

HMG response to the House of Lords EU Select Committee Report of 10 November 2009 on the Revision of the EU Directive on the protection of animals used for scientific purposes (HL Paper 164-I)

Introduction

The Government warmly welcomes the House of Lords EU Select Committee Report and its findings. This paper outlines the Government's response to the Committee's specific recommendations.

The Commission's proposal published in November 2008 sought to establish revised measures for the protection of animals used for scientific purposes to replace those set out in Directive 86/609/EEC. This is very significant as animal experimentation continues to be a vital tool in developing improvements in healthcare, and protecting man and the environment.

Getting this legislation right is key to the long term competitiveness of academic and commercial research in the UK and Europe. It is also key to ensuring consistent high animal welfare standards across Europe.

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.

The European Parliament adopted its first reading report in May 2009. The Council of Ministers has not yet adopted an agreed position. However, trilogue discussions between the Presidency, the Commission and the European Parliament have made significant progress towards agreement of a common text. This progress is reflected in the current Presidency compromise text (Document 17299/09).

This text is more flexible and less prescriptive than the Commission's proposal and, overall, provides a regulatory framework which, we believe, is balanced and will allow the UK to maintain high standards of welfare and animal protection after transposition and implementation without the imposition of unnecessary bureaucracy.

We believe the compromise text provides a sound basis for the future regulation of animal research in Europe.

COMMITTEE RECOMMENDATIONS

Rationale for a revised directive

100. We agree that the 1986 Directive should be revised; a new Directive should contain effective safeguards to ensure consistent implementation. (para 15)

We share the Committee's view that Directive 86/609/EEC should be revised. Directive 86/609 has not succeeded in creating a level European economic playing field as it was intended to do. It is also necessary to bring its provisions into line with progress in science, animal welfare and the development of alternatives.

We agree also that the success of the new Directive will depend on effective and consistent implementation and enforcement both at national level and by the Commission. We support the provisions enabling the Commission to carry out 'controls' of the infrastructure and operation of national inspections in Member States where there is reason for concern supported by evidence.

Scope

101. Based upon the available scientific knowledge about sentience, we consider that, while cephalopods should be included, decapods should be excluded. We also take the view that independently feeding larval forms of invertebrates should be excluded. We consider that cyclostomes should be included. (para 19)

We agree. We have previously explained our reservations about the strength of the evidence presented to support the inclusion of invertebrate species within the scope of the new Directive. Other Member States have taken a similar view and decapod crustaceans have now been excluded from scope in Document 17299/09, as has reference to independently feeding larval forms of invertebrates. Cyclostomes and live cephalopods remain within scope.

One species of cephalopod – the common octopus - is already covered by current UK legislation and although the evidence of sentience is not in our view conclusive, we believe the inclusion of other cephalopod species will not create a significant additional regulatory burden for scientific research.

102. We think that it should be possible for the emergence of new, scientific evidence pertaining to sentience to lead relatively readily to the inclusion (or exclusion) of invertebrate species in the control regime of the Directive; we would hope that further consideration of the framing of these provisions would allow a more flexible approach to be followed. (para 20)

We were advised during the initial negotiation of the Directive that comitology cannot, generally, be used to effect changes to essential elements of a Directive, such as its scope. However, we agree that it would be desirable for Member States to be permitted to extend protection to other animals where this is justified by new scientific evidence. We will explore further whether this might be achievable, for example under the new arrangements for delegated and implementing acts introduced in the Lisbon Treaty by articles 290 and 291, the operational details of which are still being negotiated by Member States.

103. We support the proposal that independently feeding larval forms and embryonic or foetal forms (from the last third of their normal development) of live non-human vertebrate animals would also be included. (para 21)

We agree. Such forms are included within scope in Document 17299/09.

104. The provisions of the Directive should be amended to ensure that the breeding and humane killing of animals for their tissues and organs should not be regarded as a “project” within the terms of the Directive. While the care and welfare of these animals should be ensured, we regard it as disproportionate to require that work involving them should be subject to the authorisation processes required of projects. (para 23)

We agree that a proportionate approach is required to the controls applied to the breeding and killing of animals for their tissues and organs. This principle is reflected in the text of Document 17299/09 which makes clear that the killing of animals for this purpose is not to be defined as a ‘procedure’. As a result, such killing would not require authorisation as a project.

Severity classifications

105. We consider that the definitions for severity classifications proposed in July 2009 by the expert working group could appropriately be adopted in the revised directive. (para 25)

We agree. Annex IX in Document 17299/09 sets out the criteria for the assignment of severity categories and incorporates the relevant material from the report of the expert working group.

106. The European Parliament amendments to Article 15 allowing exceptions to the prohibition on prolonged severe procedures imply a lower level of animal welfare than is currently maintained in the UK. We would see any such change as unacceptable. (para 26)

We intend to ensure that current standards of welfare and animal protection are maintained and, where possible, improved when the new Directive is transposed and implemented in the UK. We can think of no examples of legitimate animal use which could not be accommodated within the upper limit on severity set out in article 15 and have pressed for the derogation in Article 15(2) to be deleted. Some Member States take a different view and discussion is continuing on the best way forward. The expected compromise solution will be to make exceptional cases subject to the safeguard clause at Article 50.

Re-use

107. The re-use provisions must be amended in order to avoid unintended consequences for animal welfare. As presented in the Commission’s proposal, the provisions would be likely, in certain

specific circumstances, to increase the number of animals and degree of suffering that would need to be used. (para 31)

Responsible re-use is fully consistent with the principles of reduction and refinement. We were, therefore, also initially concerned that the framework for the re-use of animals in the Commission's proposal would have increased the number of animals used in the UK and the suffering caused to the additional animals.

Document 17299/09 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 it is in accordance with veterinary advice. A derogation would exceptionally allow re-use of an animal following veterinary examination where it has previously been used in a single procedure entailing severe pain, or equivalent suffering

While, in general, we believe that these changes make better provision for the responsible re-use of animals, we have concerns regarding the derogation. In any further discussions, we will be pressing to ensure that it will only be invoked in genuinely exceptional circumstances, for example where the higher level of suffering was brief and completely resolved.

Care and accommodation standards

108. The timescale for implementation of these standards in the academic sector should be extended. We think that the timescale for the introduction of the stocking densities proposed for rodents at breeding establishments should also be extended, since it is unclear that the resulting increase in cage sizes will offer any measurable animal welfare benefits. More generally, we accept the case made to us that explanatory text which accompanied the standards as first embodied in Council of Europe guidelines should be restored. (paras 39, 40)

Annex IV in Document 17299/09 – setting out mandatory care and accommodation standards – has been substantially amended (with detailed technical input from the UK) to correct the numerous errors and omissions in the original Commission proposal. The technical content is now broadly acceptable from a UK perspective, as is the implementation date. This has been set at 1 January 2017, allowing almost seven years for establishments to adapt.

Promotion of the 3Rs

109. We support the general promotion of the 3Rs: the replacement, reduction and refinement of the scientific use of animals, through the development and implementation of relevant methods. The specific proposal that national reference laboratories be set up is too prescriptive; we see a risk that such a centralised model would fail to draw on the expertise and innovation that are found in the wider

scientific community. We are persuaded that a system of national centres along the lines of the UK's National Centre for the 3Rs might well be a better route to follow. (para 47)

We strongly support measures to promote the development, validation and use of alternatives. This is an area in which the UK already plays a leading role. The 3Rs framework was developed in the UK, is a key component of the harm-benefit assessment in our current legislation, and is supported by our National Centre for the 3Rs.

Articles 45 and 46 have been substantially revised and restructured in Document 17299/09. Article 45 now requires the Commission and Member States to contribute to the development and validation of alternative approaches. It also places a new requirement on the Commission to consult Member States in setting priorities for validation studies and Member States will assist in placing validation studies in suitable laboratories.

There is no longer a requirement for national reference laboratories. Article 46 instead creates a requirement for a Community Reference Laboratory, the duties and tasks of which are set out in a new Annex VIII.

These revised provisions, which, we believe, are consistent with the Committee's recommendation, are a substantial improvement on the proposal as originally presented and provide a sound basis for the further development of alternatives.

Use of non-human primates in research

110. We firmly support a robust ethical review process in the case of all species used in scientific procedures, but we see the need to go further in respect of non-human primates. While we recognise that, at present, there is a need to continue the use of non-human primates in research, we think that it is appropriate for the revised Directive to set clear limits beyond those applicable to other species. In the light of the evidence which we heard from the Commission's representative, we are persuaded that the proposed restriction of such use to life-threatening or debilitating clinical conditions in Article 8 strikes the right balance between animal welfare and scientific research. While the wording of Article 8 could be clarified to reflect the understanding in Recital 16 that these conditions include those which have a substantial impact on patients' day-to-day functioning, we would still look to the new Directive to place tighter limits on the use of non-human primates than on the use of other species. (paras 55, 56)

We agree that non-human primates should be given special protection – as they already are under current UK legislation – and support the inclusion of similar measures in the new directive.

We were concerned that the proposed restriction of non-human primate use to research into life-threatening or debilitating clinical conditions in human beings

could have ruled out a number of important areas of work involving unmet clinical needs, such as vision research and research into infertility and fertility control. Document 17299/09 now includes a definition of 'debilitating clinical condition' which we believe encompasses almost all essential uses of non-human primates.

Document 17299/09 also includes provision for borderline cases to be provisionally authorised by a Member State and subject to final decision by the Commission via comitology (under Articles 50 and 51). The Commission has also given a commitment to convene an expert working group to provide further guidance on the interpretation of the restrictions in Article 8.

Taken together, we believe the safeguard clause and guidance will provide the clarity we require and a suitable mechanism to resolve any areas of uncertainty.

111. We endorse the aspiration that supply of non-human primates should be restricted to F2 animals, and it may be that this can be achieved against the time-limits suggested in Annex III of the proposal. We consider it crucial that this aspect of the Directive be monitored closely, and that the feasibility of the time-limits should be reviewed on a species-by-species basis. (para 63)

We agree that it is appropriate that all reasonable steps should be taken to move towards the use of F2 and F2+ non-human primates. We also agree that Member States should encourage breeders, suppliers and users to adopt strategies to achieve this aim. However, it is essential that the feasibility of achieving full use of F2 and F2+ animals within the specified timescales is considered carefully and that there is a mechanism to allow those timescales to be amended, where necessary.

Document 17299/09 includes a requirement that the Commission should undertake and publish a feasibility study, including an animal health and welfare assessment, on the required move to the use of F2 and F2+ non-human primates within five years from transposition of the Directive. We welcome this.

Document 17299/09 also requires the Commission to keep under review the sourcing of non-human primates from self-sustaining colonies and to conduct a study to establish the feasibility of ultimately sourcing animals exclusively from such colonies. This study is to be published no later than ten years after transposition. This is also welcome.

Data-sharing

112. Mutual acceptance between Member States of data from tests required under Community legislation is highly desirable; we consider that Member States should implement legislation to ensure that, at least, the use of animals for ratification of such data will be sanctioned only in exceptional circumstances and for strictly scientific reasons. (para 71)

We agree. Document 17299/09 requires the mutual acceptance by Member States of data generated by procedures recognised by Community legislation unless further procedures need to be carried out for the protection of public health, safety or the environment.

113. We consider that the case has not been made that there is widespread duplication of procedures. In the absence of cogent evidence, and bearing in mind the principle of proportionality, we have reservations about the provisions of Article 44(2). By the same token, we consider the European Parliament amendments on data-sharing to be undesirable. (para 72)

While recognising the need to guard against complacency, we share the Committee's view that the case has not been made that there is widespread duplication of procedures and note that the Commission's impact assessment provides no evidence that this is a significant problem in practice. The requirement for data sharing in Article 44.2 of the Commission's proposal was not supported by Member States and has been deleted in Document 17299/09. Similarly, there has been no support amongst Member States for European Parliament Amendments 134 to 137 and 180.

Authorisation or notification

114. We are concerned over the concept of "tacit approval" which, in our view, may open the way to importing notification arrangements into the control regime. We therefore support the authorisation requirements set out in the Commission's proposal and reject any move to require notification, or tacit approval (rather than authorisation), for "mild" procedures. (para 88)

Whilst we are fully committed to efficient regulation, we share the Committee's concerns about the concept of 'tacit approval' of specified categories of project and its potential to allow notification of projects to be imported into the Directive. Member States agree that all projects should be subject to ethical evaluation and prior authorisation and have expressed little support for European Parliament Amendment 167, which would allow projects involving mild and non-recovery procedures to be notified to the competent authority.

We are pleased that Document 17299/09 has dropped the provision for 'tacit approval'. Instead Member States will be free to introduce 'simplified administrative procedures' for projects containing procedures classified as 'non-recovery', 'mild' or 'moderate' where they are necessary to satisfy regulatory requirements. Projects using animals for production or diagnostic purposes with established methods may also be subject to this approach. However, all such projects would be subject to project authorisation, including ethical evaluation. Projects using non-human primates would not be eligible for such simplified procedures.

These revised provisions are a substantial improvement on the proposal they replace and provide welcome flexibility allowing a proportionate approach to the submission, assessment and authorisation of project applications.

Authorisation and competitiveness

115. We support calls for the authorisation processes contained in the proposal to be justified by the scientifically demonstrated needs of animal welfare. (para 91)

We have noted the concerns of the research community that implementation of the Directive might lead to the imposition of unjustified administrative burdens affecting EU competitiveness. We are committed to ensuring this does not happen. We are confident that the regulatory framework provided by Document 17299/09 is workable and would allow current UK standards of welfare and animal protection to be maintained. We believe also that in some areas they will allow administrative processes to be simplified and made less burdensome.

116. The ethical review process proposed must be dovetailed into the procedure, including specifying time-limits for that process which are consistent with the 30-day time-limit for authorisation. (para 92)

We agree that authorisation processes must be efficient and should not hinder or delay new lines of scientific inquiry as they emerge. Document 17299/09 provides for project authorisation decisions to be communicated to applicants within 40 working days. This period includes the time required for ethical evaluation. An additional 15 working days will be allowed for decisions in respect of more complex projects.

Inspection and review

117. Given the importance of ensuring the application of common standards across all Member States, we fully endorse the need for effective national inspection arrangements, including a minimum frequency which ensures that all relevant sites are visited at least once a year. We support the European Parliament amendment which would oblige, rather than permit, the Commission to undertake controls of the infrastructure and operation of national inspections in Member States. Without this, we fear that a new Directive will do little to remedy the widely varying approaches of Member States, including standards of animal welfare, which currently exist. (para 97)

The original text of Article 33 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 in this article in Document 17299/09 is instead now placed on a risk-based approach.

The revised Article 33 requires that regular inspections are carried out and that an appropriate proportion are unannounced. 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. These provisions are acceptable from a UK perspective.

We agree that the success of the new Directive in harmonising national measures will depend, in part, on effective enforcement by the Commission. However, the European Parliament amendment which would have obliged, rather than permitted, the Commission to undertake controls of the infrastructure and operation of national inspections in Member States has not been adopted in Document 17299/09. Instead, the Commission will be under an obligation to carry out controls where there is reason for concern.

118. The Commission should review the Directive no later than five years after it has come into force (and not ten, as proposed). (para 99)

We agree that the Directive should be kept under review. Document 17299/09 now provides for the Directive to be reviewed five years after transposition. Separately, we strongly support the provision in Article 53 for periodic, thematic reviews of the use of animals.

**Home Office
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