**SUPPLEMENTARY NOTE ON THE TRANSPOSITION OF DIRECTIVE 2010/63/EU ON THE PROTECTION OF ANIMALS USED FOR SCIENTIFIC PURPOSES**

## Transparency

Like its predecessor (Directive 86/609/EEC), which it replaces, Directive 2010/63/EU recognises the need to ensure that the confidentiality of commercially sensitive information is protected (see Recital 41). The new Directive also recognises the need for the public to have objective information about projects using live animals. It seeks to achieve this principally through Article 43 which requires the publication of anonymous, non-technical summaries of authorised projects.

Under Article 43 of the new Directive, non-technical summaries are to be provided by project licence applicants and include information on the objectives of the project, the predicted harms and benefits, and the number and types of animals to be used and should also explain how the 3Rs have been satisfied. The UK has a long-standing commitment to transparency in this area and has published project licence abstracts with similar content since 2005.

Under Article 37(2), Member States may waive the requirement for non-technical summaries for the categories of project to which simplified administrative procedures may apply (those classified as non-recovery, mild or moderate; not involving non-human primates; and falling into specified categories of work).

Regulation 9(1) of the draft Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 (the draft Regulations), inserts new ASPA sections 5A(2), 5A(3), 5D(6), 5D(7) and 5F(3) to transpose the relevant provisions of Article 43. The discretion in Article 37(2) to waive the requirement for non-technical summaries for some categories of project has not been transposed as it is our intention to require and publish such summaries for all projects. We believe this demonstrates our continued, strong commitment to transparency.

## Section 24

Section 24 (s24) of the Animals (Scientific Procedures) Act 1986 (ASPA) states:

> *(1) A person is guilty of an offence if otherwise than for the purpose of discharging his functions under this Act he discloses any information which has been obtained by him in the exercise of those functions and which he knows or has reasonable grounds for believing to have been given in confidence.*
>
> *(2) A person guilty of an offence under this section shall be liable—*
> *(a) on conviction on indictment, to imprisonment for a term not exceeding two years or to a fine or to both;*
> *(b) on summary conviction, to imprisonment for a term not exceeding six months or to a fine not exceeding the statutory maximum or to both.*

The effect of ASPA s24 is to prohibit the disclosure of confidential information relating to the use of animals in scientific procedures by Home Office Ministers and officials, and members of the Animal Procedures Committee, other than in the discharge of their functions under ASPA.

The public consultation on the options for the transposition of Directive 2010/63/EU, held between June and September 2011, sought views on how ASPA s24 might be amended to provide greater flexibility regarding the disclosure of information while at the same time protecting proprietary rights and intellectual property. The Government response to the public consultation, published in May 2012, reported that most respondents across all sectors did not support retention of ASPA s24 in its current form. However, no clear consensus emerged on its repeal or amendment.

We have noted the consultation responses and have given an undertaking to consider the options for revising section 24 and publish conclusions separately, in due course. As the issues are complex, this review has been deferred until 2013. No immediate action is required in relation to transposition of Directive 201/63/EU. Any changes proposed in due course to ASPA s24 can be made through domestic legislation.

## Public participation and accountability

Article 38 sets out the requirements to be met by the competent authority when evaluating a project application. The first part of Article 38(1) requires that *"the project evaluation shall be carried out with a degree of detail appropriate for the type of project ..."* Article 38(4) of Directive 2010/63/EU requires that "*the project evaluation shall be performed in an impartial manner …"* Regulation 9(1) of the draft Regulations inserts new ASPA section 5B(8) to transpose these requirements.

Article 38(4) also requires that "*The project evaluation process shall be transparent."* This provision is transposed by new ASPA section 5B(9).

Finally, Article 38(4) provides that *"… the project evaluation … may integrate the opinion of independent parties."* This is transposed by ASPA section 9. The current provision enabling the Secretary of State to consult an independent assessor, or the Committee for the Protection of Animals Used for Scientific Purposes, before granting a project licence is retained unchanged.

We do not interpret Article 38(4) to permit, or require, the publication of project applications for comment by the general public or special interest groups. We consider the requirement in Article 38(4) to safeguard intellectual property and confidential information renders such an approach impractical.

## Thematic reviews

Article 58 (second paragraph) of Directive 2010/63/EU states:

"The Commission shall, where appropriate, and in consultation with the Member States and stakeholders, conduct periodic thematic reviews of the replacement, reduction and refinement of the use of animals in procedures, paying specific attention to non-human primates, technological developments, and new scientific and animal-welfare knowledge."

This places an obligation on the Commission – not Member States – and does not require transposition into national legislation. Hence, no provision is made in the regulations relating to this requirement. However, historically, it has been our

practice from time to time to carry out reviews of particular aspects of regulation in the UK and we propose to continue doing so. A mechanism for collecting information for such reviews from project licence holders is provided by new standard condition 22 set out in Part 4 of Schedule 3 inserted by Regulation 42.

At the request of a stakeholder group, we included a supplementary question in the public consultation on the options for transposing Directive 2010/63/EU, held in 2011, seeking views on the structure of the proposed thematic review process and any further issues we should consider in relation to Article 58. In doing so, we confirmed our strong support for periodic thematic reviews.

In the Government response to the public consultation, published in May 2012, we undertook to give careful consideration to the suggestions provided by respondents and to consult further with stakeholders to develop a programme of reviews. We also confirmed that we will work closely with the Commission and other Member States in this area. We will do so through existing arrangements for dialogue and collective discussions between Member States and the Commission.

**Animal Welfare and Ethical Review Bodies**

Through the standard conditions of certificates of designation, the UK currently requires designated establishments to have a local ethical review process (ERP). This requirement has been in place since 1999. The aims, membership and mode of operation of ERPs are set out at Appendix J to the published *"Guidance on the Operation of the Animals (Scientific Procedures) Act 1986"* (HC321).

Membership of an ERP includes the establishment's Named Veterinary Surgeon and Named Animal Care and Welfare Officers and, in user establishments, project licensees and personal licences. Where possible, the views of persons who do not have responsibilities under ASPA are to be taken into account and the inclusion of one or more lay persons, independent of the establishment is encouraged.

Article 26 of Directive 2010/63/EU requires each breeder, supplier and user to set up an animal welfare body (AWB) comprising, as a minimum, the person(s) responsible for the welfare and care of the animals and, in the case of a user, a scientific member. Article 27 sets out the tasks of the Animal Welfare Body.

Regulation 10(2) establishes Animal Welfare and Ethical Review Bodies (AWERBs), to replace existing local ERPs in each breeding, supplying and user establishment with effect from 1 January 2013. Regulation 42 inserts Schedule 3 setting out transitional provisions. Paragraphs 6 and 15 of Part 1 of Schedule 3 provide that, until revised guidance on the membership and functions of AWERBs is published, existing ERPs shall operate as AWERBs provided that they continue to include as participants at least those individuals required by Article 26 of the Animals Directive and carry out all of the tasks set out in Article 27 of the Directive.

**National Committee for the protection of animals used for scientific purposes.**

Article 49 of European Directive 2010/63/EU requires each Member State to establish a national committee for the protection of animals used for scientific

purposes to advise the national competent authority and the local animal welfare bodies (AWERBs) required at each establishment (under Article 26) on the acquisition, breeding, accommodation, care and use of animals in procedures and to ensure sharing of best practices. National committees are also to exchange information on the operation of animal welfare bodies and project evaluation and share best practices with the national committees of other Member States.

Regulation 20 replaces the current sections 19 and 20 of the Animals (Scientific Procedures) Act 1986 (ASPA) dealing with the Animal Procedures Committee with revised sections 19 and 20 setting out the functions and membership of the new Committee, but omitting the detailed requirements relating to the size of the Committee and the qualifications and background of members currently set out in ASPA sections 19(2) and 19(3).

The issues relating to the size of the Committee and the qualifications and background of members will be dealt with in a 'working protocol' to be agreed initially with the Committee Chair, when appointed. This working protocol will be published and will also set out issues which will be automatically submitted to the Committee for advice and cover other important issues such as the promotion of replacement, reduction and refinement.

New ASPA s20(2) inserted by Regulation 20 - quoted in full – states:

(2) In its consideration of any matter the Committee shall have regard both to the legitimate requirements of science and industry and to the protection of animals against avoidable suffering and unnecessary use in scientific procedures.

This directly reproduces current ASPA section 20(2) which places the same requirements on the Animal Procedures Committee. We believe retention of these requirements is essential to emphasise the need for a balanced approach to the issues on which the Committee will be required to advise.

**Animals in Science Regulation Unit**
**Home Office**

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