EXPLANATORY MEMORANDUM TO

THE ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986 (AMENDMENT) REGULATIONS 2026

2026 No. [XXXX]

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Home Office and is laid before Parliament by Command of His Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments and the Secondary Legislation Scrutiny Committee.

2. Declaration

2.1 Lord Hanson of Flint at the Home Office confirms that this Explanatory Memorandum meets the required standard.

2.2 Will Reynolds, Strategic Lead for Science Regulation and Innovation at the Home Office confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Mamataj Begum at the Home Office can be contacted by email at the following address with any queries regarding the instrument: animalsinsciencepolicy@homeoffice.gov.uk

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 The Animals (Scientific Procedures) Act 1986 (the ASPA) is the UK's legislation relating to the use of animals in science. It permits animal testing and research within a strict regulatory framework, safeguarded by the principles of Replacement, Refinement and Reduction, with harm-benefit analysis as the cornerstone of project evaluation.

4.2 This instrument restates, revokes and replaces assimilated law relating to animals used in scientific research, maintaining the current legislative framework by consolidating the provisions into the ASPA. The Regulations do not create any new requirements for those operating under the ASPA, nor do they alter existing policy or introduce new regulatory requirements.

4.3 These Regulations are a technical, continuity measure under the 2023 Act, and will come into force shortly after approval and making.

Where does the legislation extend to, and apply?

4.4 The extent of this instrument (that is, the jurisdiction which the instrument forms part of the law of) is of the United Kingdom.

4.5 The territorial application of this instrument (that is, where the instrument produces a practical effect) is UK-wide.

5. Policy Context

What is being done and why?

5.1 This instrument updates the legal framework for the regulation of animals used in scientific procedures. Its purpose is to maintain the existing regulatory standards under the ASPA while ensuring that legislation is clear, accessible and operates effectively following the UK's exit from the European Union with all relevant requirements contained within a single, domestic statute.

5.2 The ASPA currently contains a number of references to EU legislation. These provisions were retained after the EU Exit to ensure continuity, but they result in a framework in which certain requirements are expressed by reference to EU instruments, meaning they are not fully contained within the ASPA itself.

5.3 Restating, revoking and replacing relevant provisions of assimilated law such as keeping records of animals used in science, removes reference to EU instruments, avoids legal ambiguity, and supports a consistent and coherent regulatory framework across the UK. This includes consolidating requirements that were previously set out in EU instruments or operated by reference to them.

5.4 This instrument does not alter the duties placed on licence holders or establishments. Those conducting scientific work under the ASPA will continue to follow the same standards, processes and protection requirements.

5.5 For both the GB Regulator (the Animals in Science Regulation Unit (ASRU)), and the Northern Ireland Regulator (The Department of Health Northern Ireland) core regulatory functions, including the issuing of licences, compliance activity, inspections and the publication of summaries, remain unchanged. The consolidation of the legal framework will support clearer interpretation and reduce the need to cross-refer to EU legislation.

What was the previous policy, how is this different?

5.6 Previously the relevant requirements were set out in assimilated law, which relied on EU-specific structures and cross-references. These Regulations do not change existing policy. Instead, they consolidate the existing requirements into the ASPA, ensuring that the framework is fully contained within domestic legislation and drafted in a way that reflects the UK system.

6. Legislative and Legal Context

How has the law changed?

6.1 The key EU legislation on the use of animals in scientific research is 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) and amended the ASPA.

6.2 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.

6.3 These Regulations amend the ASPA by using powers conferred by sections 12(1), 13(7) and 14(2), (3) and (7) of the 2023 Act, to restate, revoke and replace assimilated law relating to animals used in scientific research, maintaining the current legislative framework by consolidating the provisions into the ASPA.

6.4 These Regulations incorporate into the ASPA provisions relating to the authorisation of project licences (including multi-project programmes), the information required for project applications, the classification of procedures by severity, publication requirements for project summaries and retrospective assessments, and recordkeeping and governance arrangements for licensed establishments.

6.5 They also replace references to the Animals Directive and its annexes including introducing the Schedule 2AA on severity classification, and substitute references to Directive annexes with references to a Code of Practice issued under section 21 of the ASPA that has effect from time to time.

6.6 Finally, they revoke Article 6(1) of Regulation (EU) 2019/1010, the substance of which is now fully restated in the ASPA.

6.7 Section 12 of the 2023 Act allows the Secretary of State to make regulations restating to any extent, any secondary assimilated law. Section 14 allows the Secretary of State to make regulations which revoke assimilated law and replace it with provisions considered appropriate to achieve the same or similar objectives, or to revoke assimilated law and make alternative provisions which they consider appropriate.

6.8 In exercising these powers, the Secretary of State considers the revocation and replacement of the relevant assimilated law to be appropriate, and that the replacement provisions achieve the same or similar objectives as the legislation being revoked. Any regulations under sections 12 and 14 must be made by no later than 23 June 2026.

6.9 Section 14(5) of the 2023 Act requires that the overall effect of any changes made to assimilated law using section 14 powers must not increase the regulatory burden in the relevant subject area. The amendments made by these Regulations do not create any new requirements for those that operate under the ASPA, nor alter existing policy or introduce new regulatory requirements. As such, the amendments made by these Regulations do not increase the regulatory burden.

Why was this approach taken to change the law?

6.10 The policy objectives can be achieved only by amending the ASPA, which after 23 June 2026, would require primary legislation. In the interests of delivering these necessary changes as quickly as possible, Ministers have decided to use the powers in the 2023 Act while they remain available.

7. Consultation

Summary of consultation outcome and methodology

7.1 The Department has not undertaken a consultation for this instrument due to the limited impact of the proposed amendments, which are confined to technical restatements, revocations and replacements of assimilated law. These changes do not alter existing policy or introduce new regulatory requirements.

7.2 In line with established arrangements for the ASPA matters, Northern Ireland were engaged since the regulation of animals used in science is a devolved matter. Consent was sought from Northern Ireland officials on 29 November 2023 by the Minister at the time, Lord Sharpe of Epsom to the Permanent Secretary of Northern Ireland's Department of Health (Peter May). Northern Ireland officials have confirmed that policy positions remain unchanged and no objections were raised. Although this consent was provided under the previous government, the position has remained consistent, and we continue to engage with Northern Ireland regularly.

8. Applicable Guidance

8.1 Guidance is not required as this instrument does not introduce any new policies or regulatory requirements; as such existing operational guidance remains sufficient.[1]

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment has not been prepared for this instrument because the regulations maintain existing standards and the changes will therefore not significantly alter the delivery of animals in science regulation.

9.2 As such, no significant economic, operational, or administrative impacts are expected for businesses, charities, voluntary bodies, or the public sector.

Impact on businesses, charities and voluntary bodies

9.3 There is no, or no significant, impact on business, charities or voluntary bodies because the regulations maintain existing standards.

9.4 The legislation does not impact small or micro businesses.

9.5 There is no, or no significant, impact on the public sector because the regulations maintain existing standards.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The approach to monitoring this legislation is that the pieces of legislation being amended by this instrument will be reviewed in line with the approach already in place for the ASPA.

10.2 As this instrument is only made under the relevant European Union Acts (as defined at 13.1), no review clause is required.

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 The Regulation contains information for the Joint Committee on Statutory Instruments and the Secondary Legislation Scrutiny Committee.

11.2 The Regulation contains an ambulatory reference to the Code of Practice, which is also being laid on the same day, under Section 21 of the ASPA. This will allow the Code of Practice to be updated in the future and remain the latest version within the ASPA. This approach avoids the need to make amendments to primary legislation should the Code of Practice be updated.

12. European Convention on Human Rights

12.1 Lord Hanson of Flint has made the following statement regarding Human Rights: "In my view the provisions of the Animals (Scientific Procedures) Act 1986 (Amendment) Regulations 2026 are compatible with the Convention rights.

[1] https://www.gov.uk/government/publications/the-operation-of-the-animals-scientific-procedures-act-1986/the-operation-of-the-animals-scientific-procedures-act-1986-aspa-accessible

13. The Relevant European Union Acts

13.1 This instrument is made, under sections 12(1), 13(7) and 14(2), (3) and (7) of the 2023 Act and therefore relates to the reform of assimilated law.