EXPLANATORY MEMORANDUM TO

THE UK CODE OF PRACTICE FOR THE HOUSING AND CARE OF ANIMALS BRED, SUPPLIED OR USED FOR SCIENTIFIC PURPOSES

DATED DECEMBER 2014

1. This explanatory memorandum has been prepared by the Home Office ("the Department") and is laid before Parliament by command of Her Majesty.

Purpose of the code of practice

2. The Animals (Scientific Procedures) Act 1986 (ASPA) regulates the use of protected animals in scientific procedures which may have the effect of causing that animal pain, suffering, distress or lasting harm. The Code of Practice sets out the standards of care and accommodation of animals required by ASPA, and provides advice about the way in which those responsible under ASPA may comply with those requirements.

Matters of special interest to the Joint Committee on Statutory Instruments

3. None.

Legislative context

- 4. The Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 (SI 2012/3039) amend the Animals (Scientific Procedures) Act 1986 (ASPA) to transpose European Directive 2010/63/EU on the protection of animals used for scientific purposes. The Directive sets out revised measures for the protection of animals used for scientific purpose. The introduction of the amendments to the 1986 Act made by the transposition of European Directive 2010/63/EU makes it necessary to issue the revised code of practice to which this memorandum relates.
- 5. The United Kingdom completed the transposition of European Union Directive 2010/63/EU, concerned with animals in scientific procedures, in December 2012 and the transposing legislation was implemented as from 1 January 2013. Section 21 of the Animals (Scientific Procedures) Act 1986 requires that we consult the Animals in Science Committee, an independent expert advisory body convened under the Act, and that we publish codes of practice as to the care of protected animals and their use for regulated procedures. Such codes of practice must be laid in Parliament under the "negative resolution" procedure.
- 6. The Code of Practice is intended to be a reference document that explains the standards for housing and care of animals bred, supplied and used for scientific purposes required by ASPA. It also provides information and advice that will assist those responsible to meet the required standards. Specifically it contains information and advice on:
 - a. How to use the Code of Practice;
 - b. The mandatory standards under ASPA that are in force until 31 December 2016 (Section 1 of the Code of Practice);
 - c. The mandatory standards under ASPA that come into force from 1 January 2017 (Section 2); and,

- d. Advice on how to meet these standards (Section 3).
- 7. The Secretary of State may issue revised codes of practice from time to time and proposes to complete the first review in approximately five years time.

Territorial extent and application

8. This revised Code of Practice applies in England, Scotland, Wales and Northern Ireland

European Convention on Human Rights

9. As the Code of Practice is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

Policy background

- 10. Directive 86/609/EEC, on which the 1986 Act was predicated and that regulated the use of animals for experimental and other scientific purposes, was out of date and not uniformly implemented in all Member States. This has left those with higher standards (such as the UK) at a competitive disadvantage. Lack of harmonisation has also restricted the free movement of labour, and there exists inefficiencies created by duplication and wastage.
- 11. The transposition of the new European Directive has provided a valuable and timely opportunity to review and strengthen our legislation. The Directive has three main objectives: first, to rectify wide variations in the implementation of the previous Directive by member states; secondly, to strengthen the protection of animals used in scientific procedures; and thirdly to promote the three Rs: strategies which Replace, Reduce and Refine the use of animals in scientific procedures. It provides a practical framework for the regulation of animal research and testing in Europe and sets a benchmark for the rest of the world.
- 12. In March 2014, The Secretary of State published Guidance on how she administers and enforces ASPA.
- 13. In addition to the Guidance, there is a requirement to publish Codes of Practice on the care of protected animals. The Secretary of State published a draft code of practice on care and accommodation standards to be applied by users, breeders and suppliers from 1 January 2013. Public consultation was undertaken on 15 February 2013 and further consultation has since been conducted with stakeholders.

Consultation outcome

- 14. A draft Code of Practice for the Housing and Care of Animals was published on 15 February 2013, following stakeholder consultation. The 2013 draft Code of Practice sets out the minimum legal standards which must be applied by all breeders, suppliers and users of animals from 1 January 2013 to 31 December 2016. All of the free text in the 2013 draft Code of Practice was taken directly from Annex III to the Directive 2010/63/EU, to which was added the relevant retained UK species-specific requirements. A commitment was made at the time to also publish, in due course, the minimum legal standards which must be applied by breeders, suppliers and users from 1 January 2017.
- 15. In July 2014, we sent a working draft of this latest version of the Code of Practice to our stakeholders and initiated an intense period of stakeholder engagement and consultation, culminating in the production of the attached

- Code of Practice. We received approximately 30 written responses to the consultation from organisations and individuals in addition to the feedback that we had during a number of stakeholder meetings.
- 16. The Home Office undertook an iterative consultation process with key stakeholder groups that have included the bioscience industry, laboratory animal professionals (including the Establishment Licence Holders' Forum), animal protection groups, animal welfare and alternatives groups, and other Government Departments), to refine the final text. We have specifically sought input from colleagues in the Department for Business Innovation & Skills (BIS) to ensure any potential regulatory impact has been appropriately and sensitively considered.
- 17. The statutory independent advisory body, the Animals in Science Committee (ASC), has also been informed and consulted throughout the process. The Chair of the Committee wrote to the Minister on 21 October 2014 to confirm that the ASC is content that the version of the Code of Practice herewith attached should now be published.

Guidance

18. This is a Code of Practice

Impact

19. The Code of Practice reflects the transposition of Directive 2010/63/EU onto the Animals (Scientific Procedures) Act 1986. A full impact assessment was conducted that is available at: http://www.legislation.gov.uk/ukia/2011/552/pdfs/ukia_20110552_en.pdf.

Regulating small business

- 20. This revised Code of Practice applies to small business licensed under ASPA.
- 21. During transposition of the Directive, when seeking Regulatory Policy Committee clearance, we provided evidence that the requirements of the Directive would not result in additional regulatory impact to businesses. Whilst the UK has retained some standards already in force prior to 2010, which exceed the minimum requirements of the Directive, this Code does not impose any additional or higher standards over and above those currently required of UK establishments by existing legislation.

Monitoring and review

22. The Code of Practice is an iterative document. The Secretary of State proposes to review it periodically. The first review will be completed in approximately five years time.

Contact

23. Giles Paiba at the Home Office, telephone 0207 0355128 or e-mail: giles.paiba@homeoffice.gsi.gov.uk can answer queries regarding the instrument.