Summary of Responses to the Consultation on Proposals for the Revision of EU Directive 86/609/EEC on the protection of animals used for scientific purposes
Summary of Responses to the Consultation on Proposals for the Revision of EU Directive 86/609/EEC

CONTENTS | PAGE
--- | ---
Introduction | 3
Summary of progress to date | 3
General views on the Commission proposal | 6
Responses on detailed issues | 6
Scope and Definitions | 6
Authorisation, Enforcement, Information Requirements | 7
Animal Welfare and Alternatives | 8
Non-human primates | 9
Procedures | 10
Personnel and Training | 11
Places | 11
Compliance | 12
The Impact Assessment | 12
Government response | 13
Annex A: Summary of main changes in the Swedish Presidency text | 14
Introduction

Background

1. European Directive 86/609/EEC makes provision for the protection of animals used for experimental or other scientific purposes and was transposed into United Kingdom law through the Animals (Scientific procedures) Act 1986\(^1\).

2. At the 19th meeting of National Competent Authorities on 29 November 2001, the European Commission announced that it intended to review and revise the Directive 86/609/EEC\(^2\).

3. In November 2008 the Commission published a proposal\(^3\) for a new directive for the protection of animals used for experimental and other scientific purposes to replace Directive 86/609.

4. The Commission’s proposal set out to rectify wide variations in the implementation of Directive 86/609/EEC in different Member States; strengthen the measures required to protect animals used in scientific procedures; and to promote the development, validation, acceptance and implementation of means to replace, reduce and refine such animal use.

Summary of progress to date

European legislative process

5. The Commission's proposal for a new directive is subject to the EU co-decision procedure under which the European Parliament and the Council of Ministers must agree a common text before new legislation can be adopted. Up to three ‘readings’ of the proposal are allowed for agreement to be reached.

6. In the present case, the European Parliament adopted its first reading report in May 2009 and a Council working party of veterinary experts and policy officials discussed the draft directive in a series of meetings between March and October 2009, first under the Czech Presidency and then under the Swedish Presidency. The dossier was then passed to attachés for final negotiation.

7. Discussions between the Swedish Presidency, the Commission and the European Parliament, started in the late autumn 2009 and were completed just before Christmas 2009. These discussions made significant progress towards agreement of a common text.

8. The Council of Ministers has not yet formally adopted an agreed position, but gave its broad support for the Swedish Presidency’s compromise text at Agriculture Council in

---


December 2009, subject to resolving a number of issues concerned with aligning the text with the Lisbon Treaty.

9. A summary of key changes in the Swedish Presidency text is provided at Annex A.

UK Parliamentary scrutiny

10. The House of Commons European Scrutiny Committee B debated the Commission’s proposal on 3 February 2009\(^4\). The proposal was also discussed in an adjournment debate on 24 February 2009\(^5\).

11. In the House of Lords, Sub-Committee D (Environment and Agriculture) of the EU Scrutiny Committee conducted an inquiry into the proposal taking evidence between May and October 2009 and publishing its final report 10 November 2009\(^6\). The Government’s response was sent to the Committee on 7 January 2010 and the Committee’s report was debated on 10 February 2010\(^7\).

Public Consultation

12. The Home Office held a formal public consultation on the Commission’s proposal between 8 May and 3 July 2009.


14. This document outlines and summarises the responses to the consultation under the following nine thematic headings.

- Scope and Definitions
- Authorisation, Enforcement, Information Requirements
- Animal Welfare and Alternatives
- Non-human primates
- Procedures
- Personnel and Training
- Places
- Compliance
- The Impact Assessment

15. In cases where responses are relevant to more than one of the thematic headings, they are reproduced under each of the headings for ease of reference.

\(^4\) See the Parliament Uk website to read the Scrutiny Committee debate [here](http://www.publications.parliament.uk/pa/cm200809/cmgeneral/euro/090203/90203s01.htm).

\(^5\) See the Parliament UK website to read the Adjournment debate [here](http://www.publications.parliament.uk/pa/cm200809/cm090224/halltext/90224h0004.htm#9022447000002).


\(^7\) [Here](http://www.publications.parliament.uk/pa/ld200910/ldhansrd/text/100210-0008.htm#10021067000651)
16. Although not every point made in response to the consultation has been itemised below, the Government’s input to the negotiation of the proposal has taken account of all points of view expressed.

Responses to the consultation

17. The consultation document contained a total of 94 questions. Of these, 72 related to the Commission’s proposal and the remaining 22 related to the provisional impact assessment.

18. Responses were received from 87 organisations and over 1000 individuals. Figure 1 and Table 1 provide a breakdown by respondent type.

Table 1 – Responses by Category

<table>
<thead>
<tr>
<th>Category</th>
<th>Number of Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Academic Institutions</td>
<td>33</td>
</tr>
<tr>
<td>Animal Welfare Groups</td>
<td>19</td>
</tr>
<tr>
<td>Charities</td>
<td>3</td>
</tr>
<tr>
<td>Government Agencies/ Arms-Length Bodies</td>
<td>4</td>
</tr>
<tr>
<td>Practitioners</td>
<td>6</td>
</tr>
<tr>
<td>Representative Bodies</td>
<td>17</td>
</tr>
<tr>
<td>Others</td>
<td>5</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>87</strong></td>
</tr>
</tbody>
</table>

Figure 1 – Responses by Category (%)
General views on the proposal

19. There was general support for the Commission’s high level objectives.

20. Those involved in animal research tended to agree that the proposal failed to fully reflect the Commission’s better regulation agenda and that elements of the proposal were over-prescriptive and would disproportionately increase costs and the regulatory burden.

21. Animal welfare and protection groups in general supported measures to reduce or eliminate the use of animals in scientific procedures, but also tended to take the pragmatic view that while such use continues it is essential to ensure it is appropriately regulated.

22. There was general or qualified support for many of the provisional Government positions set out in the consultation document.

23. Respondents tended to be sceptical that the Commission could or would ensure that the technical annexes to the directive keep pace with technical progress, even though provision is made for them to be amended by means of comitology.

24. A number of respondents favoured the inclusion of absolute prohibitions relating to a range of uses, such as the testing of household products, and a requirement that the Commission routinely undertake thematic reviews of animal production and use.

Responses on detailed issues

Scope and Definitions

25. Animal welfare and protection groups all wanted to expand the scope of the directive to give full protection to animals bred and used to provide organs and tissues; to all surplus stock animals; and to immature forms of mammalian and non-mammalian species, but not necessarily to include them in the annual statistics.

26. Animal researchers tended to support the provisional UK position that the welfare of animals bred and used to provide organs and tissues for scientific use is already adequately protected by other UK legislation.

27. There was general support for the extension of protection to invertebrate animals where there is evidence that they can experience pain, suffering or distress. There was, however, no clear consensus on what the current scientific evidence would support.

---

8 The term used to describe the procedures by which decisions to implement European Union legislation are made. Historically, these procedures have involved committees made up of representatives from member states and chaired by the Commission. Revised arrangements will apply under the Lisbon Treaty.
28. There was clear support for the inclusion of *veterinary clinical trials* within the scope of a revised directive unless animal welfare is protected by other regulations. Also that the marking and identification of animals by the least painful method should not be regulated; and that some non-invasive scientific procedures should be regulated. It was generally accepted that procedures not resulting in pain, suffering, distress or lasting harm to protected animals should not be covered by the directive.

29. There was general agreement that some of the proposed *definitions* were poorly drafted, and that additional definitions might be included.

30. Whilst there was significant support for the *permissible purposes* set out in the proposal, some respondents felt they were scoped too widely and that some classes of animal use (for example ‘education and training’ and ‘forensic enquiries’) should not be permitted. There were also specific suggestions for the imposition of absolute bans on a range of uses, such as the testing of household products, alcohol and tobacco products, weapons, food additives and shellfish testing.

**Authorisation, Enforcement, Information Requirements**

31. There was wide support for the Commission’s proposals for the *authorisation of establishments*, subject in some cases to authorisation of breeders and suppliers being limited to those producing and supplying the classes of animal that must be purpose bred.

32. A number of respondents commented on a European Parliament amendment requiring that *competent staff* should be available at all times, animal researchers arguing that staff need not be on site 24-hours a day.

33. There was general support for the proposals for *record keeping* and for the specific requirements relating to cats, dogs and non-human primates.

34. Animal welfare and protection groups considered that all *projects* should require prior authorisation by the national competent authority and opposed the suggestion that project authorisations could in some circumstances be issued by default or that *notification* could substitute for authorisation. There was only limited support for this latter proposal from other respondents, although a number felt it might be appropriate in limited circumstances.

35. There was general support for a proportionate approach to the content and structure of *project applications*, but also a view that full documentation might be needed even for procedures of mild severity and those “required by law”.

36. Respondents generally agreed that responsibility for the *ethical evaluation of project proposals* should rest with the competent authority, with a number of respondents commenting favourably on the proposal that the process be transparent and involve the opinion of independent parties.

37. There was qualified support for the development of a proportionate framework for *retrospective review and reporting* of some project outcomes, but no clear
consensus of how projects should be selected for review, or who should undertake such reviews.

38. There was support for the publication of summary information about all authorised projects, providing proper provision is made for the protection of personal and confidential information; but animal welfare and protection groups argued that non-technical summaries were not in themselves sufficient to ensure transparency and accountability. Some argued that inspection reports and details of infringements should also be published and that the directive should include a definition of what should be classed as confidential information.

39. There was wide support for extension of the maximum duration of project licence authorities to five years as is currently the case in the UK. Those not directly involved in animal research tended to oppose the granting of ‘multiple licences’.

40. Respondents supported the measures relating to project amendment, renewal and withdrawal; with a subset of users also supporting the concept that some minor amendments could be approved at establishment level, with some concern about the additional local resource this might require.

41. There was general support for the view that the ethical evaluation and authorisation of applications should be dealt with promptly, with applicants knowing how long the process should take. It was also generally agreed that no authorisations should be granted by default and that target-times for decisions were preferable to deadlines.

42. With respect to statistical reporting requirements, there was general support for developing a common European framework, but concerns that if the format and content could not be agreed and commented on before the directive was concluded the needs of different audiences might not be met.

43. There was strong support for nomination of an accountable, public body as the single UK competent authority.

Animal Welfare and Alternatives

44. Most animal welfare and protection groups agreed strongly with Article 4 requiring the use of alternative methods and the proposals for data sharing. Many in the research community argued strongly that there is no evidence of widespread unnecessary duplication of animal use and that compulsory data sharing would be unworkable.

45. Respondents tended to share the Government’s concerns that Annex V dealing with humane killing methods did not make good provision for animal welfare. Respondents also stressed that the persons killing animals must be appropriately trained and competent.

46. Respondents agreed that the provisions on endangered species other than non-human primates are consistent with current UK policy and practice. Although most felt
a robust cost/benefit assessment would provide the necessary protections, a smaller subset of respondents expressed support for additional restrictions.

47. A large majority of respondents argued for retaining the status quo in the UK with respect to the use of **animals taken from the wild**. A small number of respondents supported further restrictions or an absolute prohibition on their use.

48. There was support for restricting use to **purpose-bred animals** of the commonly used laboratory animal species. Some respondents favoured additional restrictions and the inclusion of animals omitted from the list at Annex II to the proposal.

49. Whilst the majority of respondents supported a prohibition on the use of **stray and feral domestic animals**, some could see potential benefits in allowing their use for the benefit of these classes of animal.

50. Most in the research community agreed with the concerns expressed in the consultation document about the technical quality of the **care and accommodation standards** set out in Annex IV and some voiced concerns about the costs of compliance. Most animal welfare and protection groups supported application of mandatory care and accommodation standards across Europe. There was also general support for the maintenance of UK standards where they are higher than those in Annex IV.

51. With respect to **national reference laboratories**, many respondents cited the UK’s National Centre (NC3Rs) as a potential model. Additional comments supported enhancing the roles and responsibilities of the current European Centre (ECVAM⁹), and broadening its scope to include procedures used in academic research.

52. With regard to **Great apes**, most respondents agreed with a continuing prohibition on their use.

**Non-human primates**

53. As expected, there were a large number of comments on the provisions of the proposal relating to **non-human primates**. Users tended to agree that as worded the proposal might prohibit some current lines research.

   ‘The proposed restrictions to the use of NHPs are disproportionate, potentially detrimental and would impair EU competitiveness…limiting the use of NHPs to ‘life threatening or debilitating clinical conditions’ … could: (i) substantially restrict fundamental research crucial to further development of therapies for human and animal health; (ii) limit R&D investment in health-related sectors; and (iii) slow innovation and vaccine and drug development and commercial collaboration.’

54. However, subsets of respondents, including animal welfare and protection groups, supported the proposal, negotiating further restrictions, or an outright ban.

⁹ The European Centre for the Validation of Alternative Methods
55. There was general support for restricting use of non-human primates to purpose-bred animals and for the use of animals which are themselves the offspring of animals bred in captivity. However, this support was often qualified by a need to confirm that this would not, of itself, add to welfare costs. There was also a clear desire to see that a strategy (and sufficient funding and time) would be available to make the necessary changes. Although many respondents agreed that seven years might be insufficient time and that a feasibility study was required, there was no consensus on an alternative timeframe.

56. Animal welfare and protection groups considered that the switch to the use of F2 animals should go ahead to the proposed timetable (or faster), without a feasibility study, and viewed the switch as only a step towards the eventual abolition of primate use.

‘…their use should be phased out completely….The Directive should put in place a strategy for the complete replacement of primate use in research and testing. In that context, we regard the proposed restrictions as only a step in the right direction.’

‘Fundamental research on primates should also be banned as an essential measure to reflect public opinion… and to promote the development and application of alternatives…’

57. There was general agreement that the proposals for record keeping were consistent with UK policy and practice and that the specific proposals for non-human primates were acceptable.

58. With regard to Great Apes, most respondents supported a continuing absolute prohibition on their use, but others supported the availability of a safeguard clause.

‘Great Apes have not been used in research in Europe since 2000. This is not cause, however, for an outright legislative ban… we strongly argue that the safeguard clause be retained.’

‘The prohibition on Great Ape use is appropriate…The subsequent safeguard clause should be deleted.’

‘…the ban on the use of Great Apes should be absolute.’

59. Users agreed that the provisions dealing with procedures were largely consistent with current UK policy and practice, but felt they should be redrafted to provide a clearer framework for field studies.
60. Some argued strongly that death as an endpoint should never be allowed. Others accepted that death would in some circumstances be a legitimate endpoint, but that specific justification would be required and all reasonable efforts would need to be made to minimise animal suffering.

61. Respondents agreed that the provisions relating to anaesthesia and analgesia were not well drafted and made insufficient provision for the protection of animals, for example in respect of post-operative care and the use of analgesics and neuromuscular blocking agents.

62. Respondents agreed that it was essential that the severity classification framework should be developed before the revised directive is concluded. Users foresaw problems if there were restrictions on the use of severe disease models while some other respondents favoured prohibiting severe procedures.

63. The majority of respondents favoured retaining the UK status quo regarding permissible re-use (even if it meant changing the means of determining what is permissible). Some favoured a prohibition or additional restrictions on re-use.

64. Respondents agreed that at the end of a procedure any decision as to whether an animal should be kept alive should involve veterinary input, and consideration of whether any procedure-related suffering or lasting harm was to be expected. Some felt that 'non-harmful' lines of genetically altered animals could be discharged from control. Others felt this should not be permitted.

65. Some users highlighted potential logistical problems if sharing of organs were made a mandatory requirement.

66. Subject to there being suitable safeguards, respondents supported in principle the provision for the setting free and re-homing of animals with some pointing out that setting free would be an integral part of some field studies.

Personnel and Training

67. There was support for a common accredited training framework across the Community, including practical training, for key persons as well as for the mutual recognition of qualifications and competence to facilitate the free movement of skilled labour.

68. Animal protection groups tended to support the proposal that the animal care and welfare role should include responsibility for compliance. Most users did not support this proposal.

Places

69. Most respondents drew a parallel between the proposal for permanent ethical review bodies at each establishment and the current UK requirement for local ethical review processes. A number expressed concerns about the proposed membership and functions. There was general agreement that the designated veterinary surgeon
should be a member and general, but not universal, support for including lay and/or external people and others.

70. Some non-users argued strongly that the outputs of the local ethical review body should be available to the competent authority and publicly available.

71. Respondents tended to agree with the proposed requirements for re-homing schemes.

72. There was clear support for the marking and identification of animals to be done using the least painful method.

Compliance

73. There was general agreement that the penalties for non-compliance should be proportionate and dissuasive. There was almost no support for the automatic suspension or revocation of authorities for non-compliance, but strong support from animal welfare and protection groups for mandatory suspension for any breach adversely affecting animal welfare.

74. There was support for a risk-based national inspection programme, including unannounced inspections. Most animal welfare and protection groups considered that twice yearly inspection should be the minimum required. A small subset of respondents felt inspection reports should be published.

75. Some respondents argued that the Commission should be required to review the directive at more frequent intervals than provided for in the proposal and to carry out thematic reviews.

76. Most respondents supported in principle the proposal for national animal welfare and ethics committees.

The Impact Assessment

77. We received relatively few comments on the preliminary impact assessment.

78. A number of those who did comment believed that some of the costings provided were, or seemed, unrealistically low or high. However, no robust new evidence was received permitting more accurate costings to be derived.

79. Many agreed that several important potential benefits had been identified that could not be monetised for the purposes of a money-based impact assessment. In some cases respondents offered surrogate measures or indices that might be considered to reflect these non-monetised benefits.
Government response

80. We are very grateful to everyone who responded to the consultation.

81. In many cases, the responses confirmed and expanded on points made in earlier stakeholder discussions and many had already been taken into account in developing the initial UK negotiating position outlined in the consultation document.

82. It was, nevertheless, extremely helpful to receive detailed comments on the issues covered in those stakeholder discussions and in the consultation document and the responses have been fully taken into account in the UK’s input to the negotiation of the directive.

Animals Scientific Procedures division
Home Office

1 April 2010
Annex B: Summary of main changes in the Swedish Presidency text

In negotiating the proposal we have aimed to ensure that the revised directive makes proper provision for the welfare of experimental animals and at the same time avoids imposing disproportionate or unjustified regulatory burdens which could undermine the success and sustainability of European research. Many of the detailed concerns expressed by respondents to the consultation have been addressed and we believe the resulting text delivers on each of the objectives we set at the outset of the negotiation. In particular, it contains practical, proportionate and enforceable measures that make proper provision for the welfare of experimental animals; will facilitate their responsible use; and can be adapted to further technical progress.

Authorisation of persons and places

The provisions relating to the authorisation of persons and places have been the subject of extensive discussion, reflecting concern about the bureaucratic burden involved. In the revised text each breeder, supplier and user (establishment) must be authorised and registered with the competent authority and the authorisation must specify a person responsible for ensuring compliance with the detailed requirements placed on establishments by the Directive.

In addition, each establishment must have sufficient, adequately educated and trained staff to carry out procedures on animals; design procedures or projects; take care of animals; and kill animals. Member States may, if they wish, choose to authorise these individuals. Ensuring compliance with project authorisations will be the primary responsibility of the equivalent to our current UK project licence holder.

Each breeder, supplier and user must also have a designated veterinarian or other suitably qualified person and one or more persons responsible for overseeing the welfare and care of the animals bred, kept, killed or used in the establishment; ensuring staff have access to species-specific information; and ensuring staff are adequately educated, trained and supervised.

Many of these requirements are similar to current UK arrangements.

Use of non-human primates

The draft directive now includes a definition of ‘debilitating clinical condition’ which encompasses almost all current uses of non-human primates. The draft directive also includes provision for borderline applications involving the use of non-human primates to be provisionally authorised by a Member State and subject to final decision by the Commission via comitology. In addition, the Commission has given a commitment to convene an expert working group to provide further guidance on how to interpret the restrictions on primate use. Taken together, we believe the new definition, the safeguard clause and the promised guidance will provide sufficient clarity and a suitable mechanism to resolve any areas of uncertainty about the use of primates – such that well-justified research and testing can continue.
**Revision of EU Directive 86/609/EEC**

**Acquisition and use of non-human primates**

Although not a requirement of the current Directive, only purpose-bred non-human primates are currently used in the UK. The revised directive will make the use of purpose-bred non-human primates the European norm. In addition, the revised text includes a requirement for a feasibility study to look at the required move to the exclusive use of non-human primates which are the offspring of captive-bred animals – so-called F2 animals. This provides welcome reassurance that the deadline for this requirement will be adjusted if it is found to be unrealistic. The draft also now requires the Commission to conduct a study to establish the feasibility of sourcing non-human primates exclusively from self-sustaining colonies. This study is to be published no later than ten years after transposition.

**Severity classification of procedures**

Details of a severity classification system are now set out in a new Annex IX based on the work of an expert working group which met in July 2009. UK experts were closely involved. The draft directive also sets an upper limit to the severity of procedures that may be authorised. Although we can think of no examples of legitimate animal use which could not be accommodated within this upper limit, there is the possibility to exceed this limit with the approval of the Commission.

**Re-use of animals**

The revised text now provides for the re-use of animals where the previous procedures were ‘mild’ or ‘moderate’; the animal’s health and well-being has been fully restored; the further procedure is classified as ‘mild’, ‘moderate’ or ‘non-recovery’; and follows veterinary advice.

**Care and accommodation standards and humane killing**

Annexes IV and V setting out mandatory standards for the care and accommodation of animals and specifying humane killing methods have been substantially amended - with detailed input from the UK - to correct technical errors and omissions in the original text. In addition, the deadline for implementation of the care and accommodation standards has been set at January 2017, allowing up to six years for establishments to adapt their facilities.

**Ethical evaluation and authorisation of projects**

Member States have agreed that all projects should be subject to ethical evaluation and prior authorisation – as is currently the case in the UK. Proposals for ‘notification’ and ‘tacit approval’ of projects have been dropped.

**Data sharing**

The requirement for data sharing has been removed from the text, but a requirement for mutual acceptance by Member States of data generated by procedures recognised by Community legislation has been retained.
National reference laboratories

There is no longer a requirement for national reference laboratories. Instead a requirement is to be placed on the Commission to consult Member States in setting priorities for validation studies and over the allocation of tasks to laboratories nominated by Member States. A requirement has also been created for a Community Reference Laboratory, the duties and tasks of which are set out in a new Annex VIII.

Inspections

The Commission proposal requiring at least two inspections at each establishment each year was viewed by many Member States (but not the UK) as too resource intensive and prescriptive. The emphasis is now placed on a risk-based approach. The revised text requires that regular inspections are carried out and that an appropriate proportion are unannounced. A minimum of one third of users are to be inspected each year, but breeders, suppliers and users of non-human primates will be inspected at least once a year.

Thematic reviews

The text now provides for the directive to be reviewed five years after transposition. and provision is also made for periodic, thematic reviews of the use of animals.