



EU bibliographies: Animal Experiments Directive

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Section International Affairs and Defence Section

This Note brings together documents relevant to the draft EU Directive replacing Directive Dir86/609/EEC on animal testing. It is not an attempt to define policy in this area. For information on policy developments contact Elena Ares on extn 6348.

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Contents

1	Animal Testing Directive Dir86/609/EEC	2
1.1	European Court of Justice cases	2
2	Proposal replacing DIR86/609/EEC	2
2.1	Treaty Base	3
2.2	Related documents	3
3	EU Scrutiny	3
4	UK Parliament Scrutiny	4
4.1	House of Commons	4
4.2	House of Lords	5
5	Comment	5
5.1	EurActiv	5
5.2	EU Observer	5
5.3	Parliamentary Questions	5
5.4	Early Day Motions	8
5.5	Press releases	9
5.6	Press articles	9

1 Animal Testing Directive Dir86/609/EEC

Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes

Published in OJL 358, 18.12.1986, p. 1–28.

1.1 European Court of Justice cases

Commission v Luxemburg. - Failure by a Member State to fulfil obligations - Failure to implement Council Directive 86/609/EEC - Protection of animals used for experimental and other scientific purposes. - Case C-274/93. [Judgment given 25th April 1996.](#)

Commission v the Netherlands: Failure of a Member State to fulfil its obligations - Directive 86/609/EEC - Protection of animals used for experimental and other scientific purposes - Incomplete transposition. Case C-205/01. [Judgment given 16 January 2003.](#)

2 Proposal replacing DIR86/609/EEC

The [Proposal for a Directive of the European Parliament and of the Council on the protection of animals used for scientific purposes](#) EC Draft 15546/2008, COM(2008)543 was issued on 5th November 2008.

The purpose of the draft Directive, as stated in its explanatory memorandum, is as follows:

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 the current Directive, a number of Member States have established considerably more far reaching measures in their national implementation whereas others apply only minimum rules. The present uneven situation needs to be rectified to ensure that the objectives of the internal market are re-established. The current 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 Welfare¹. The proposal supports the Commission's overall strategy on animal experimentation, including enhanced promotion of the development, validation, acceptance and implementation of alternative methods and provides a solid basis for a full implementation of the principles of the Three Rs² - Replacement, Reduction and Refinement of animals in experiments.

2.1 Treaty Base

The provisions of this Directive relate to the harmonisation of the internal market in the field of breeding, supplying and use of animals and consequently Article 95 of the EC Treaty was kept as the legal basis.

2.2 Related documents

Commission staff working paper accompanying the proposal for a Directive of the European Parliament and of the Council on the protection of animals used for scientific purposes: [Impact assessment SEC\(2008\)2410](#)

Commission staff working paper accompanying the proposal for a Directive of the European Parliament and of the Council on the protection of animals used for scientific purposes: [Summary of impact assessment SEC\(2008\)2411](#).

[Explanatory memorandum](#) from the Home Office dated 25th November 2008

The Home Office issued a consultation on the draft Directive on 8 May 2009. The consultation closed on 3rd July 2009. [A summary report on the public consultation on the Revision of EC Directive 86-609](#) was published on 30 March 2010.

Following the adoption of the proposal as Directive 2010/63/EU the Home Office ran a further [consultation](#) on the options for transposing Directive 2010/63/EU on the protection of animals used for scientific purposes and on the accompanying impact assessment. This consultation closed on 5 September 2011.

The Home Office issued a [report](#) on 17 May 2012 summarising responses to the consultation on the protection of animals used for scientific purposes and outlining the Government's next steps in transposing the Directive.

3 EU Scrutiny

The draft Directive is subject to the co-decision procedure. This procedure is outlined in Standard Note SN/IA/2120 [The European Parliament: its role and powers](#). It is also explained, with a graphic, on the [Europa website](#).

EP Draft report by the Committee on Agriculture and Rural Development [18.2.2009](#)

EP final report [A6-0240/2009](#) 3 April 2009 by the Committee for Agriculture and Rural Development. Rapporteur: Neil Parish.

EP resolution co-decision 1st reading [5 May 2009](#)

[Opinion](#) of the European Economic and Social Committee of 13 May 2009 given in OJC 277, 17 November 2009.

[Commission communication](#) on the action taken on opinions and resolutions adopted by Parliament on 5 May 2009.(stating Commission's position on European Parliament amendments)

Further discussions in Council 14-16 December 2009. See summary in press release [17488/09 \(Presse 375\)](#) p31

Adoption of (a) the Council's position (b) the statement of the Council's reasons in [9968/2010](#) and [9968/2010 ADD1](#) dated 31 May 2010.

Position of the Council at first reading in [6106/2010](#) and [6106/2010 ADD 1](#) dated 21 May 2010.

Commission's communication on the Common Position [COM\(2010\)324](#) dated 15 June 2010.

[EP Draft report](#) with recommendation for second reading by the Committee for Agriculture and Rural Development, Rapporteur Elisabeth Jeggle published 30 June 2010

EP final Report for second reading A7-0230/2010 dated 13 July 2010. See press release [Limiting animal testing without hindering scientific research](#) 12 July 2010.

EP Resolution co-decision 2nd reading [8 September 2010](#)

EP Press release 8 September 2010 [Fewer animals to be used for scientific experiments](#).

Proposal adopted as [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](#) OJL 276, 20 October 2010 p33-79. Article 61 states:

Member States shall adopt and publish, by 10 November 2012, the laws, regulations and administrative provisions necessary to comply with this Directive. ...They shall apply those provisions from 1 January 2013.

4 UK Parliament Scrutiny

For a description of the scrutiny process for EU documents within Parliament see House of Commons Information Sheet L11 [EU Legislation and Scrutiny Procedures](#). For general background to the EU scrutiny see Research Paper 05/85 [The UK Parliament and European Business](#).

4.1 House of Commons

European Scrutiny Committee

10 December 2008 (Published in 1st report [HC 19-i 2008-09](#))

European Standing Committee B

3rd February 2009

4.2 House of Lords

Select Committee on the European Union Sub-Committee D (Environment and Agriculture)

The revision of the EU Directive on the protection of animals used for scientific purposes. [Volume I Report](#) and [Volume II Evidence](#) HL 164 2009-2010. Published 10 November 2009.

Government Response published [5 January 2010](#).

Report debated in the House of Lords [10th February 2010](#) HL Deb vol 717 c781-805.

5 Comment

5.1 EurActiv

EurActiv is an independent organisation which runs a website specialising in EU news and analysis. *EurActiv* published the following news briefing on animal testing which gives some background:

[EU wants fewer animals used in research](#) (9 September 2010)

[Commission-industry partnership aims to reduce animal testing](#) (7 November 2005)

5.2 EU Observer

EU observer is an independent news service founded in 2000 “to support the debate on - and development of European affairs”.

[EU tightens up animal testing rules](#) (8 September 2010)

5.3 Parliamentary Questions

Mark Pritchard: To ask the Secretary of State for the Home Department what her policy is on EC Directive 86/609/EEC, with particular reference to the use of apes for experimental and other scientific purposes. [193669]

Meg Hillier [*holding answer 13 March 2008*]: The objectives of the Government during the review of European Directive 86/609 on animal experimentation will be to ensure efficient and effective regulation that properly balances the protection of animals against the legitimate needs of science and industry. We do not believe that wholesale changes to the Directive are necessary to achieve the main benefits sought of harmonisation and animal welfare. We believe that the Directive has stood the test of time well and still provides a sound framework for regulation.

We feel that the current revision of the Directive should aim to improve the regulation of animal use by focusing on key areas where regulation and harmonisation would improve animal welfare, improve scientific outputs, provide a more level playing field within the EU and improve the EU’s competitiveness with other economic regions without compromising science and welfare.

The vast majority of primates used in scientific procedures regulated by the Animals (Scientific Procedures) Act 1986 in the UK are marmosets and macaques. Then Home Secretary Jack Straw said in 1997:

“Great Apes (chimpanzees, gorillas, pygmy gorillas and orang-utans) have never been used under the 1986 Act as laboratory animals. But this has not previously been banned. The Government will not allow their use in the future. This is a matter of morality. The cognitive and behavioural characteristics and qualities of these animals mean it is unethical to treat them as expendable for research.”

There are no plans to change this policy.

HC Deb 25 March 2008 c68W

David Amess: To ask the Secretary of State for the Home Department what her policy is on EC Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes; what recent representations she has received on this Directive; if she will publish copies of the representations she has received, together with her replies; and if she will make a statement. [245067]

Meg Hillier: The requirements of European Union directive 86/609/EEC are implemented in United Kingdom law through the Animals (Scientific Procedures) Act 1986. The 1986 Act puts into effect, and in some ways exceeds, the requirements of directive 86/609/EEC and of Council of Europe Convention ETS 123. I have received no recent formal representation.

A proposal for the revision of directive 86/609 has now been published and pending a formal public consultation to inform the Government's negotiating position my officials are undertaking a range of meetings with stakeholders including other Government Departments, users, funding bodies; and those with a special interest in alternatives, animal welfare and animal protection.

The UK Government supports the Commission's aims to harmonise the regulation of the use of animals for experimental and other scientific purposes across the European Union. In particular we support elements of the proposal that will promote high European animal welfare standards, and the development and use of alternative methods.

We believe that it is essential the regulation properly balances the protection of animals and the legitimate needs of science, industry and society, ensuring high quality scientific outputs while maintaining public confidence that animals do not suffer unnecessarily.

We will not support any unnecessary or disproportionate increase in the regulatory burden that would not further those objectives, or would damage the success, sustainability or competitiveness of the UK science base.

HC Deb 12 January 2009 c265-6W

Mr. Todd: To ask the Secretary of State for Health whether he has made an assessment of the potential effects of the proposed revisions to the EU Animals in Research Directive on medical research activity in England; what proposals he has made to the European Commission on the matter; and if he will make a statement. [265550]

Mr. Malik: I have been asked to reply.

The Government welcome the publication of the European Commission's proposal for a revised directive. We support the Commission's aim to harmonise the regulation of animal experimentation across the European Union. We also support measures to promote high welfare standards for laboratory animals and to promote the development and use of

alternatives. At the same time we believe it is vital that regulation properly balances the protection of animals and the legitimate needs of science and industry while maintaining public confidence that animals are not allowed to suffer unnecessarily.

We are in the process of assessing the detailed, technical provisions of the draft directive and will shortly launch a public consultation to assist in developing the Government's negotiating position. Our key priority in negotiating the revised directive will be to develop practical, proportionate and enforceable legislation that makes proper provision for the welfare of laboratory animals, facilitates their responsible use, and can adapt to further technical progress.

HC Deb 26 March 2009 c669W

Kerry McCarthy: To ask the Secretary of State for the Home Department if she will take steps to ensure standards of animal welfare are maintained following implementation of the European Directive on the protection of animals used for scientific purposes.

Lynne Featherstone: I am satisfied that European Directive 2010/63/EU provides a sound and practical framework for the regulation of animal experimentation and testing in Europe and will allow the United Kingdom to maintain its traditionally high standards of welfare and animal protection. At the same time it avoids unnecessary bureaucracy and may offer opportunities to reduce the current regulatory burden in some areas without harming animal welfare.

HC Deb 17 November 2010 c808W

Lord Wills: To ask Her Majesty's Government what assessment they have made of the consequences of replacing the need for a personal licence to carry out experiments on animals with a requirement for registration.

The Minister of State, Home Office (Baroness Neville-Jones): The new European Union Directive 2010/63/EU requires authorisation (or by other means) of those who currently work in the UK under personal licences.

We are weighing up the implications of the various requirements of the directive with a view to seeking views in the public consultation. We plan to reach firm decisions on the way forward before the Summer Recess after considering the responses.

We are considering two options in the impact assessment (which will form part of the consultation)-"copy out" in which we would transpose the minimum requirements of the directive (some of which are lower than current United Kingdom requirements); and a second option in which we would retain current United Kingdom requirements where they are higher. We are not yet at a point where we can say which option we favour. The United Kingdom's current requirements for personal licences are more detailed than required by the directive and a decision will need to be taken in due course.

HL Deb 17 January 2011 c1WA

Caroline Lucas: To ask the Secretary of State for the Home Department pursuant to the answer of 17 January 2011, *Official Report, House of Lords*, column WA2, on animal

experimentation, which minimum requirements of the new EU Directive 2010/63/EU on animal experimentation are lower than current UK requirements; in what ways such requirements are lower than current UK requirements; and if she will make a statement.

Lynne Featherstone: Many of the provisions of Directive 210/63/EU are similar to current United Kingdom requirements; some are new and go further; and a few are potentially less stringent. For example, unlike the Animals (Scientific Procedures) Act 1986, the directive does not provide special protection for cats, dogs and equids. In addition, some of the mandatory standards of care and accommodation set out in Annex III to the directive are lower such as cage height for rats, hamsters and gerbils; minimum floor areas for sheep, goats, dogs, rabbits, guinea pigs, pigs, mini-pigs and equids. The directive also excludes from protection foetal forms of birds and reptiles and protects foetal forms of mammals from the last third of gestation rather than the halfway point. The required membership and functions of the proposed animal welfare bodies in establishments are also less extensive in the directive than the current requirement for local ethical processes in the United Kingdom. This is not a full and final list of differences and further details will be included in the impact assessment currently in preparation which will be published in due course.

HC Deb 10 February 2011 c376-7W

Mr Sanders: To ask the Secretary of State for the Home Department if she will bring forward proposals to reduce the 12-year period for ending the use of wild caught primates for scientific research in the UK.

Lynne Featherstone: Article 10 of European Directive 2010/63 requires that animals of all species of non-human primate used in scientific procedures must be purpose bred unless there is justification for the use of wild caught animals. The United Kingdom has operated a similar policy since 1995 and has not authorised the first time use of wild caught primates for more than 10 years.

Article 10 also requires that from the dates set out in Annex II to the Directive all non-human primates should be the offspring of animals bred in captivity or sourced from self sustaining colonies. Under Article 10, the European Commission must carry out a feasibility study by 10 November 2017 to confirm or amend the dates in Annex II. The United Kingdom contribution to the feasibility study will be considered at the appropriate time when consulted by the Commission.

HC Deb 18 May 2011 c218-219W

The following debate is also relevant:

Animals: Experimentation [HL Deb 24 October 2011 c618-633](#)

5.4 Early Day Motions

EDM 1842

Tabling Member: Alan Meale. 23.05.2011

EU DIRECTIVE 2010/63 ON ANIMAL TESTING

That this House notes that more than three million animals are killed each year in British laboratories, including several thousand non-human primates; is concerned that EU Directive 2010/63/EU, dealing with the protection of animals involved in scientific testing, falls short of

current UK animal welfare standards; regrets that this House has never been consulted on this new Directive, especially as the use of animals in such a way is a source of great concern to the British public; supports the National Anti-Vivisection Society's campaign aimed at replacing animal testing with cruelty-free alternatives; and urges the Government to hold a democratic debate on this issue and the said EU Directive at the earliest opportunity.

5.5 Press releases

RSPCA

[Government prepares to weaken law as animal experiments hit record high.](#) 13 July 2011.

5.6 Press articles

“Alternatives to animals; Anti-vivisectionists and scientists who experiment on animals share more common ground than you might think.” By Vicky Robinson. *New Scientist* 7 March 2009

“Animal ruling 'threatens vital research'. By Mark Henderson. *The Times* 26 March 2009

“EU to act over 'cruel' experiments on animals”. By Daniel Foggo. *The Sunday Times*. 5 April 2009

“Animal welfare plea over EU report”. *Yorkshire Post* 4 May 2009

“Catheter and mouse”. *The Economist*. 9 May 2009