
EXPLANATORY NOTE

(This note is not part of the Regulations)

These regulations amend the Animals (Scientific Procedures) Act 1986 (“the Act”) to transpose EC Directive 2010/63/EU on the protection of animals used for scientific purposes (“the Directive”). The Directive replaces Directive [86/609/EEC](#) which is repealed.

Regulation 3 lengthens the period of gestation that must have elapsed before an animal in a foetal, larval or embryonic form becomes a “protected animal” for the purposes of the Act. Regulation 3 also extends protection to cephalopods.

Regulation 4 amends the definition of a ‘regulated procedure’ in section 2 of the Act so as to include, amongst other things, the modification of an animal’s genes in particular circumstances.

Regulation 5 inserts a new section 2A requiring the Secretary of State to exercise his or her functions with a view to ensuring compliance with the principles of replacement, reduction and refinement. Regulation 5 also inserts definitions of these terms.

Regulations 6, 7 and 8 change the licensing system; the certificates of designation of premises for breeding, supplying and scientific research are now amalgamated into one licence; project and personal licences remain part of the licensing system but there are minor amendments to personal licences to remove the current requirement for the place where regulated procedures are performed to be specified in the personal licence. This will enable personal licence holders to carry out regulated procedures at any place specified in the project licence that authorises the procedures and will obviate the need to amend the personal licence before working at additional places; in addition the holder of a personal licence will be authorised to apply categories of techniques rather than specified individual techniques.

Regulation 9 replaces section 5 of the Act and amongst other things provides that project licences may specify multiple generic projects as set out in article 40.4 of the Directive. There is also a requirement for the applicant for a project licence to provide the Secretary of State with a non-technical summary of the proposed project which will be published if the application is successful. Regulation 9 also provides timescales for acknowledging applications and making decisions whether to grant a project licence. In addition some programmes of work will now be subject to a retrospective assessment regarding whether the severity level of the procedures have been correctly assessed.

Regulation 10 replaces section 10 of the Act relating to the conditions to be included in licences granted under the Act. Regulation 10 also inserts a new Schedule 2C into the Act which sets out certain conditions that must be included in licences granted under the Act. Schedule 2C is divided into three parts: Part 1 sets out the requirements for the conditions to be applied to section 2C licences; Part 2 sets out the requirements for the conditions to be applied to personal licences; Part 3 sets out the requirements for the conditions to be applied to project licences.

Regulations 11, 12 and 13 deal with failure to comply with licence conditions and the right of the licence holder to appeal, regulation 11 inserts a new section 11 which allows Secretary of State to issue a compliance notice and variation, suspension or revocation of a licence.

Regulation 14 replaces section 14 of the Act; the new section provides that an animal that has already been subjected to one or more procedures must not be re-used unless the Secretary of State consents to the re-use and certain conditions are met.

Regulation 15 inserts new section 15A which sets out detailed requirements relating to the killing of animals, protected animals as defined in the Directive have to be killed using a particular method

unless the Secretary of State has authorised another method or the animal has been caught in the wild and is killed for its organs or tissues.

Regulation 17 replaces section 17 of the Act to prohibit the use of a neuromuscular blocking agent in the course of a regulated procedure unless (a) the person is expressly authorised to do so by the personal licence and the project licence under which the procedure is carried out; and (b) the agent is used in combination with such level of anaesthesia or analgesia as is determined in accordance with the project licence. It also stipulates that the Secretary of State must not grant a project licence that authorises the use of a neuromuscular blocking agent unless he or she is satisfied, on the basis of a scientific justification, that the purposes of the programme of work specified in the licence cannot be achieved without the use of such an agent.

Regulation 18 inserts a new section 17A prohibiting the setting free or re-homing of protected animals without the consent of the Secretary of State and setting out the conditions which must be met before such consent is given.

Regulation 19 amends section 18 of the Act relating to the duties and functions of inspectors. In relation to visits of inspection the regulation introduces a requirement on the Secretary of State to determine an appropriate risk-based inspection programme to be followed by the Inspectorate.

Regulation 20 replaces sections 19 and 20 of the Act dealing with the Animal Procedures Committee which is to be replaced with a new committee to be known as the Committee for the Protection of Animals Used for Scientific Purposes.

Regulation 21 inserts new section 20A providing that the Secretary of State should take such steps as he or she considers appropriate to facilitate the establishment of programmes for the sharing of the organs and tissues of animals killed for use for scientific purposes.

Regulation 22 inserts new section 20B which requires the Secretary of State to support the development of alternative strategies (i.e. scientific methods and testing strategies which do not use protected animals, or which, compared to existing scientific methods and testing strategies, use fewer protected animals or reduce the pain, suffering, distress or lasting harm caused to protected animals).

Regulation 23 inserts new section 21A which deals with the publication of annual statistics in which there is now a requirement to report on the actual severity of the regulated procedures; the origin and the species of any primates used in regulated procedures; and on methods of killing specified which are used but which are not specified in Annex IV to the Directive. (Annex IV methods are set out in Schedule 1 to the Act).

Section 21A also requires the Secretary of State to send information on the implementation of the Directive to the European Commission by 10 November 2018 and every five years thereafter.

Regulations 24 and 25 provide penalties and deal with powers of entry under the Act.

Regulations 26 to 41 make minor and consequential amendments to the Act and other legislation; schedule 2 to the Act is amended to include frogs (*Rana* and *Xenopus* species) and zebra fish in the list of animals that will be “relevant protected animals” for the purposes of new section 2B. Regulation 42 introduces Schedule 3 to the regulations which sets out transitional provisions.

The regulations insert a new schedule 2B into the Act This Schedule provides for additional conditions which must be met before the Secretary of State grants certain project licences. These relate to conditions which must be satisfied before authorisation can be given for the use of endangered and non-endangered primates, the use of endangered animals that are not primates and the use of cats, dogs and equidae.