EXPLANATORY MEMORANDUM TO

THE EXOTIC DISEASE (AMENDMENT ETC.) (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 (Defra) and is laid by Act of Parliament.
- 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 This instrument is being made using powers in the European Union (Withdrawal) Act 2018 in order to address deficiencies and failures of retained direct EU legislation relating to exotic notifiable disease in livestock to ensure such legislation is fully operable and operates effectively after the United Kingdom leaves the European Union. A notifiable disease is one where owners and their veterinarians are obliged to notify the Department of suspicion of the relevant disease.

2.2 Explanations

What did any relevant EU law do before exit day?

Direct EU legislation for exotic notifiable diseases ensures that if there is an outbreak of an exotic notifiable disease of animals such as Foot and Mouth Disease, Bluetongue or Avian Influenza, the Department are able to respond in a timely, effective and coordinated manner to control and eradicate disease, demonstrate disease freedom, restore normal trade and work to assist the recovery of local communities.

Why is it being changed?

The amendments in this instrument are necessary to correct deficiencies in and ensure the operability of retained EU law and EU derived legislation at the point of the UK's exit from the European Union in a way that continues to allow the UK to respond effectively to a suspect case, or an outbreak of exotic notifiable disease following withdrawal from the European Union.

What will it now do?

After the amendments made by this instrument, the UK will continue to be able to respond to outbreaks of exotic notifiable animal disease as before. There are no substantive policy changes introduced in this instrument.

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 The instrument is being laid for sifting and scrutiny by the European Statutory Instruments Committee and the Secondary Legislation Scrutiny Committee, as

required by the Withdrawal Act. A statement regarding the use of legislative powers in the Withdrawal Act is contained in Part 2 of the Annex to this memorandum.

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 Part 2 of this instrument is the whole of the United Kingdom and for the domestic EU-derived statutory instrument in Part 3, Scotland, England and Wales.
- 4.2 The territorial application of Part 2 of this instrument is the whole of the United Kingdom and for the domestic EU-derived statutory instrument in Part 3, Scotland, England and Wales.

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 This instrument makes amendments using correcting powers in the European Union (Withdrawal) Act 2018 to address deficiencies and inoperable aspects of the following retained direct EU legislation listed in Part 2 of the instrument:
 - Commission Decision 88/397/EEC coordinating rules laid down by Member States in application of Article 6 of Council Directive 85/511/EEC
 - Commission Decision 93/52/EC recording the compliance by certain Member States or regions with the requirements relating to brucellosis (B. melitensis) and according them the status of a Member State or region officially free of the disease
 - Commission Decision 1993/152/EC laying down the criteria for vaccines to be used against Newcastle disease in the context of routine vaccination programmes
 - Commission Decision 2000/258/EC designating a specific institute responsible for establishing the criteria necessary for standardising the serological tests to monitor the effectiveness of rabies vaccines
 - Commission Decision 2000/428/EC establishing diagnostic procedures, sampling methods and criteria for the evaluation of the results of laboratory tests for the confirmation and differential diagnosis of swine vesicular disease
 - Commission Decision 2002/106/EC approving a Diagnostic Manual establishing diagnostic procedures, sampling methods and criteria for evaluation of the laboratory tests for the confirmation of classical swine fever
 - Commission Decision 2003/422/EC approving an African swine fever diagnostic manual

- Commission Decision 2006/415/EC concerning certain protection measures in relation to highly pathogenic avian influenza of the subtype H5N1 in poultry in the Community and repealing Decision 2006/135/EC
- Commission Decision 2006/437/EC approving a Diagnostic Manual for avian influenza
- Commission Decision 2006/563/EC concerning certain protection measures in relation to highly pathogenic avian influenza of subtype H5N1 in wild bird
- Commission Decision 2007/118/EC laying down detailed rules in relation to an alternative identification mark pursuant to Council Directive 2002/99/EC
- Commission Decision 2007/598/EC concerning measures to prevent the spread of highly pathogenic avian influenza to other captive birds kept in zoos and approved bodies, institutes or centres
- Commission Regulation (EC) No 1266/2007 on implementing rules for Council Directive 2000/75/EC as regards the control, monitoring, surveillance and restrictions on movements of certain animals of susceptible species in relation to bluetongue
- Commission Regulation (EC) No 616/2009 implementing Council Directive 2005/94/EC as regards the approval of poultry compartments and other captive birds compartments with respect to avian influenza and additional preventive biosecurity measures in such compartments
- Commission Decision 2010/367/EC on the implementation by Member States of surveillance programmes for avian influenza in poultry and wild birds
- Regulation (EU) No 652/2014 of the European Parliament and of the Council laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material
- Commission Implementing Decision 2018/1136 on risk mitigating and reinforced biosecurity measures and early detection systems in relation to the risks posed by wild birds for the transmission of highly pathogenic avian influenza viruses to poultry
- 6.2 Part 3 of the instrument addresses operability issues in the Great Britain-wide Diseases of Swine Regulations 2014.
- 6.3 The instrument makes minor and technical amendments to address these deficiencies. There are no substantive policy changes introduced in this instrument.

7. Policy background

What is being done and why?

- 7.1 Outbreaks of exotic notifiable disease can cause significant impacts and costs to both industry and the taxpayer. If an outbreak occurs, government intervention is important in order to eradicate disease and regain disease freedom.
- 7.2 The amendments made by this instrument do not amount to a change in policy, but are necessary to ensure that Government can respond to outbreaks of exotic notifiable disease in the same way after the UK's withdrawal from the European Union.
- 7.3 As the UK will no longer be a Member State of the EU, there are various amendments made by this instrument to remove redundant EU references in the Decisions and Regulations. These include references to Member States', 'Member State competent authority', the 'Commission', 'Community' and to 'intra-community trade', and

- where necessary these are replaced with references to the UK or the territories of England, Northern Ireland, Scotland and Wales, to appropriate Ministers and to trade with the EU.
- 7.4 Redundant cross references to EU legislation are removed or replaced with the correct references to EU or domestic legislation by these Regulations. Other references are amended to include the date of exit so these will apply as they stand at the time the UK leaves the EU.
- 7.5 Certain obligations that will no longer have effect after the withdrawal of the UK from the EU have also been amended or removed such as the requirement to notify, inform or report to the Commission. Where applicable these have been replaced with obligations to make information available to the public such as in cases where the presence of highly pathogenic avian influenza of the subtype H5N1 is confirmed in poultry or when bluetongue restricted zones are in force.
 - 7.6 In the diagnostic manual Decisions covering swine vesicular disease, classical swine fever, African swine fever and avian influenza, all references to the Community reference laboratories, their duties and responsibilities are replaced with references to the appropriate UK national reference laboratory for each disease.

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

8.1 This instrument is being made using the power in section 8(1) of, and paragraph 21 of Schedule 7 to the European Union (Withdrawal) Act 2018 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. 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 None.

10. Consultation outcome

10.1 The Scottish, Welsh and Northern Irish devolved administrations have been consulted about the proposed amendments. There has been no other consultation.

11. Guidance

11.1 There is no associated guidance.

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 the instrument will maintain the status quo 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 maintains the status quo and does not introduce any policy change.

14. Monitoring & review

- 14.1 No specific monitoring arrangements are needed
- 14.2 As this instrument is made under the EU Withdrawal Act 2018, no review clause is required.

15. Contact

- 15.1 Janet Dixon at the Department for Environment, Food and Rural Affairs Telephone: 02080263325 or email: janet.dixon@defra.gsi.gov.uk can be contacted with any queries regarding the instrument.
- 15.2 Marc Casale at the Department for Environment, Food and Rural Affairs can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 Lord Gardiner at the Department for Environment, Food and Rural affairs can confirm that this Explanatory Memorandum meets the required standard.

Annex I

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 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	Sub-paragraphs (3) and (7)	Ministers of the Crown	Set out the 'good reasons' for creating a

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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 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:
- 1.2 "In my view The Exotic Disease (Amendment etc.) (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 this instrument addresses technical deficiencies in retained EU law and EU derived legislation that will arise from withdrawal.

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:
- 2.2 "In my view The Exotic Disease (Amendment etc.) (EU Exit) Regulations 2018 does no more than is appropriate". This is the case because this instrument addresses technical deficiencies in retained EU law and EU derived legislation that will arise from withdrawal.

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:
- 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". These are ensuring that legislation relating to exotic notifiable diseases of livestock continues to function correctly once the UK leaves the EU. This ensures the UK can continue to respond in a timely, effective and coordinated manner to control and eradicate disease, demonstrate disease freedom, restore normal trade and work to assist the recovery of local communities.

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 Secr1etary 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:

4.3 "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." 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.