



Animals (Scientific Procedures) Act 1986

1986 CHAPTER 14

Personal and project licences

[^{F1}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

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- 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.]

Textual Amendments

- F1** Ss. 5-5G substituted for s. 5 (1.1.2013) by [The Animals \(Scientific Procedures\) Act 1986 Amendment Regulations 2012 \(S.I. 2012/3039\)](#), regs. 1(2), **9(1)** (with Sch. 3)

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