EXPLANATORY MEMORANDUM TO

THE ANIMAL FEED (AMENDMENT) (EU EXIT) REGULATIONS 2019

2019 No. [XXXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Act.

2. Purpose of the instrument

2.1 *The Animal Feed (Amendment) (EU Exit) Regulations 2019* ("the instrument") are being made to fix inoperabilities in the retained EU legislation on animal feed; namely Regulation (EC) No 1831/2003, Regulation (EC) No 183/2005, Regulation (EC) No 378/2005, Regulation (EC) No 429/2008, Regulation (EC) No 152/2009, Regulation (EC) No 767/2009, Regulation, Regulation (EU) No. 892/2010, (EC) No 619/2011, Regulation (EC) No. 68/2013, and Regulation (EU) No 2015/786 that will arise as a consequence of the UK's exit from the European Union (EU).

2.2 This instrument is a legislative consequence of the UK's decision to leave the EU and will apply from day 1 of withdrawal from the EU in order to ensure the continued safety of animal feed.

2.3 As a responsible government, we will continue to proportionately prepare to ensure readiness on exit day in all scenarios. The purpose of this instrument therefore, is to ensure that there will continue to be a functioning statute book on exit day which maintains continuity in relation to food and feed (animal feed) policy and legislation.

Explanations

What did any relevant EU law do before exit day?

2.4 Regulation 1831/2003 (EC) established a Community procedure for authorising the placing on the market and use of feed additives and laid down rules for the supervision and labelling of feed additives and premixtures. It provided assurance of a high level of protection of human health, animal health and welfare, environment and users' and consumers' interests in relation to feed additives, whilst ensuring the effective functioning of the market.

2.5 Regulation 183/2005 (EC) provided a high level of consumer protection with regard to food and feed safety. Almost all feed businesses that produce, supply or use animal feed, were covered by the scope of the Regulation (including importers of feed as well as livestock and arable farms). The Regulation stated that primary responsibility for feed safety rests with the feed business operator; ensured the need to maintain feed safety throughout the food chain from primary production of feed, up to and including the feeding of food-producing animals. It required most feed businesses to be registered or approved by the appropriate enforcement authority and set down basic hygiene requirements - including the use of HACCP (Hazard Analysis and Critical Control Points) where appropriate. The Regulation laid down:

- general rules on feed hygiene;
- conditions and arrangements ensuring traceability of feed;

- conditions and arrangements for registration and approval of establishments.

2.6 Regulation 378/2005 (EC) laid down detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards the duties and tasks of the Community Reference Laboratory (the CRL).

2.7 Regulation 152/2009 set out provisions on the methods of sampling and analysis for the official control of feed.

2.8 Regulation 767/2009 harmonised the conditions for the placing on the market and the use of feed, in order to ensure a high level of feed safety and thus a high level of protection of public health. These provisions applied to the marketing and use of feed for both food-producing and non-food producing animals within the European Community, including requirements for labelling, packaging and presentation.

2.9 Regulation (EU) No 892/2010 on the status of certain products with regard to feed additives within the scope of Regulation (EC) No1831/2003. Part 1 of the Annex to the Regulation lists products which were authorised as feed additives and Part 2 lists products which were not authorised as feed additives.

2.10 Regulation 619/2011 laid down provisions governing the official control of feed with respect to the presence of genetically modified material which had been authorised for marketing in a third country but for which an authorisation procedure within the European Union was pending or had expired. The control provisions concerned sample preparation, methods of analysis of samples and interpretation of results.

2.11 Regulation (EC) No. 68/2013, establishes a Catalogue of feed materials, laid down in the Annex, the use of which is voluntary by the FBO.

2.12 Directive 2002/32/EC prohibited the use of products intended for animal feed which contain levels of undesirable substances exceeding the maximum levels laid down in Annex I of that Directive.

2.13 Regulation 2015/786 provided for a process through which any undesirable substances could be removed from non-compliant contaminated feed using certain detoxification methods.

Why is it being changed?

2.14 The retained EU law will need to be adapted in order for it to be operable in the UK after EU exit. All rules will remain the same. The changes introduced by the instrument will enable the retained EU law to work within the UK after exit day allowing for a smooth transition for businesses, the feed sector and consumers. There will be no change to the day-to-day legal requirements and obligations for businesses.

2.15 The minor technical amendments being made through this instrument will rectify deficiencies in the retained EU law that arise as consequence of the UK's exit from the EU. These deficiencies relate to the assignment of functions to EU institutions and processes to which the UK will no longer have access or replace reliance on after exit. For example, all tasks and roles assigned to the European Commission and European Food Safety Authority (EFSA) in retained EU legislation must be assigned to an appropriate UK entity. This instrument also removes references to the "EU", "Union" and "Single Market", and replaces them with "United Kingdom", "appropriate authority" etc.

What will it now do?

2.16 The new instrument will ensure that appropriate legislation remains in place after exit. The changes introduced do not affect the essence of the current legislation but ensures that the retained EU legislation (Regulations (EC) 1831/2003, 183/2005, 378/2005, 152/2009, 767/2009, 892/2010, 619/2011, 68/2013 and 2015/786) remains operable in the UK after exit.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

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 The territorial application of this includes Scotland and Northern Ireland.

3.3 The powers under which this instrument is made cover the entire United Kingdom under powers afforded by section 8 of the Act to correct deficiencies in retained legislation and the territorial application of this instrument is not limited either by the Act or by the instrument.

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 entirety of the United Kingdom for those aspects amending deficiencies in retained EU law. The elements of the instrument addressing deficiencies in the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015 apply only in England and equivalent measures to amend the respective legislation in the devolved administrations will be made there.

5. European Convention on Human Rights

5.1 The Parliamentary Under Secretary of State for Public Health and Primary Care, Steve Brine has made the following statement regarding Human Rights:

"In my view the provisions of the Animal Feed (Amendment) (EU Exit) Regulations 2019 are compatible with the Convention rights."

6. Legislative Context

6.1 The Act repeals the European Communities Act 1972 on exit day. It maintains all domestic law and retains previously directly applicable EU legislation provided it is in the English language. Section 8(1) and 8(2) of the Act enable Ministers to fix deficiencies in retained EU law enabling retained legislation and the safeguards it provides to operate effectively following the UK's exit from the EU.

6.2 The individual European Regulations ((EC) 1831/2003, 183/2005, 378/2005, 152/2009, 767/2009, 619/2011 and 2015/786) are being retained in UK law. The Regulations principally aim to ensure that feed that is placed in the market or is used is safe. They also set out conditions for labelling, packaging, sampling and analysis and hygiene as well as the process of authorisation of feed additives.

6.3 Article 9 of Regulation (EC) No. 178/2002 states that there will be open and transparent public consultation during the preparation, evaluation and revision of food law, except in urgent circumstances. Following EU Exit, this will continue to be the case with all future revisions of food law. Public consultation has been completed, as shown below, in accordance with this.

7. Policy background

What is being done and why?

7.1 In order to maintain feed safety after the UK leaves the EU, this instrument provides the necessary legislative changes to ensure that retained EU law continues to be operable in the UK. It will thus ensure and maintain protection for consumers and continuity for businesses.

7.2 This instrument will fix the inoperabilities in retained EU law relating to the controls on food and feed and ensures a high level of food and feed safety to protect members of the public; failure to maintain effective controls may increase the risk to UK consumers.

7.3 The changes introduced in this instrument and listed below will ensure that the legislation remains operable.

- Functions currently undertaken by the European Commission in reviewing and making changes to legislation will in future be the responsibility of the 'appropriate authority';

"appropriate authority" means–

(a) in relation to England, the Secretary of State;

(b) in relation to Wales, the Welsh Ministers;

(c) in relation to Scotland, the Scottish Ministers;

(d) in relation to Northern Ireland, the Northern Ireland devolved authority.

- Under retained EU Law, the "Food Safety Authority" will have a role in providing food safety advice for the appropriate authority. The "Food Safety Authority" means

(a) as regards England, Wales and Northern Ireland, the Food Standards Agency (FSA);

(b) as regards Scotland, Food Standards Scotland.

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 of the European Union (Withdrawal) Act 2018, which allows Ministers to regulate to prevent, remedy or mitigate deficiencies in retained EU law that arise as a consequence of the UK's withdrawal from the European Union. This instrument is being enacted on a UK wide basis. Amendments made through this instrument will enable the retained EU law to operate effectively across the UK. 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 The instrument does not consolidate either existing EU or UK law.

10. Consultation outcome

10.1 A full public consultation was carried out from 4 September until 14 October 2018 on the FSA's proposed approach to retained EU law for food and feed safety and hygiene. This approach proposed making a number of corrections to the retained EU law which includes the Animal Feed (Amendment) (EU Exit) Regulations 2019, using powers under the European Union Withdrawal Act. It was proposed in our approach that the corrections would be made by way of statutory instruments of which 15 had been prepared. Key corrections would provide a suitable replacement for the risk management function currently undertaken by the European Commission and for the risk assessment function currently undertaken by the European Food Safety Authority (EFSA), amongst other minor, non-controversial amendments. The corrections would not result in any material change in the level of protection to human or animal health, or to the high standard of domestic or imported food and feed which consumers expect. The statutory instruments which would make the corrections will be subject to review and approval by Parliament.

10.2 The consultation covered the proposed approach used for all of the FSA's Statutory Instruments in relation to EU Exit. It received 50 responses of which 82% supported or did not disagree with the proposed approach being outlined by the Food Standards Agency. 16% of replies contain mixed comments. The main concerns regarding the FSA approach in general were related to the communication of change and ensuring sufficient lead time is given. A more detailed analysis of the responses can be seen at the published link below.

10.3 One respondent raised concerns around the timeframe for delivering the legislation needed for day one readiness.

10.4 The consultation and its responses can be viewed at:

https://www.food.gov.uk/news-alerts/consultations/proposed-approach-to-retained-eu-law-for-food-and-feed-safety-and-hygiene

11. Guidance

11.1 It is considered that guidance is not required for this instrument, as it generally maintains existing regulations and does not introduce new requirements.

12. Impact

12.1 The impact on business, charities or voluntary bodies is minimal. According to the ONS Inter Departmental Business Register (IDBR) there were 214,175 businesses active in the agri-food sector in 2017. The FSA envisages minimal one-off familiarisation costs to businesses, charities and voluntary bodies; where we estimate that it will take each organisation less than 60 minutes[1] to read and understand the proposed regulations and then disseminate the information to key staff within their organisation. However, it is unlikely that the envisaged changes will present any other impact on businesses', charities or voluntary bodies' day to day operations as the rules

[1] Please note the familiarisation time has been amended from less than 30 to less than 60 minutes following consultation feedback.

are not changing as a result of this instrument. The associated direct cost for businesses has been calculated by applying the 2017 median annual wage for "production managers and directors" of £22.05 and uprating it by 20% to account for overheads[2]. Multiplying this wage rate with the expected familiarisation time gives an estimated total one-off cost to businesses of £5.7m. After adjusting for inflation and applying a discount rate of 3.5% as per HMT Green Book guidance, this translates to an Equivalent Annual Net Direct Cost to Business (EANDCB) of approximately £600,000.

12.2 In terms of the impact on the public sector, there are approximately 419 Local Authorities (LAs) and 35 Port Health Authorities (PHAs) in the UK, which enforce existing food and feed law and will continue to enforce the retained EU law after the UK's EU Exit. The FSA envisages minimal one-off familiarisation time costs to LAs and PHAs; where we estimated that it will take authorities less than 60 minutes to read and familiarise themselves with the EU Regulations and then disseminate to staff and key stakeholders. It is estimated that one officer in each of these authorities (one Food/Feed Officer from each local authority; and one 'Port Health Officer' from each PHA) will need to undertake this task. The instrument is not considered to add additional or new burdens on enforcement bodies, other than those identified here.

12.3 An impact assessment has not been produced for these Regulations, which the FSA has certified as being below the *de minimis* threshold of +/- £5m equivalent annual net direct cost to business. The Regulations are designed only to fix the inoperability of retained EU law (detailed in Section 6) and ensure the continued safety of food and feed after the UK leaves the EU. The Regulations provide continuity for stakeholders and the FSA has not identified any significant impact on stakeholders other than in relation to a negligible one-off familiarisation cost from the legislative change.

13. Regulating small business

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

13.2 Over 90% of the UK food industry sector comprises small and micro businesses and EU legislation generally applies to food and feed businesses regardless of size, as requirements are intended to be risk based to reflect the activities undertaken by business. Due to the high ratio of small and micro food businesses in the UK, it is often not feasible to exempt smaller businesses from new food measures, as this would fail to achieve the intended effect of reducing risks to public health. The FSA makes every effort to identify the impacts and minimise burdens on small and micro businesses where possible.

13.3 The changes made to the legislation will provide continuity for business and should not impact on the day-to-day workload of small and micro businesses as all food and feed safety standards and legal definitions are maintained.

14. Monitoring & review

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

[2] Wage rate taken from the ONS' 2017 Annual Survey of Hours and Earnings (ASHE), table 14.6a.

15. Contact

15.1 Mandy Jumnoodoo at the Food Standards Agency Telephone: 020 7276 8468 or email: mandy.jumnoodoo@food.gov.uk can be contacted with any queries regarding the instrument. Alternatively, Karen Pratt at the Food Standards Agency can be contacted with any queries regarding the instrument. Telephone: 020 7276 8790 or email: karen.pratt@food.gov.uk .

15.2 Michael Wight, Deputy Director for Food Policy, at the Food Standards Agency can confirm that this Explanatory Memorandum meets the required standard.

15.3 Steve Brine Parliamentary Under Secretary of State for Public Health and Primary Care at the Department for Health and Social Care 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	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.

		23(1) or jointly exercising 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. Appropriateness statement

1.1 The Parliamentary Under Secretary of State for Public Health and Primary Care, Steve Brine has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view the Animal Feed (Amendment) (EU Exit) Regulations 2019 does no more than is appropriate."

1.2 This is the case because: the instrument only fixes the inoperabilities detailed in section 2 of this Explanatory Memorandum and adds no additional legislative measures.

2. Good reasons

2.1 The Parliamentary Under Secretary of State for Public Health and Primary Care, Steve Brine 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".

2.2 These are: because the legislation will create a level playing field in the area of animal feeds preventing UK businesses from being placed in a disadvantageous position when trading overseas.

3. Equalities

3.1 The Parliamentary Under Secretary of State for Public Health and Primary Care, Steve Brine 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.

3.2 The Parliamentary Under Secretary of State for Public Health and Primary Care, Steve Brine has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the draft instrument, I, Steve Brine 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. Explanations

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