

EXPLANATORY MEMORANDUM TO

THE ANIMALS (SCIENTIFIC PROCEDURES) ACT 1986 (EU EXIT) REGULATIONS 2018

2018 No. [XXXX]

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Home Office and is laid before Parliament by Act.
- 1.2 This memorandum contains information for the Committees on the UK's exit from the European Union.

2. Purpose of the instrument

- 2.1 These regulations amend the Animals (Scientific Procedures) Act 1986 to ensure a seamless animals in science regulatory system, following the UK's withdrawal from the European Union. Mandatory requirements for the UK to provide information or assistance to the European Commission or Member States are cancelled.
- 2.2 These regulations do not create any new requirements for those that operate under ASPA, nor will they create any new functions for the Home Office animals in science regulator.

3. Matters of special interest to Parliament

Matters of special interest to the Committees on the UK's exit from the European Union

- 3.1 None.
- 3.2 The instrument is being laid for sifting to the EU (Withdrawal) Act 2018.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws).

- 3.3 As the instrument is subject to negative resolution procedure there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

4. Extent and Territorial Application

- 4.1 The territorial extent of this instrument is the United Kingdom.
- 4.2 The territorial application of this instrument is the United Kingdom.

5. European Convention on Human Rights

- 5.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

- 6.1 The use of animals in science is regulated by ASPA. Enforcement and administration is provided by published Guidance and Codes of Practice which are laid in parliament

and published. Regulation is delivered by the Home Office regulator: the Animals in Science Regulation Unit.

- 6.2 European Directive 2010/63/EU on the protection of animals used for scientific purposes came into force on 9 November 2010. It was transposed into UK legislation in 2012 and contained obligations to work with the European Commission, which would no longer be appropriate after the UK's withdrawal from the European Union. This instrument removes those obligations.
- 6.3 The delivery of the animals in science regulatory framework will continue with the same standards of oversight, rigour and scrutiny following the UK's withdrawal from the European Union.

7. Policy background

- 7.1 These regulations are required to amend current UK legislation – the Animals (Scientific Procedures) Act 1986 – to ensure seamless animals in science regulation following EU exit. The changes being made are the minimum necessary to allow the regulatory scheme to operate after exit day.
- 7.2 This instrument only provides for changes under the European Union Withdrawal Act. The regulatory system remains otherwise unchanged. It removes mandatory requirements to share data and engage with the European Commission or Member States, which would no longer be appropriate once the UK has left the European Union.
- 7.3 This instrument does not alter the requirement for the UK to publish annual statistics on the use of animals in science.
- 7.4 There are no changes to the high standards of animal welfare required under ASPA. ASPA continues to place the same, strong emphasis on minimising the use of animals and promotion of the 3Rs (Replacement, Reduction and Refinement). Implementation of the 3Rs will contribute to the final goal of full replacement of procedures on live animals for scientific and educational purposes as soon as it is scientifically possible to do so, which was an aim enshrined in Directive 2010/63/EU.
- 7.5 The process of rigorous project evaluation, for the purposes of granting licences, remains unchanged. The process of harm-benefit analysis will continue to be the cornerstone of the decision making process.
- 7.6 These regulations do not alter either the Guidance of the Operation of ASPA, which sets out its administration and enforcement, nor the published Code of Practice on the housing and care requirements. The Code of Practice will retain the Directive requirements and any other higher standards already adopted by the United Kingdom.
- 7.7 References to Directive 2010/63/EU in ASPA remain functional, and refer to the Directive as it was on the date of the UK's withdrawal from the European Union.

8. European Union (Withdrawal) Act

- 8.1 This instrument is being made using the power in section 8 the European Union (Withdrawal) Act 2018 to address failures of retained European law to operate effectively or other deficiencies arising from the withdrawal of the UK from the European Union.

9. Consolidation

9.1 Not relevant

10. Consultation outcome

10.1 Consultation is not considered necessary, as the instrument is making a minor, technical change resulting from the UK's withdrawal from the European Union.

11. Guidance

11.1 There is no guidance accompanying this Statutory Instrument.

12. Impact

12.1 An Impact Assessment has not been prepared because the changes will not significantly alter the delivery of animals in science regulation.

13. Regulating small business

13.1 There is no significant change to the way animals in science is regulated.

14. Monitoring & review

14.1 ASRU will continue to monitor legislation on the protection of animals at the time of killing (EC 1099/2009) and on the protection of species of wild fauna and flora (EC 338/97), in accordance with DEFRA. These regulations will be mirrored in UK legislation after exit day.

14.2 As this instrument is made under the EU Withdrawal Act 2018, no review clause is required.

15. Contact

15.1 Kate Chandler at the Home Office. Telephone: 0207 035 4794 or email: kate.chandler@homeoffice.gsi.gov.uk can be contacted with any queries regarding the instrument.

15.2 William Reynolds, Deputy Director for the Animals in Science Regulation Unit, at the Home Office can confirm that this Explanatory Memorandum meets the required standard.

15.3 Baroness Williams at the Home Office can confirm that this Explanatory Memorandum meets the required standard.

Annex

Statements under the European Union (Withdrawal) Act 2018

Part 1

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA SIs	Explain the instrument, identify the relevant law before exit day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.

Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9, and 23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	Set out the ‘good reasons’ for creating a criminal offence, and the penalty attached.
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising sections 10(1), 12 and part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 4 or 14, Schedule 7.	Statement of the reasons for the Minister’s opinion that the SI is urgent.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 13, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA, identifying the relevant law before exit day, and explaining the instrument’s effect on retained EU law.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 16, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority’s response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and, c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.

Part 2

Statements required when using enabling powers under the European Union (Withdrawal) 2018 Act

1. Sifting statement

- 1.1 The Minister of State for Countering Extremism and Minister for Equalities, Baroness Williams, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

“In my view, the **Animals (Scientific Procedures) Act 1986 (EU Exit) Regulations 2018** should be subject to annulment in pursuance of a resolution of either House of Parliament (i.e. the negative procedure)”. This is the case because of the reasons set out in paragraph below.

2. Appropriateness statement

- 2.1 The Minister of State for Countering Extremism and Minister for Equalities, Baroness Williams, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

- 2.2 “In my view the **Animals (Scientific Procedures) Act 1986 (EU Exit) Regulations 2018** does no more than is appropriate”. The Regulations deal only with matters which need to be addressed pursuant to the UK’s withdrawal from the European Union, whilst assuring that animals in science regulation continues seamlessly. The regulations remove mandatory requirements to share data and engage with the European Commission or Member States. This is within the vires set out in section 10 of the European Union (Withdrawal Act) 2018. Mandatory commitments to work with the European Commission would no longer be appropriate after the UK’s withdrawal from the European Union.

3. Good reasons

- 3.1 The Minister of State for Countering Extremism and Minister for Equalities, Baroness Williams, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

“In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action”. These are: that that the regulations only focus on inoperabilities that arise as a consequence of the UK’s decision to leave the European Union. Without these Regulations, there would be mandatory requirements to share statistical data and other information with the Commission despite it no longer being appropriate given the UK’s withdrawal from the European Union.

4. Equalities

- 4.1 The Minister of State for Countering Extremism and Minister for Equalities, Baroness Williams, has made the following statement(s) “The [draft] instrument does not amend, repeal or revoke a provision or provisions in the Equality Act 2006 or the Equality Act 2010 or subordinate legislation made under those Acts.
- 4.2 The Minister of State for Countering Extremism and Minister for Equalities, Baroness Williams, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018: “In relation to the [draft] instrument, I, Baroness Williams, the Minister of State for Countering Extremism and Minister for Equalities, have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010.”

5. Explanations

What did any relevant EU law do before exit day?

- 5.1 The Animals (Scientific Procedures) Act 1986 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 (the 3Rs), with harm-benefit analysis as the cornerstone of project evaluation.

Why is it being changed?

- 5.2 Without these Regulations, there would be mandatory requirements to share statistical data and to engage with the Commission despite it no longer being appropriate given the UK’s withdrawal from the European Union.

What will it now do?

- 5.3 This instrument only alters changes required for operability following the UK’s withdrawal from the European Union, by removing mandatory commitments to the European Union. The regulatory system otherwise remains unchanged.