Draft Regulations laid before Parliament under paragraph 5(1) of Schedule 5 to the Retained EU Law (Revocation and Reform) Act 2023 (c. 28), for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2026 No.

RETAINED EU LAW REFORM

ANIMALS

The Animals (Scientific Procedures) Act 1986 (Amendment) Regulations 2026

Made - - - -	***
Coming into force in accordance with regulation 1(1)	***

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 12(1), 13(7) and 14(2), (3) and (7) of the Retained EU Law (Revocation and Reform) Act 2023 ("the 2023 Act")(**a**).

The Secretary of State is a relevant national authority for the purposes of sections 12(1) and 14(2) and (3) of the 2023 Act(**b**).

In accordance with paragraph 5(1) of Schedule 5 to the 2023 Act, a draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament.

PART 1

General

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Animals (Scientific Procedures) Act 1986 (Amendment) Regulations 2026 and come into force on the day after the day on which they are made.

(2) These Regulations extend to England and Wales, Scotland and Northern Ireland.

(**a**) 2023 c. 28.
(**b**) The term "relevant national authority" is defined in section 21(1) of the Retained EU Law (Revocation and Reform) Act 2023.

PART 2

Amendment of the Animals (Scientific Procedures) Act 1986

Amendment of the Animals (Scientific Procedures) Act 1986

2. The Animals (Scientific Procedures) Act 1986(**a**) is amended in accordance with this Part.

Amendment to section 5 (project licences: general)

3. In section 5 (project licences: general)(**b**), for subsection (4) substitute—

"(4) A project licence may specify a programme of work which consists of multiple generic projects if the projects—

(a) are to be carried out to satisfy regulatory requirements, or

(b) use animals for production or diagnostic purposes, in accordance with established methods.".

Amendment to section 5A (application for a project licence)

4. In section 5A (application for a project licence)(**c**)—

(a) in subsection (1)(c), for "Annex 6 of the Animals Directive" substitute "subsection (1A)";

(b) after subsection (1), insert—

"(1A) The matters referred to in subsection (1)(c) are—

(a) the relevance of, and justification for, the regulated procedures specified in the application;

(b) the proposed application of methods to replace, reduce or refine the use of animals in those procedures;

(c) the proposed severity classification of the procedures specified in the application (see section 5B(3)(c));

(d) the relevance of, and justification for, the use of animals in those procedures;

(e) the following matters in relation to the animals to be used in those procedures—

(i) their estimated number;

(ii) their type and species;

(iii) their life stages;

(iv) their origin;

(f) the proposed housing conditions, husbandry conditions and care conditions of those animals;

(g) the steps proposed for the avoidance, reduction or alleviation of pain, suffering or distress in those animals, from birth to death where appropriate, including, in particular—

(i) the planned use of anaesthesia, analgesia or other methods of relieving pain;

(**a**) 1986 c. 14.
(**b**) Section 5 was substituted by S.I. 2012/3039.
(**c**) Section 5A was inserted by S.I. 2012/3039.

(ii) the use of humane end-points;

(h) any proposed experimental or observational strategy or statistical design for minimising the following where appropriate—

(i) the number of animals to be used;

(ii) their pain, suffering or distress;

(iii) the environmental impact of the procedures;

(i) the cumulative effects of any proposed reuse on those animals;

(j) any proposed methods of killing those animals;

(k) the steps proposed for the avoidance of any unjustified duplication of procedures where appropriate;

(l) the competence of persons involved in the proposed programme of work.".

Amendment to section 5B (determining an application: evaluation of the programme of work)

5. In section 5B (determining an application: evaluation of the programme of work)(**a**)—

(a) in subsection (3)(c), after "work" insert "(see section 5BA)";

(b) omit subsection (6).

Insertion of section 5BA (determining an application: classification of the severity of the procedure)

6. After section 5B, insert—

"5BA Determining an application: classification of the severity of the procedure

(1) This section applies for the purposes of classifying the likely severity of a regulated procedure under section 5B(3)(c).

(2) The likely severity of the procedure is to be determined by the degree of pain, suffering, distress or lasting harm expected to be experienced by an animal during the course of the procedure.

(3) A procedure that falls within a description set out in column 1 of the following Table is to be assigned to the category that is specified in column 2 of the Table in relation to that description—

Description of procedure performed on animal	Category of severity
A procedure that does not cause any significant impairment of the well-being or general condition of the animal. A procedure as a result of which the animal is likely to experience short-term mild pain, suffering or distress.	Mild
A procedure that is likely to cause moderate impairment of the well-being or general condition of the animal.	Moderate

(**a**) Section 5B was inserted by S.I. 2012/3039.

A procedure as a result of which the animal is likely to experience short-term moderate pain, suffering or distress or long-lasting mild pain, suffering or distress.	
A procedure that is likely to cause severe impairment of the well-being or general condition of the animal. A procedure as a result of which the animal is likely to experience severe pain, suffering or distress or long-lasting moderate pain, suffering or distress.	Severe
A procedure performed entirely under general anaesthesia from which the animal will not regain consciousness.	Non-recovery

(4) The assignment of a procedure to a category in accordance with subsection (3)—

(a) must be based on the most severe effects likely to be experienced by the animal after all appropriate refinement techniques have been applied, and

(b) must take into account any manipulation of the animal.

(5) When assigning a procedure to a category in accordance with subsection (3), the Secretary of State—

(a) must first assign the procedure to a category on the basis of factors relating to the type of procedure only ("step 1"), and

(b) must then determine whether to assign the procedure to a different category on the basis of additional factors ("step 2").

(6) The following factors relating to the type of procedure must be taken into account for the purposes of step 1—

(a) the type of manipulation or handling involved in the procedure;

(b) the nature and intensity of the pain, suffering, distress or lasting harm that would be caused by the procedure;

(c) the duration, frequency and number of techniques to be used in the procedure;

(d) the cumulative effects of the procedure;

(e) the extent to which the animal used in the procedure would be prevented from expressing their natural behaviour, including any restrictions on their housing, husbandry or care.

(7) Where the procedure is of a description that has been assigned by Schedule 2AA to a particular category of severity, the procedure is to be assigned to that category for the purposes of step 1.

(8) The following additional factors must be taken into account for the purposes of step 2—

(a) the species and genotype of the animal to be used in the procedure;

(b) the maturity, age and gender of the animal;

(c) the habituation of the animal with respect to the procedure;

(d) if the animal is to be reused, the actual severity and cumulative severity of each previous procedure;

(e) the methods used to reduce or eliminate pain, suffering and distress, including refinement of housing, husbandry and care conditions;

(f) use of humane end-points.

(9) The factors to be taken into account for the purposes of subsection (5) must be considered on a case-by-case basis.

(10) Section 5B(5) applies for the purposes of this section as it applies for the purposes of section 5B(3)(c).".

Amendment to section 5D (granting a project licence)

7. In section 5D(6) (granting a project licence)(**a**), after "licence" insert "before the end of the period of six months beginning with the day on which the project licence was granted".

Amendment to section 5F (retrospective assessment of programme of work)

8. In section 5F(3)(b) (retrospective assessment of programme of work)(**b**), after "altered" insert "before the end of the period of six months beginning with the day on which the assessment was completed".

Amendment to section 30 (short title, interpretation and commencement)

9. In section 30 (short title, interpretation and commencement)(**c**)—

(a) in subsection (2), omit the definition of "the Animals Directive";

(b) omit subsection (2A).

Insertion of Schedule 2AA (severity of procedures)

10. Before Schedule 2B, insert Schedule 2AA set out in the Schedule to these Regulations.

Amendment of Schedule 2C (conditions in licences)

11. In Schedule 2C (conditions in licences)(**d**)—

(a) in paragraph 4—

(i) in sub-paragraph (3), for the words from "applicable" to the end substitute "standard concerning installations and equipment which is set out in a relevant code of practice is met";

(ii) for sub-paragraph (4), substitute—

"(4) In sub-paragraph (3), "relevant code of practice" means a code of practice issued or approved under section 21 (as that code has effect from time to time).";

(b) in paragraph 6—

(i) in sub-paragraph (1)(b), for "paragraphs (a) to (e) of Article 27.1 of the Animals Directive" substitute "sub-paragraph (2A)";

(ii) after sub-paragraph (2), insert—

"(2A) The tasks referred to in sub-paragraph (1)(b) are—

(a) advising the staff dealing with animals on matters related to the welfare of animals, so far as relating to their acquisition, accommodation, care and use;

(**a**) Section 5D was inserted by S.I. 2012/3039.
(**b**) Section 5F was inserted by S.I. 2012/3039.
(**c**) Section 30 was amended by S.I. 2012/3039.
(**d**) Schedule 2C was inserted by S.I. 2012/3039 and amended by S.I. 2019/72.

(b) advising the staff on the application of the principles of replacement, reduction and refinement, and keeping them informed of technical and scientific developments concerning the application of those principles;

(c) establishing and reviewing internal operational processes as regards monitoring, reporting and follow-up actions in relation to the welfare of animals housed or used in the place specified in the licence;

(d) following the development and outcome of projects, taking into account the effect on the animals used, and identifying and advising on elements that would further contribute to replacement, reduction and refinement; and

(e) advising on rehoming schemes, including the appropriate socialisation of the animals to be rehomed.";

(c) in paragraph 8—

(i) the existing text becomes sub-paragraph (1);

(ii) in sub-paragraph (1)(a), for the words from "paragraphs" to the end substitute "sub-paragraph (2)";

(iii) after sub-paragraph (1), insert—

"(2) The information referred to in sub-paragraph (1)(a) is—

(a) the origin of each of the animals kept in the place specified in the licence;

(b) the number and species of animals that have been—

(i) bred at that place for use in procedures;

(ii) acquired for the purposes of the undertaking carried on in accordance with the licence;

(iii) supplied elsewhere in the course of that undertaking;

(iv) used in procedures at the place specified in the licence;

(v) released or rehomed;

(c) in the case of any animal acquired for the purposes of the undertaking, the date on which, and the person from whom, it was acquired;

(d) in the case of any animal supplied elsewhere or rehomed, the date on which the animal was supplied or rehomed, and the name and address of the person to whom the animal was provided;

(e) in the case of any animal released, the date on which the animal was released;

(f) in the case of any animal used in a procedure, the project in which it was used;

(g) the number and species of animals that have died in the place specified in the licence and, where known, the cause of death.";

(d) in paragraph 11—

(i) in sub-paragraph (2), for the words from "the following" to the end substitute "any standard concerning the care and accommodation of animals which is set out in a relevant code of practice is met";

(ii) for sub-paragraph (3), substitute—

"(3) In sub-paragraph (2) "relevant code of practice" means a code of practice issued or approved under section 21 (as that code has effect from time to time).";

(e) in paragraph 23—

(i) in sub-paragraph (1), omit "using the criteria in Annex 8 of the Animals Directive";

(ii) after sub-paragraph (1), insert—

"(1A) Section 5BA applies for the purposes of sub-paragraph (1) as it applies for the purposes of section 5B(3)(c), but as if the reference in section 5BA(5) to the Secretary of State were a reference to the suitably qualified person mentioned in sub-paragraph (1).".

PART 3

Revocation of Article 6(1) of Regulation (EU) 2019/1010

Revocation of Article 6(1) of Regulation (EU) 2019/1010

12. Article 6(1) of Regulation (EU) 2019/1010 of the European Parliament and of the Council of 5 June 2019 on the alignment of reporting obligations in the field of legislation related to the environment is revoked.

Minister of State
Home Office

Date

SCHEDULE

Regulation 10

Severity of procedures

"SCHEDULE 2AA

Section 5BA(7)

Severity of procedures

PART 1

General

1. This Schedule contains descriptions of procedures assigned to a particular category of severity on the basis of factors relating to the type of procedure only.

2. Part 2 of this Schedule contains a list of procedures categorised as "mild".

3. Part 3 of this Schedule contains a list of procedures categorised as "moderate".

4. Part 4 of this Schedule contains a list of procedures categorised as "severe".

PART 2

Mild procedures

5. The administration of anaesthesia except for the sole purpose of killing.

6. A pharmacokinetic study where a single dose is administered, a limited number of blood samples are taken totalling less than 10 per cent of circulating volume and the substance is not expected to cause any detectable adverse effect.

7. The non-invasive imaging of an animal with appropriate sedation or anaesthesia including, in particular, magnetic resonance imaging.

8. A superficial procedure including, in particular—

(a) ear and tail biopsies;

(b) non-surgical subcutaneous implantation of mini-pumps or transponders.

9. The application of external telemetry devices that cause only minor impairment to the animal or minor interference with normal activity and behaviour.

10. The administration of a substance where—

(a) the substance has no more than a mild impact on an animal,

(b) the volume of the substance administered is within appropriate limits for the size and species of the animal, and

(c) the substance is administered by any of the following routes—

(i) subcutaneous;

(ii) intramuscular;

(iii) intraperitoneal;

(iv) gavage;

(v) intravenous, using superficial blood vessels.

11. The induction of tumours, or spontaneous tumours, that cause no detectable clinical adverse effects including, in particular, small, subcutaneous, non-invasive nodules.

12. The breeding of a genetically altered animal, which is expected to result in a phenotype with mild effects.

13. The feeding of a modified diet that does not meet all of the animal's nutritional needs and is expected to cause mild clinical abnormality within the time-scale of the procedure.

14. Restraint in metabolic cages for less than 24 hours.

15. A study involving—

(a) short-term deprivation of a social partner, or

(b) short-term solitary caging of an adult rat of a sociable strain or an adult mouse of a sociable strain.

16. Experimental models which expose an animal to noxious stimuli which—

(a) are associated with mild pain, suffering or distress, and

(b) the animal can successfully avoid.

17. A repetition or combination of any of the following procedures, as a result of which the animal is likely to experience short-term mild pain, suffering or distress or which does not cause significant impairment of the animal's well-being or general condition—

(a) the assessment of body composition by non-invasive measures with minimal restraint;

(b) a monitoring electrocardiogram with non-invasive techniques with minimal or no restraint of a habituated animal;

(c) the application of external telemetry devices that is expected to cause no impairment to a socially adapted animal and does not interfere with normal activity and behaviour;

(d) the breeding of a genetically altered animal which is expected to have no clinically detectable adverse phenotype;

(e) the addition of inert markers in the diet to follow passage of digesta;

(f) the withdrawal of food for less than 24 hours in an adult rat;

(g) open field behavioural testing of a mouse.

PART 3

Moderate procedures

18. The repeated application of test substances which produce moderate clinical effects.

19. The withdrawal of blood samples from a conscious animal where—

(a) the blood withdrawn within an appropriate period for the animal exceeds 10% of the circulating volume of blood in the animal at the start of the period, and

(b) the volume of blood withdrawn is not replaced within that period.

20. An acute dose-range finding study, or chronic toxicity or carcinogenicity test, with non-lethal end-points.

21. Surgery under general anaesthesia and appropriate analgesia, associated with post surgical pain, suffering or impairment of general condition including, in particular—

(a) thoracotomy, craniotomy, laparotomy, orchidectomy, lymphadenectomy or thyroidectomy;

(b) orthopaedic surgery with effective stabilisation and wound management;

(c) organ transplantation with effective management of rejection;

(d) surgical implantation of catheters or biomedical devices such as telemetry transmitters or minipumps.

22. Models of induction of tumours, or spontaneous tumours, that are expected to cause moderate pain or distress or moderate interference with normal behaviour.

23. Irradiation or chemotherapy with—

(a) a sublethal dose, or

(b) an otherwise lethal dose with reconstitution of the immune system,

where any adverse effects are expected to be mild or moderate and to last for less than five days.

24. The breeding of a genetically altered animal which is expected to result in a phenotype with moderate effects, such as impaired organ dysfunction, or an underdeveloped physiological function.

25. The creation of a genetically altered animal through a surgical procedure.

26. The use of metabolic cages involving moderate restriction of movement over a period of up to five days.

27. A study with a modified diet that does not meet all of the animal's nutritional needs and is expected to cause moderate clinical abnormality within the time-scale of the study.

28. The withdrawal of food for 48 hours in an adult rat.

29. Evoking escape and avoidance reactions where the animal is—

(a) unable to escape or avoid the stimulus, and

(b) expected to suffer moderate distress.

PART 4

Severe procedures

30. Toxicity testing, including in particular single dose acute toxicity testing, where—

(a) death is the end-point, or

(b) fatality is to be expected and a severe pathophysiological state is induced.

31. The testing of a device where failure may cause severe pain, distress or death of the animal including, in particular, cardiac assist devices.

32. Vaccine potency testing that is—

(a) characterised by—

(i) persistent impairment of the animal's condition, or

(ii) progressive disease leading to death, and

(b) associated with long-lasting moderate pain, suffering or distress.

33. Irradiation or chemotherapy with a lethal dose—

(a) without reconstitution of the immune system, or

(b) with reconstitution of the immune system with production of graft versus host disease.

34. The induction of tumours, or spontaneous tumours, that are expected to progress to cause lethal disease associated with long-lasting moderate pain, suffering or distress including, in particular—

(a) tumours causing cachexia;

(b) invasive bone tumours;

(c) tumours resulting in metastatic spread;

(d) tumours that are allowed to ulcerate.

35. Surgical and other interventions in an animal under general anaesthesia which are expected to result in severe or persistent moderate postoperative pain, suffering or distress or severe and persistent impairment of the animal's general condition.

36. Production of unstable fractures, or thoracotomy without adequate analgesia.

37. A procedure expected to result in multiple organ failure.

38. Organ transplantation where organ rejection is likely to lead to severe distress or impairment of the general condition of the animal including, in particular, xenotransplantation.

39. Breeding an animal with a genetic disorder that is expected to experience severe and persistent impairment of general condition including, in particular—

(a) Huntington's disease;

(b) muscular dystrophy;

(c) chronic relapsing neuritis models.

40. The use of metabolic cages involving severe restriction of movement over a prolonged period.

41. Inescapable electric shock including, in particular, where it produces learned helplessness.

42. The complete isolation for a prolonged period of a social species, whether occurring once or on more than one occasion, including, in particular, a dog or non-human primate.

43. Immobilisation stress expected to result in gastric ulcers or cardiac failure in a rat.

44. Forced swim or exercise tests with exhaustion as the end-point.".

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations restate, revoke and replace assimilated law relating to animals used in scientific research, maintaining the current legislative framework by consolidating the provisions into the Animals (Scientific Procedures) Act 1986 (c.14) ("the ASPA").

The key EU legislation on the use of animals in scientific research was Directive 2010/63/EU of the European Parliament and of the Council on the protection of animals used for scientific purposes ("the Animals Directive"), which was transposed into domestic legislation through the Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 (S.I. 2012/3039) which amended the ASPA.

Article 6 of Regulation (EU) 2019/1010 amended Article 43(2) and (3) of the Animals Directive in 2019 and impacted the corresponding provisions in the ASPA, sections 5D(6) and 5F(3) and (4), due to having direct effect.

Regulations 3 to 11 amend the ASPA by restating, revoking and replacing relevant provisions of assimilated law that were previously reflected in, or operated by reference to, the Animals Directive.

Regulation 3 amends section 5(4) of the ASPA to set out the circumstances, previously reflected in Article 40.4 of the Animals Directive, in which a project licence may authorise a programme of work comprising of multiple generic projects.

Regulation 4 amends the ASPA by replacing assimilated law corresponding to Annex 6 of the Animals Directive with equivalent provision and updates a textual reference to Annex 6 in section 5A(1)(c). Annex 6 sets out the information that must be included in an application for a project authorisation.

Regulations 5 and 6 replace assimilated law corresponding to Annex 8 of the Animals Directive with equivalent provision, setting out the severity classification of procedures, with the text adapted for clarity and to ensure consistency with the ASPA. Regulation 5 also substitutes a reference to Annex 8 with new section 5BA and Schedule 2AA of the ASPA.

Regulation 7 amends section 5D(6) of the ASPA and specifies the requirement to publish a copy of the project summary that accompanied the application for the project licence within six months of granting a project licence, reflecting the amendments made to Article 43 of the Animals Directive by Article 6 of Regulation (EU) 2019/1010.

Regulation 8 amends section 5F(3)(b) of the ASPA and specifies the requirement to publish a retrospective assessment of a project summary within six months of completing the assessment, reflecting the amendments previously made to Article 43 of the Animals Directive by Article 6 of Regulation (EU) 2019/1010.

Regulation 9 omits references to the Animals Directive in section 30 of the ASPA.

Regulation 10 inserts Schedule 2AA into the ASPA for the purposes of new section 5BA(7). Schedule 2AA contains a list of procedures by reference to severity classification, replacing assimilated law corresponding to Annex 8 of the Animals Directive with equivalent provision.

Regulation 11 amends Schedule 2C to the ASPA. Regulation 11(a) and (d) substitute references that previously operated by reference to Annex 3 of the Animals Directive with references to any code of practice issued or approved under section 21 of the ASPA. Regulation 11(b) sets out the

tasks of the Animal Welfare and Ethical Review Body that previously operated by reference to Article 27.1 of the Animals Directive. Regulation 11(c) sets out the information keeping requirements for licensed establishments that previously operated by reference to Article 30.1 of the Animals Directive. Regulation 11(e) substitutes references that previously operated by reference to Annex 8 of the Animals Directive with new section 5BA and Schedule 2AA of the ASPA.

Regulation 12 revokes Article 6(1) of Regulation (EU) 2019/1010, the substance of which is now reflected in the ASPA, having been restated by these Regulations.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sector is foreseen.

© Crown Copyright 2026

Printed and published in the UK by The Stationery Office Limited under the authority and superintendence of Saul Nassé, Controller of His Majesty's Stationery Office and King's Printer of Acts of Parliament.

£8.90

http://www.legislation.gov.uk/id/ukdsi/2026/9780348281750

ISBN 978-0-34-828175-0

9 780348 281750