EXPLANATORY MEMORANDUM TO

THE ANIMAL BY-PRODUCTS AND TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES (AMENDMENT) (ENGLAND) (EU EXIT) REGULATIONS 2018 No. [XXXX]

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department for Environment, Food and Rural Affairs and is laid before Parliament by Act.
- 1.2 This memorandum contains information for the sifting Committees on the UK's exit from the European Union.

2. Purpose of the instrument

2.1 The purpose of this instrument is to make deficiency amendments under the EU (Withdrawal) Act 2018 (the "Withdrawal Act") to English secondary legislation which enforces directly applicable EU legislation, in relation to the control and eradication of transmissible spongiform encephalopathies (TSEs) and the use, disposal, placing on market and import of animal by-products (ABPs). This EU Exit instrument ensures that there will be no operability deficiencies in the two relevant domestic enforcement statutory instruments.

2.2 Explanations

What did any relevant EU law do before exit day?

The relevant directly applicable EU legislation, listed below, were first introduced by the EU as a result of the Bovine Spongiform Encephalopathy (BSE) epidemic in the late 1980s and early 1990s and have been updated frequently over subsequent years to reflect the development and decline of that particular epidemic. Animal by-products legislation is relevant to TSE controls because scientific evidence has demonstrated that infectivity is concentrated in certain organs which are classified as Specified Risk Material (SRM) and are destroyed to prevent their entry into the food chain. However, in addition, the legislation controls use and disposal of ABPs to protect public and animal health against other diseases as well. These are:

- (i) Regulation (EC) No. 999/2001 of the European Parliament and the Council (amended 61 times), lays down rules for the prevention, control and eradication of certain TSEs, including BSE in cattle and scrapie in sheep and goats.
- (ii) Regulation (EC) No. 1069/2009 of the European Parliament and the Council lays down health rules as regards animal by-products and derived products not intended for human consumption.
- (iii) Commission Regulation (EU) No. 142/2011 (amended 14 times) implements the detailed technical requirements for Regulation (EC) No. 1069/2009.

Why is it being changed?

This instrument uses powers conferred by the Withdrawal Act to make the necessary changes to the domestic legislation to ensure that the following English legislation enforcing the retained direct EU legislation mentioned above will continue to operate effectively after the UK has left the EU. The instruments being amended are the Animal By-Products (Enforcement) (England) Regulations, 2018 S.I. 2013/2952 and the Transmissible Spongiform Encephalopathies (England) Regulations, 2018 S.I. 2018/731.

What will it now do?

This instrument will address deficiencies in domestic legislation arising from the withdrawal of the UK from the EU, and ensures that controls on ABPs and TSEs continue to operate on EU exit to protect animal and public health.

3. Matters of special interest to Parliament

Matters of special interest to the Sifting Committees

3.1 This instrument is being laid for sifting by the Sifting Committees.

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)

3.2 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 England and Wales.
- 4.2 The territorial application of this instrument is England only.

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

TSE and ABP controls listed in 2.2 will be retained in UK law by the Withdrawal Act. They are enforced in England by the Animal By-Products (Enforcement) (England) Regulations, 2013 S.I. 2013/2952 and the Transmissible Spongiform Encephalopathies (England) Regulations, 2018 S.I. 2018/731. This instrument makes necessary changes to these two instruments to ensure that the law functions correctly in England after the UK has left the EU.

7. Policy background

What is being done and why?

7.1 This instrument ensures that the law functions correctly after the UK has left the EU by addressing deficiencies arising from EU exit.

7.2 EU rules for the control of TSEs and ABPs are at least equivalent to, and in some cases higher than, the international standards set by the World Organisation for Animal Health (Office International des Epizooties - OIE). Whilst the UK will be under no legal obligation to adhere to EU rules for TSE and ABP controls following EU Exit, due to the history of the BSE epidemic in Europe (particularly within the UK in the 1980/90s), third countries will expect the UK to at least mirror the key EU controls, even though these exceed OIE safeguard standards. This makes negotiation of our future position on TSEs/ABPs important, and any future move to diverge significantly from existing EU ABP and TSE rules would therefore need to be considered very carefully in the light of a review of the latest scientific evidence on risks and impact on the UK's reputation and trading position.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

8.1 The instrument is being made under section 8(1) of the (Withdrawal) Act in order to address deficiencies in domestic legislation that enforces direct EU legislation arising out of the withdrawal of the UK from the EU. In accordance with the requirements of the Withdrawal Act the Minister has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

9. Consolidation

9.1 No consolidation is required.

10. Consultation outcome

10.1 The Scottish, Welsh and Northern Irish devolved administrations have been consulted about the proposed amendments and their views have been taken into account in the drafting of the Instrument. No consultation with industry or other stakeholders is required.

11. Guidance

11.1 There is no associated guidance in respect of this Statutory Instrument.

12. Impact

- 12.1 There is no, or no significant, impact on business, charities or voluntary bodies.
- 12.2 There is no, or no significant, impact on the public sector.
- 12.3 An Impact Assessment has not been prepared for this instrument because there are no, or no significant, impacts on business, charities, voluntary bodies or the public sector.

13. Regulating small business

- 13.1 The legislation applies to activities that are undertaken by small businesses.
- 13.2 This instrument does not introduce duties or burdens on small businesses.

14. Monitoring & review

14.1 As this instrument is made under the Withdrawal Act no extra review arrangement is required.

15. Contact

- 15.1 Ravi Nagrath at the Department for Environment, Food and Rural Affairs Telephone: 0208026 3918 or email: Ravi.Nagrath@defra.gsi.gov.uk can be contacted with any queries regarding the instrument.
- 15.2 Catherine Harrold at the Department for Environment, Food and Rural Affairs can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 Lord Gardiner of Kimble at the Department for Environment, Food and Rural Affairs can confirm that this Explanatory Memorandum meets the required standard.

Annex 1

Statements under the European Union (Withdrawal) Act 2018

Part 1 Table of Statements under the 2018 Act

This table sets out the statements that <u>may</u> 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/ESIC
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	Sub-paragraphs (3) and (7)	Ministers of the Crown	Set out the 'good reasons' for creating a

offences	of paragraph 28, Schedule 7	exercising sections 8(1), 9, and 23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	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.

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Part 2

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

1. Sifting statement(s)

- 1.1 The Parliamentary Under Secretary of State for the Department for Environment, Food and Rural Affairs, Lord Gardiner of Kimble, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:
- 1.2 "In my view the Animal By-Products and Transmissible Spongiform Encephalopathies (Amendment) (England) (EU Exit) Regulations 2018 should be subject to annulment in pursuance of a resolution of either House of Parliament (i.e. the negative procedure)".
- 1.3 This is the case because it relates to maintenance of existing regulatory standards and will not introduce any new policy.

2. Appropriateness statement

- 2.1 The Parliamentary Under Secretary of State for the Department for Environment, Food and Rural Affairs, Lord Gardiner of Kimble, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:
- 2.2 "In my view the Animal By-Products and Transmissible Spongiform Encephalopathies (Amendment) (England) (EU Exit) Regulations 2018 does no more than is appropriate as it relates to maintenance of existing regulatory standards and will not introduce any new policy".

3. Good reasons

- 3.1 The Parliamentary Under Secretary of State for the Department for Environment, Food and Rural Affairs, Lord Gardiner of Kimble, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:
- 3.2 "In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action and relate to maintenance of existing regulatory standards".

4. Equalities

- 4.1 The Parliamentary Under Secretary of State for the Department for Environment, Food and Rural Affairs, Lord Gardiner of Kimble, has made the following statement "The 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 relevant Minister within the United Kingdom has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:
- 4.3 "In relation to the instrument, I, Lord Gardiner of Kimble, being the relevant Minister, 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."

4.4 Little or no impact on equalities is expected.

5. Explanations

5.1 The explanations statement has been made in section 2 of the main body of this explanatory memorandum.