EXPLANATORY MEMORANDUM TO

THE TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES AND ANIMAL BY-PRODUCTS (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019

2019 No. 170

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 Command of Her Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 The purpose of this EU exit instrument is to ensure that five pieces of direct EU legislation will be fully operable when the UK leaves the EU. It relates to animal disease prevention which is a devolved matter and is implemented and enforced by similar EU-derived domestic legislation in each constituent nation of the UK. The retained direct EU legislation is being amended using powers contained in the EU (Withdrawal) Act 2018 (the "Withdrawal Act") and relates to the control and eradication of transmissible spongiform encephalopathies ("TSEs") and to the use, disposal, placing on the market and import of animal by-products ("ABPs"). This instrument will enable the retained direct EU legislation to operate effectively immediately after the UK's exit from the European Union.

Explanations

What did any relevant EU law do before exit day?

2.2 The relevant five pieces of direct EU legislation were first put in place as a result of the Bovine Spongiform Encephalopathy ("BSE") epidemic in the late 1980s and early 1990s and have been updated frequently over the years to reflect the development and decline of the 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 the use and disposal of ABPs to protect public and animal health against the spread of other diseases.

(i) Regulation (EC) No. 999/2001 of the European Parliament and the Council lays down rules for the prevention, control and eradication of certain TSEs, including BSE in cattle and scrapie in sheep and goats. Related Decisions subject to minor technical operability amendments are:

a. Commission Decision 2007/453 establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk, and

b. Commission Decision 2009/719 authorising certain Member States to revise their annual BSE monitoring programmes.

(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 implements Regulation (EC) No. 1069/2009 of the European Parliament and the Council, which lays down health rules as regards animal by-products and derived products not intended for human consumption.

Why is it being changed?

2.3 When the UK leaves the EU, the above pieces of directly applicable EU legislation will become retained EU law. To ensure that they remain operable following EU Exit, this amending instrument will redress deficiencies as set out in section 8 of the Withdrawal Act.

What will it now do?

2.4 With the amendments made by this instrument, the UK will continue to be able to effectively enforce TSE and ABP controls. To facilitate trade in animals and animal products, including permitted trade in animal by-products, it is anticipated that following EU exit, the TSE and ABP controls in the UK will (at least initially) remain harmonised with those in the EU. The impact upon UK industry of these changes is expected to be low given that no changes to existing systems or processes is envisaged. The instrument makes no policy changes.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 The Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 were presented to the Sifting Committees for consideration on 22nd December 2018. It was considered by the Secondary Legislation Sifting Committee on 17th January 2019 and by the European Statutory Instruments Committee on 22nd January 2019. Both the Sifting Committees agreed with the Government that this instrument does not have to have a debate in parliament, though one may still occur. The instrument will therefore remain subject to the negative resolution procedure.

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 the United Kingdom.

4.2 The territorial application of this instrument is England, Wales, Scotland and Northern Ireland.

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 TSE and ABP controls in the UK are contained in the directly applicable EU Regulations and Decisions described at paragraph 2.2 (i) to (iii), which are implemented in the UK via enforcement secondary legislation in each constituent nation of the UK. To ensure that TSE and ABP controls remain fully operable in the UK immediately following EU exit, this instrument amends numerous deficiencies in accordance with the Withdrawal Act.

7. Policy background

What is being done and why?

7.1 This instrument will ensure that EU TSE and ABP controls remain fully operable following 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). Subject to any deal agreed, the UK may be under no legal obligation to adhere to EU rules for TSE and ABP controls following EU exit. However, the government is committed to maintaining the highest standards to protect public and animal health and this along with the history of the BSE epidemic in Europe (particularly within the UK in the 1980/90s), means that we can anticipate that third countries will expect the UK to at least mirror the key EU controls, even though these exceed OIE safeguard standards.

7.3 In Article 6 (4) of Regulation (EC) 999/2001 there is a requirement for Member States to report to the European Commission on monitoring programmes. This is being replaced by a requirement to report to national bodies. However because at present Northern Ireland has no Assembly the words “where possible” (to submit an annual report) has been inserted.

7.4 In Article 14 of Regulation (EC) 999/2001there is a requirement for Member States to draw up contingency plans for implementation where cases of TSE are confirmed. This requirement is not necessary because it is already covered in domestic legislation by Section 14A of the Animal Health Act 1981. Substantial information is available to the public at https://www.gov.uk/guidance/bse which sets out the steps taken following initial suspicion and subsequent confirmation of a case of BSE.

7.5 In Annex III, Chapter A, Part II, point (ii) (b) of Regulation (EC) 999/2001 there is a requirement for Member States in which the population of goats which have already kidded and goats mated exceeds 750 000 animals to test a minimum annual sample of 10 000 caprine animals slaughtered for human consumption. This requirement has never been necessary in the UK because the UK’s caprine population is at present approximately 85,000 and is not expected to increase to a level where the testing of healthy slaughtered goats would be required.

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

8.1 This instrument is being made in using the power in section 8 of the Withdrawal Act in order to address failures of retained EU law to operate effectively or other deficiencies arising from the withdrawal of the United Kingdom from the European Union. The instrument is also made under paragraph 21 of schedule 7 of the Withdrawal Act. In accordance with the requirements of that Act, the Minister has made the relevant statements as detailed in Part 2 of the Annex to this explanatory memorandum.

9. Consolidation

9.1 It is not intended to consolidate the relevant EU legislation because this is not necessary to ensure operability following EU Exit.

10. Consultation outcome

10.1 As animal health is a fully devolved matter, there has been ongoing dialogue with officials from Scottish, Welsh and Northern Irish devolved administrations about these proposed amendments.

10.2 Devolved Administrations ("DAs") were involved in discussions from the earliest stages of drafting, that Defra shared all drafts with their policy officials and lawyers, and that comments provided by DAs were taken into account at all stages. Aside from the resolution of minor technical issues and corrections of inconsistencies and typographical errors, the most discussion revolved around the use of the term "the appropriate authority" and where distinctions needed to be made involving trade with countries inside and out of the European Union.

10.3 There has been no other consultation.

11. Guidance

11.1 The Department for Environment, Food and Rural Affairs does not propose to issue guidance specifically with regard to this 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 it relates to maintenance of existing regulatory standards and will not introduce any new policy, and there are no significant impacts on business or the public sector.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 There is no additional impact on small businesses because this instrument does not introduce any policy change.

14. Monitoring & review

14.1 The approach to monitoring of this legislation is: this legislation relates to maintenance of existing regulatory standards and will not introduce any new policy. Monitoring of the policy content of the instrument will take place in the course of normal departmental business.

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

15. Contact

15.1 Katie Barnes at the Department for Environment, Food and Rural Affairs Telephone: 0208026 3469 or email: katie.barnes@defra.gov.uk can be contacted with any queries regarding the instrument.

15.2 Catherine Harrold, Deputy Director at the Department for Environment, Food and Rural Affairs can confirm that this explanatory memorandum meets the required standard.

15.3 Lord Gardiner, the Parliamentary Under Secretary of State for Rural Affairs and Biosecurity 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 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/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 77	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	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.

		powers in Schedule 2 to create a criminal offence	
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(s)

1.1 The Parliamentary Under Secretary of State for Rural Affairs and Biosecurity, Lord Gardiner of Kimble, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view the Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 should be subject to annulment in pursuance of a resolution of either House of Parliament (i.e. the negative procedure)".

1.2 This is because it relates to maintenance of existing regulatory standards and does not contain provision falling within paragraph 1(2) of Schedule 7. Functions of a legislative character are being transferred to appropriate UK authorities in a separate affirmative instrument.

2. Appropriateness statement

2.1 The Parliamentary Under Secretary of State for Rural Affairs and Biosecurity, Lord Gardiner of Kimble, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view the Transmissible Spongiform Encephalopathies and Animal By-Products (Amendment etc.) (EU Exit) Regulations 2019 does no more than is appropriate".

2.2 This is the case because 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 Rural Affairs and Biosecurity, Lord Gardiner of Kimble, 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".

3.2 These are: that there is real public concern about the risk to human and animal health from transmissible spongiform encephalopathies (TSEs) and safe use and disposal of animal by products and that the government should at least maintain the protections that currently exist. The public will also expect us to be able to take enforcement action to ensure that our key TSE controls on feed production and the removal of specified risk materials are maintained and that use and disposal of animal by-products is properly controlled to protect the food chain.

4. Equalities

4.1 The Parliamentary Under Secretary of State for Rural Affairs and Biosecurity, 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 Parliamentary Under Secretary of State for Rural Affairs and Biosecurity, Lord Gardiner of Kimble, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the instrument, I, Lord Gardiner of Kimble, 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."

4.3 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.