

**CONSULTATION ON OPTIONS FOR THE TRANSPOSITION OF
EUROPEAN DIRECTIVE 2010/63/EU
ON THE PROTECTION OF ANIMALS USED FOR SCIENTIFIC PURPOSES**

APPENDIX III

**COMPARISON OF THE ANIMAL WELFARE BODY
AND THE UK ETHICAL REVIEW PROCESS**

COMPARISON OF THE ANIMAL WELFARE BODY AND THE UK ETHICAL REVIEW PROCESS

Directive 2010/63/EU	ASPA ¹	Comment
26(1) Member States shall ensure that each breeder, supplier and user sets up an animal-welfare body.	1. The Secretary of State requires that an <i>ethical review process</i> be established and maintained in each [designated breeding, supplying and user] establishment.	The requirements of ASPA and the Directive are broadly similar.
20(2) The [breeder, supplier or user] authorisation shall specify the person responsible for ensuring compliance with the provisions of this Directive...	4. The certificate holder will be responsible to the Home Office for the operation of the local <i>ethical review process</i> and for the appointment of people to implement its procedures.	We assume the 'person responsible for ensuring compliance' with the provisions of the directive (Article 20) will have a similar responsibility.
No equivalent provision.	2. The certificate holder should ensure as wide an involvement of establishment staff as possible in a local framework acting to ensure that all use of animals in the establishment, as regulated by the Animals (Scientific Procedures) Act 1986, is carefully considered and justified; that proper account is taken of all possibilities for reduction, refinement and replacement (the 3Rs); and that high standards of accommodation and care are achieved.	These requirements could be included in further guidance to accompany the UK legislation transposing the new Directive,
Animal-welfare considerations should be given the highest priority in the context of animal keeping, breeding and use. Breeders, suppliers and users should therefore have an animal-welfare body in place with the primary task of focusing on giving advice on animal-welfare issues. The body should also follow the development and outcome of projects at establishment level, foster a climate of care and provide tools for the practical application and timely implementation of recent technical and scientific developments in relation to the principles of replacement, reduction and refinement, in order to enhance the life-time experience of the animals. The advice given by the animal-welfare body should be properly documented and open to scrutiny during inspections. (Recital 31)	3. (1) To provide independent ethical advice to the certificate holder, particularly with respect to project licence applications and standards of animal care and welfare. (2) To provide support to named people and advice to licensees regarding animal welfare and ethical issues arising from their work. (3) To promote the use of ethical analysis to increase awareness of animal welfare issues and develop initiatives leading to the widest possible application of the 3Rs.	The emphasis on ethical considerations under ASPA is not expressed in recital 31, but is arguably implicit in the aims of animal welfare bodies. This can be made explicit in further guidance.

¹ See Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (HC321), Appendix J

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Directive 2010/63/EU	ASPA	Comment
26(2) The animal-welfare body shall include at least the person or persons responsible for the welfare and care of the animals and, in the case of a user, a scientific member. The animal- welfare body shall also receive input from the designated veterinarian or the expert referred to in Article 25.	5. A Named Veterinary Surgeon and representatives from among the Named Animal Care & Welfare Officers should be involved. In user establishments, project licensees and personal licensees should also be represented. As many people as possible should be involved in the <i>ethical review process</i> . Where possible, the views of those who do not have responsibilities under the Act should be taken into account. One or more lay persons, independent of the establishment, should also be considered. Home Office inspectors should have the right to attend any meetings...	ASPA provides for more extensive membership of ERPS, including lay members.
No equivalent provision.	6. These people should deliberate regularly and keep records of discussions and advice. All licensees and Named Animal Care & Welfare Officers must be informed of the <i>ethical review process</i> and should be encouraged to bring matters to its attention. An operating description should allow for input by colleagues and other people from outside the establishment. It should be clear how submissions can be made. The people involved should be regarded as approachable, dealing in confidence with complaints and processing all suggestions for improvement.	These requirements could be included in further guidance to accompany the UK legislation transposing the new Directive,
26(3) Member States may allow small breeders, suppliers and users to fulfil the tasks laid down in Article 27(1) by other means.	No equivalent provision.	'Small' is not defined.
27(1) The animal-welfare body shall, as a minimum, carry out the following tasks:	7. Specifically, the process should allow (where appropriate) the following:-	

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(a) advise the staff dealing with animals on matters related to the welfare of animals, in relation to their acquisition, accommodation, care and use;	(3) providing a forum for discussion of issues relating to the use of animals and considering how staff can be kept up to date with relevant ethical advice, best practice, and relevant legislation; (5) considering the care and accommodation standards applied to all animals in the establishment, including breeding stock, and the humane killing of protected animals;	The requirements of ASPA and the Directive are broadly similar.
No equivalent provision.	(2) examining proposed applications for new project licences and amendments to existing licences, with reference to the likely costs to the animals, the expected benefits of the work and how these considerations balance;	Omission of this function from the AWB was deliberate to avoid overlap of responsibility for project evaluation which rests solely with the competent authority.
(b) advise the staff on the application of the requirement of replacement, reduction and refinement, and keep it informed of technical and scientific developments concerning the application of that requirement;	(1) promoting the development and uptake of reduction, replacement and refinement alternatives in animal use, where they exist, and ensuring the availability of relevant sources of information;	The requirements of ASPA and the Directive are broadly similar.
(c) establish and review internal operational processes as regards monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the establishment;	(6) regularly reviewing the establishment's managerial systems, procedures and protocols where these bear on the proper use of animals;	The requirements of ASPA and the Directive are broadly similar.
(d) follow the development and outcome of projects, taking into account the effect on the animals used, and identify and advise as regards elements that further contribute to replacement, reduction and refinement; and	(4) undertaking retrospective project reviews and continuing to apply the 3Rs to all projects, throughout their duration;	The requirements of ASPA and the Directive are broadly similar.
(e) advise on rehoming schemes, including the appropriate socialisation of the animals to be rehomed.	No equivalent provision.	
No equivalent provision.	(7) advising on how all staff involved with the animals can be appropriately trained and how competence can be ensured.	These functions are dealt with in Article 24 of the new Directive.

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<p>27(2) Member States shall ensure that the records of any advice given by the animal-welfare body and decisions taken regarding that advice are kept for at least 3 years.</p> <p>The records shall be made available to the competent authority upon request.</p>	<p>5. Home Office inspectors should have ... access to the records of the <i>ethical review process</i>.</p>	<p>The requirements of ASPA and the Directive are broadly similar.</p>
<p>No equivalent provision.</p>	<p>8. Commonly, there should be a promotional role, seeking to educate users (in applying the 3Rs) and non-users (by explaining why and how animals are used), as appropriate. There should be some formal output from the <i>ethical review process</i> for staff and colleagues in the establishment, made as widely available as security and commercial/intellectual confidentiality allow.</p>	<p>These requirements could be included in further guidance to accompany the UK legislation transposing the new Directive,</p>
<p>No equivalent provision.</p>	<p>9. Receipt of a project licence application signed by the certificate holder will be taken by the Home Office to mean that the application has been through the <i>ethical review process</i> for that establishment.</p>	<p>Not applicable in the absence of ERP function (2).</p>
<p>No equivalent provision.</p>	<p>10. Inspectors will still be happy to discuss early ideas with prospective project licence holders and will be available for advice and clarification at any point. But an application will not be considered for formal authorisation by the Home Office until the prospective project has been considered appropriately within the <i>ethical review process</i>. The inspector will not negotiate with any advisory group. Local arrangements and the individual case will dictate whether amended applications must re-enter the <i>ethical review process</i>. It will be a matter of judgement in the particular case how best to balance the inputs of the <i>ethical review process</i> and the Inspectorate without duplicating effort or creating undue delay.</p>	<p>Not applicable in the absence of ERP function (2).</p>