that non-technical summaries of authorised projects are published to inform the public on live animal use. As experience grew, the content improved, and the time to publication was reduced, thanks to IT systems to host these non-technical project summaries. From 2021 onwards, the publication of non-technical project summaries will be required through a central EU database and within six months of the authorisation of the project.

Together with stakeholders, the Commission developed guidance documents addressing key concepts in the Directive, available in all 23 Union languages. It is also addressing future scientists through development of education and training tools focusing on alternatives to animal use.

Monitoring transposition

As guardian of the Treaties and in line with its commitment in response to the European Citizens' Initiative "Stop Vivisection", the Commission is examining the conformity of the transposition into national legislation. As a result, structured dialogues (EU Pilot) have been launched with all Member States. If cases of non-compliance are identified, the Commission may launch new infringement procedures.