
STATUTORY INSTRUMENTS

2012 No. 3039

**The Animals (Scientific Procedures)
Act 1986 Amendment Regulations 2012**

Project licences

9.—(1) For section 5 substitute—

“5 Project licences: general

(1) A project licence is a licence granted by the Secretary of State which specifies a programme of work and authorises the application, as part of that programme, of specified regulated procedures to animals of specified descriptions at a specified place or specified places.

(2) A place may not be specified in a project licence unless it is a place at which a person is authorised by a section 2C licence to carry on an undertaking involving the applying of regulated procedures to protected animals.

(3) But subsection (2) does not apply in any case in which it appears to the Secretary of State, on the basis of a scientific justification, that the programme or procedures authorised by the project licence require a different place to be specified.

(4) In the circumstances set out in Article 40.4 of the Animals Directive, a project licence may specify a programme of work which consists of multiple generic projects.

5A Application for a project licence

(1) An application for a project licence must—

- (a) specify the programme of work the applicant wishes to be specified in the project licence;
- (b) specify the regulated procedures, the descriptions of animal and the place or places the applicant wishes to be specified in the project licence;
- (c) include information on the matters set out in Annex 6 of the Animals Directive;
- (d) include such other information as the Secretary of State may reasonably require; and
- (e) be accompanied by a project summary.

(2) A project summary is a statement, in non-technical language, which (subject to subsection (3)(a))—

- (a) describes the proposed programme of work and states the objectives of the programme, the predicted harm and benefits of the programme and the number and types of animal to be used in the programme;
- (b) demonstrates that the proposed programme of work would be carried out in compliance with the principles of replacement, reduction and refinement.

(3) A project summary must not contain—

- (a) any information of a confidential nature or any information the publication of which may lead to the infringement of any person's intellectual property rights;
 - (b) names or addresses or any other information from which the identity of the applicant or any other person can be ascertained.
- (4) If the Secretary of State receives an incomplete or incorrect application for a project licence the Secretary of State must, as soon as practicable, inform the applicant of the following matters—
- (a) the fact that the application is incomplete or incorrect;
 - (b) the additional information that needs to be provided by the applicant to complete or correct the application; and
 - (c) the fact that the period mentioned in subsection (7) will not begin until the Secretary of State has received the additional information.
- (5) Subsections (6) to (9) apply if the Secretary of State receives a complete and correct application for a project licence or receives information from an applicant that completes or corrects an application for a project licence.
- (6) The Secretary of State must as soon as practicable—
- (a) acknowledge receipt of the application or (as the case may be) receipt of the information; and
 - (b) inform the applicant of the effect of subsections (7) to (9).
- (7) Within the period of 40 working days beginning with the day on which the Secretary of State receives the application or (as the case may be) the information, the Secretary of State must—
- (a) grant a project licence to the applicant (in the terms specified in the application under subsection (1)(a) and (b) or in those terms with such modifications as the Secretary of State thinks appropriate); or
 - (b) serve on the applicant a notice under section 12(1) indicating the Secretary of State's intention to refuse the project licence.
- (8) On one occasion within the period mentioned in subsection (7), the Secretary of State may by notice to the applicant extend the period by up to 15 working days.
- (9) The Secretary of State may exercise the power in subsection (8) only if, and to the extent that, the Secretary of State considers its exercise is justified by the complexity or multi-disciplinary nature of the proposed programme of work.

5B Determining an application: evaluation of the programme of work

- (1) A project licence must not be granted unless the Secretary of State has carried out in accordance with this section a favourable evaluation of the programme of work to be specified in the licence.
- (2) For this purpose, the evaluation of a programme of work is favourable only if it verifies—
- (a) that carrying out the programme of work is justified from a scientific or educational point of view or is required by law;
 - (b) that the purposes of the programme of work justify the use of protected animals; and
 - (c) that the programme of work is designed so as to enable the regulated procedures applied as part of it to be applied in the most humane and environmentally sensitive manner possible.
- (3) In carrying out the evaluation of a programme of work the Secretary of State must—

- (a) evaluate the objectives of the programme of work and its predicted scientific benefits or educational value;
 - (b) assess the compliance of the programme of work with the principles of replacement, reduction and refinement;
 - (c) classify as “non-recovery”, “mild”, “moderate” or “severe” the likely severity of each regulated procedure that would be applied as part of the programme of work;
 - (d) carry out a harm-benefit analysis of the programme of work to assess whether the harm that would be caused to protected animals in terms of suffering, pain and distress is justified by the expected outcome, taking into account ethical considerations and the expected benefit to human beings, animals or the environment;
 - (e) assess any scientific justification which is relevant (by virtue of sections 5(3), 15A(7) or 17(2), paragraphs 1(4), 2(4) or 3(3) of Schedule 2B or paragraph 25(2), (3) or (5) of Schedule 2C) to the question of whether or on what terms a project licence may be granted in respect of the programme of work;
 - (f) assess whether there is any justification for an exemption under paragraph 26(2) of Schedule 2C;
 - (g) assess whether carrying out the programme of work would give rise to any scientific reason for an exemption under paragraph 11(5) of Schedule 2C;
 - (h) determine, on the assumption that a project licence is granted in respect of the programme of work, whether and (if so) when the programme should be retrospectively assessed under section 5F.
- (4) In carrying out the evaluation of a programme of work the Secretary of State must consider—
- (a) expertise in the area of science for which it is intended that protected animals will be used (including expertise in the application of the principles of replacement, reduction and refinement when working in that area of science);
 - (b) expertise in experimental design (including expertise in statistics where appropriate);
 - (c) expertise in veterinary practice in laboratory animal science or, where appropriate, expertise in wildlife veterinary practice;
 - (d) expertise in animal husbandry and care in relation to the species of protected animals that are intended to be used.
- (5) For the purposes of subsection (3)(c) a series of regulated procedures applied to an animal for a particular purpose is to be treated as constituting a single regulated procedure.
- (6) When classifying the likely severity of a regulated procedure under subsection (3)(c) the Secretary of State must use the criteria in Annex 8 of the Animals Directive.
- (7) The Secretary of State must determine that a programme of work should be retrospectively assessed under section 5F if the programme would involve—
- (a) the application of regulated procedures to primates; or
 - (b) the application of regulated procedures the likely severity of which has been classified under section (3)(c) as “severe”.
- (8) The evaluation of a programme of work must be carried out with a degree of detail appropriate for the type of programme and must be carried out in an impartial manner.
- (9) The Secretary of State must publish information as to the process by which he proposes to evaluate programmes of work under this section.

5C Determining an application: further provision

(1) A project licence must not be granted except to a person who undertakes responsibility for the overall implementation of the programme of work to be specified in the licence.

(2) A project licence must not be granted to a person unless the Secretary of State has verified that—

- (a) the person has received instruction in a scientific discipline relevant to the programme of work to be specified in the licence;
- (b) the person has specific knowledge relating to the species of animal that is to be subjected to regulated procedures as part of that programme of work; and
- (c) the person has appropriate education and training for the purpose of designing programmes of work involving the application of regulated procedures.

(3) A project licence must not be granted unless the Secretary of State has verified that the programme of work to be specified in the licence is to be carried out for one of the following purposes—

- (a) basic research;
- (b) translational or applied research with one of the following aims—
 - (i) the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality, or their effects, in man, animals or plants;
 - (ii) the assessment, detection, regulation or modification of physiological conditions in man, animals or plants; or
 - (iii) the improvement of the welfare of animals or of the production conditions for animals reared for agricultural purposes;
- (c) the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs or any other substances or products, with one of the aims mentioned in paragraph (b);
- (d) the protection of the natural environment in the interests of the health or welfare of man or animals;
- (e) research aimed at preserving the species of animal subjected to regulated procedures as part of the programme of work;
- (f) higher education or training for the acquisition, maintenance or improvement of vocational skills;
- (g) forensic inquiries.

(4) Schedule 2B (which requires the Secretary of State to verify that additional conditions are met before granting a project licence that would authorise the use of endangered animals, primates, cats, dogs or equidae) has effect.

(5) The Secretary of State must not grant a project licence that would authorise the application of regulated procedures to great apes.

5D Granting a project licence

(1) This section applies where a project licence is granted in relation to a programme of work.

(2) The project licence must—

- (a) specify the name of the person to whom the licence is granted; and

- (b) contain a statement that the person is responsible for the overall implementation of the programme of work and for ensuring that the programme is carried out in compliance with the conditions of the licence.
- (3) The project licence must specify the name of any person who at the time the project licence is granted holds a section 2C licence granted in respect of a place specified in the project licence.
- (4) The project licence must state how the Secretary of State classified the likely severity of each of the regulated procedures specified in the licence (see section 5B(3)(c)).
- (5) The project licence must state what determination the Secretary of State made as to whether and, if so, when the programme of work should be retrospectively assessed under section 5F (see section 5B(3)(h)).
- (6) The Secretary of State must publish a copy of the project summary that accompanied the application for the project licence.
- (7) But before doing so the Secretary of State must alter the copy so that—
 - (a) it states what determination the Secretary of State made as to whether and when the programme of work should be retrospectively assessed under section 5F; and
 - (b) it includes such additional information as the Secretary of State thinks appropriate in order to assist a person who reads the summary.

5E Duration of a project licence and further evaluation etc

- (1) Unless revoked and subject to the following provisions of this section, a project licence shall continue in force for such period as is specified in the licence and may be renewed for further periods but (without prejudice to the grant of a new licence in respect of the programme in question) no such licence shall be in force for more than five years in all.
- (2) A project licence shall terminate on the death of the holder unless a qualifying person notifies the Secretary of State of the death within seven days of becoming aware of it.
- (3) Where the Secretary of State receives a notification under subsection (2) the project licence shall, unless the Secretary of State otherwise directs, continue in force until the end of the period of 28 days beginning with the date of the notification.
- (4) For the purposes of subsection (2), a person is a “qualifying person” in relation to a project licence if—
 - (a) the person is the holder of a section 2C licence granted in respect of a place specified in the project licence; or
 - (b) in a case where the project licence does not specify a place in respect of which there is a section 2C licence, the person is the holder of a personal licence who was engaged on the programme in question.
- (5) A project licence may not be varied or renewed unless the Secretary of State has carried out a further favourable evaluation of the relevant programme of work; and for this purpose section 5B applies with any necessary modifications.
- (6) The Secretary of State must establish and publish conditions which he or she will take into account in determining whether to vary or renew a project licence.

5F Retrospective assessment of programme of work

- (1) This section applies where—
 - (a) a project licence is granted in respect of a programme of work; and

- (b) the Secretary of State made a determination under section 5B(3)(h) that the programme of work should be retrospectively assessed under this section.
- (2) At the time determined by the Secretary of State under section 5B(3)(h), the Secretary of State must assess the following matters—
- (a) whether the programme of work has been carried out;
 - (b) whether the objectives of the programme of work have been achieved;
 - (c) the amount of harm caused to animals by the carrying out of the programme of work (including the number of animals subjected to regulated procedures as part of the programme of work, the species of animals subjected to those procedures and the severity of those procedures); and
 - (d) whether any lessons can be learnt from the programme of work which may contribute to the further implementation of the principles of replacement, reduction and refinement.
- (3) Following the assessment the Secretary of State must—
- (a) alter the copy of the relevant project summary published under section 5D(6) so that it includes a report on the assessment; and
 - (b) publish the copy as altered.
- (4) The Secretary of State may by notice require the holder or former holder of the licence to provide the Secretary of State with specified information, or information of a specified kind, for the purpose of enabling the Secretary of State to assess the matters mentioned in subsection (2).
- (5) Information required to be provided by a notice under subsection (4) must be provided within such period as may be specified.

5G Documents to be kept by Secretary of State

- (1) Where a person applies for a project licence the Secretary of State must keep the documents specified in subsection (2) at least until the end of the period of three years beginning immediately after—
- (a) the expiry of the project licence (if the application for the licence is successful); or
 - (b) (if not) the period mentioned in section 5A(7), taking into account any extension of that period under section 5A(8).
- (2) The documents referred to above are—
- (a) the application for the licence and the documents submitted in support of it;
 - (b) documents setting out the results of the evaluation carried out under section 5B and of any evaluation carried out under section 5E(5);
 - (c) the project licence itself, or the notice (served under section 12(1)(a)) of intention to refuse the application for the licence;
 - (d) documents containing information provided for the purposes of any assessment under section 5F;
 - (e) documents setting out the results of any such assessment (if completed before the end of the three-year period mentioned in subsection (1)); and
 - (f) any other documents prepared or received by the Secretary of State in relation to the licence which the Secretary of State considers should be kept.
- (3) If section 5F applies in relation to a project licence and the assessment under that section is not completed until after the end of the three-year period mentioned in subsection (1), the

Secretary of State must keep the documents specified in subsection (2)(a), (b), (c), (d) and (f) until the assessment is completed.”

(2) After Schedule 2A insert the Schedule set out in Schedule 1 to these Regulations.