EXPLANATORY MEMORANDUM TO

THE GUIDANCE ON THE OPERATION OF THE ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986, DATED MARCH 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 guidance

2.1 The Animals (Scientific Procedures) Act 1986 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 Guidance is intended to be a reference document that explains how the Act is administered and enforced. The Guidance will assist all duty holders in carrying out their roles under the Act and be compliant with its requirements.

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

Legislative context

4.1 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 guidance to which this memorandum relates.

4.2 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 guidance on how we propose to implement the Act and that it is laid in Parliament under the 'negative resolution' procedure.

4.3 The Guidance is intended to be a reference document that explains how the Act is administered and enforced. It provides information and advice on: i) the scope and main provisions of the amended Act; ii) the responsibilities of those with roles under the Act; iii) licences granted

under the Act, how applications are evaluated as well as including the terms and conditions of their issue; iv) severity classification, humane killing and the accommodation and care of animals; and, v) how non-compliance is investigated and the range of sanctions available. The Guidance does not set any additional compliance requirements beyond those of the Act and the conditions included in licences.

4.4 The Secretary of State may issue revised Guidance from time to time. However, there are several topics on which the Secretary of State may wish to publish further advice on from time to time.

4.5 One such topic is actual severity monitoring where establishments have new European reporting requirements for all procedures completed after 1 January 2014. This is intended to improve transparency and provide a focus for the refinement of the most severe procedures. Further advice on actual severity monitoring has recently been published and is available at https://www.gov.uk/research-and-testing-using-animals

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4.6 A second topic is the publication of guidance on the use of Animals Containing Human Material in scientific research. While most research of this sort will only require licence authority from a single regulator (generally under either the 1986 Act or the Human Fertilisation and Embryology Act), some may require submission to more than one regulator and/or referral to a national expert body before licence authorities can be granted. This is a growing area of work and the new guidance will encourage researchers to make early contact with at least one of the regulators for advice on the authorities they will require. Further advice will be published in late 2014.

4.7 Nothing in this current draft Guidance relates to changes the Secretary of State anticipates making as part of a review of Section 24 of the 1986 Act and increasing transparency and openness. Proposals of options for public consultation on this subject will be published in Spring 2014. However, we are being more transparent about our processes.

Territorial extent and application

5.1. This revised guidance applies in England, Scotland, Wales and Northern Ireland.

European Convention on Human Rights

6.1 As the guidance is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

Policy background

7.1 Directive 86/609/EEC, on which the 1986 Act was predicated, 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.

7.2 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.

7.3 There is a requirement to publish Codes of Practice on the care of protected animals. The Secretary of State has 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 will be conducted with stakeholders and the Animals in Science Committee. It is intended a revised Code of Practice will be laid before Parliament in late 2014.

Consultation outcome

8.1 We carried out a public consultation on the options for transposition of the new Directive between June and September 2011 and published the government response to the consultation on 17 May 2012.

8.2 During the debate on the 1986 Act Amendment Regulations 2012 the Home Department gave a commitment to publish a ‘quick start guide’ before Christmas 2012 and publish a full version of draft guidance by the end of January 2013 for stakeholder consultation. The quick start guide was published on 19 December 2013 and the stakeholder consultation on the full guidance was commenced on 30 January 2013 and completed in a timely manner.

8.3 We received 98 responses to the consultation from organisations and 13,500 responses from individuals.

8.4 The guidance was shaped by the consultation responses after which the Home Department undertook an iterative consultation process with key stakeholder groups (Bioscience, Lab Animal Professionals, Animal Protection Groups, Animal Welfare and Alternatives Groups, and other Government Departments) to refine the final text. A draft version of the Guidance was

submitted to the Animals in Science Committee in October 2013. The Committee's contributed to the final version.

Guidance

9.1 This is Operational Guidance

Impact

10.1 The guidance 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

11.1 This revised guidance applies to small business licensed under ASPA.

11.2 It is expected that the amendments made as a result of the new Directive will reduce the burden on small businesses that are licensed under ASPA. The personal licence application process has been simplified and is now web based.

11.3 The resulting regulatory costs (and/or benefits) will be in proportion to their scale of protected animal production and use.

Primarily changes to smaller firms will be in administrative practices and there is not likely to be a greater impact on the operations and performance of smaller business than others.

No well run small business should incur additional annual operating costs in excess of £1K and exemption either fully or partially of smaller firms is not an option. Compliance with EU requirements will be the objective.

Monitoring and review

12.1 The Government will continue to monitor and review the statutory guidance as to their impact on licensing authorities and others to whom this guidance is relevant. The first review will take place in about two years.

Contact

13.1 Steve Newnham at the Home Office, telephone 0207 0350749 or e-mail: Stephen.Newnham@homeoffice.gsi.gov.uk can answer queries regarding the instrument.