EXPLANATORY MEMORANDUM TO

THE GENERAL FOOD LAW (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019

2019 No. [XXXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by the Food Standards Agency (FSA) and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 *The General Food Law (Amendment etc.) (EU Exit) Regulations 2019* ("the instrument") amends *Regulation (EC) No. 178/2002* which provides the basic principles underpinning food safety. The instrument also amends Regulation No. 931/2011, that implements *Regulation (EC) No. 178/2002*, in order that it can be retained in an operable form after EU Exit.

2.2 This instrument also revokes *Regulation (EU) No. 16/2011* which concerns EU Member State responsibilities under the Rapid Alert System for Food and Feed ("RASFF"); unless negotiated otherwise the UK will not retain access to that system post Exit.

2.3 Finally, the instrument makes minor amendments to ensure continued operability of domestic enforcing regulations in England, the *Food Safety and Hygiene (England) Regulations 2013* ("2013 Regulations").

2.4 The instrument designates responsibilities currently incumbent on the European Food Safety Authority ("EFSA", the body that provides scientific advice on food to the European Commission, the European Parliament and EU Member States) to the 'Food Safety Authority' (i.e. the Food Standards Agency ("FSA") in England, Wales, Northern Ireland, and Food Standards Scotland ("FSS") or other devolved administration organisations able to take up this role subject to further agreement) and designates responsibilities incumbent on the European Commission to Ministers in the four UK countries.

2.5 This instrument amends the 2013 Regulations to ensure they are operable after EU exit, so that Schedule 1 of those regulations gives effect to amendments to the Annexes of retained EU instruments listed in that schedule and also to ensure that the legislative references of specific provisions in its Schedule 2 are suitably updated.

2.6 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 General Food Law policy and legislation.

Explanations

What did any relevant EU law do before exit day?

Regulation (EC) No. 178/2002 sets out the high-level principles and definitions of food law and feed law which ensure protection of human health across the EU. It establishes the key principles of risk assessment and the precautionary principle. It requires all food and feed placed on the market to be safe and ensures the protection of consumers' interests in relation to food.

It also:

- established and provides for the operation of the EFSA and the RASFF;
- requires food and feed business operators to put in place systems and procedures to ensure the traceability of food/feed they receive and supply;
- requires food and feed business operators to notify competent authorities if they are aware that a product placed on the market does not comply with safety requirements and initiate procedures to withdraw non-compliant products from the market;
- requires a national system of official controls and other activities, including public communication of safety advice and risk arising in relation to food and feed, and food and feed safety surveillance; and,
- has an objective that where international standards exist or their completion imminent, they shall be taken into consideration in the development or adaptation of food law

Why is it being changed?

2.7 The existing EU Regulation is being retained in UK law. Unless this instrument comes into force, elements of *Regulation (EC) No. 178/2002* will be inoperable or redundant after the UK's exit from the European Union as many of the Regulation's provisions would no longer be relevant to, or appropriate for the UK post Exit.

2.8 This instrument removes from the retained EU legislation the tasks and roles assigned to the European Commission and its committees and the EFSA as these will no longer be relevant after EU exit. Where necessary, tasks and roles that need to be retained for the effective functioning of the UK legal framework have been assigned to appropriate UK entities (see section 7 for further detail).

2.9 Other amendments to *Regulation (EC) No. 178/2002* introduced by this instrument will mean there will be no change in the high-level principles underpinning the day-to-day functioning of the food safety and feed safety legal framework. This will provide continuity for business, enforcers, and the voluntary sector and maintain public health protection for consumers.

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 (see The EU Withdrawal Act 2018 ('the Act').) This instrument is being enacted under powers afforded by section 8 of the Act to correct deficiencies in the retained legislation and, except in relation to amendments being made to the 2013 Regulations (which apply only in England), the territorial application of this instrument is not limited either by the Act or by this instrument.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument covers the entire United Kingdom.

4.2 The territorial application of this instrument, except in relation to amendments being made to the 2013 Regulations (which apply only in England), covers the entire United Kingdom.

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 General Food Law (Amendment etc.) (EU Exit) Regulations 2019* are compatible with the Convention rights."

6. Legislative Context

6.1 The Act extinguishes all powers under the European Communities Act 1972. It maintains all domestic law and retains previously directly applicable European Union legislation provided it is in the English language. Section 8.1 and 8.2 of the Act enable UK Ministers to fix deficiencies in retained EU law enabling the retained legislation and the safeguards it provides to operate effectively following the UK's exit from the EU.

6.2 *Regulation (EC) No. 178/2002* lays down high-level principles governing food and feed safety and definitions that are referenced across food and feed sectoral legislation. These definitions and principles underpin the body of EU food law which is being retained in the UK.

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 to this.

7. Policy background

What is being done and why?

7.1 *Regulation (EC) No. 178/2002* provides requirements that impact every food business and feed business in the UK and is therefore a key part of the legislative framework ensuring ultimately safe food for all UK consumers. It sets out requirements and principles that *include*:

- the general responsibilities for food businesses and feed businesses to place safe food and feed on the market and to withdraw them if they are unsafe;
- definitions of 'food' and 'feed';

- that food must be safe and what considerations define safe food;
- the principle that information about food should not mislead consumers;
- that traceability records of food must be maintained; and,
- that risk assessment should be based on science and evidence and that risk management should make use of risk assessment.

7.2 No substantive policy changes are being introduced by this instrument. The policy objective is to maintain existing laws. For food safety to be maintained seamlessly after EU Exit, it is necessary that existing EU Regulations are retained in an operable form in UK law. *The General Food Law (Amendment etc.) (EU Exit) Regulations 2019* help to deliver continued safety for consumers and continuity for businesses, enforcers and the voluntary sector.

7.3 Replacing this legislation with a legal framework for food and feed safety that is fundamentally different from the principles and obligations to which the food and/or feed industry and consumers are accustomed to would be very disruptive in the short-term and would put the UK out-of-step with wider international approaches to food safety which could damage existing trade flows.

7.4 This instrument provides a definition for 'third country' to mean 'a country or state other than the United Kingdom'. 'Third country' was not defined in *Regulation (EC) No. 178/2002* or elsewhere although it is frequently used to mean countries that are not Member States of the EU.

7.5 The importance of maintaining food and feed safety is paramount, and the wording of this instrument ensures a legislative framework is maintained in the event of the UK's Exit from the EU with no Withdrawal Agreement.

7.6 The key difference between *Regulation (EC) No. 178/2002* and its incarnation as retained EU law will be that the instrument revokes the parts that deal with the functions of the European Commission and its committees, the setting up of the EFSA and its functions and the operation of RASFF. This is because those parts of *Regulation (EC) No. 178/2002* only apply to EU Member States or describe functions in such a way that they can only apply to EU Member States. Where necessary to the effective functioning of the retained EU law, these functions are assigned to appropriate UK entities via the Secretary of State for Health and Social Care as the risk manager.

7.7 To make sure we are aware of any problems arising from food and avoid any gaps in information available, on a level and scale for example, of the German E. Coli 2011 sprouting seeds outbreak, the FSA is adopting the following approach:

7.8 We are maintaining the FSA's top priority which is to ensure that UK food remains safe and is what it says it is. We are negotiating to maintain full access to the Rapid Alert System for Food and Feed (RASFF) which allows the UK to respond quickly to serious risks to public health relating to food and animal feed; we believe that maintaining full access to the RASFF network is mutually beneficial for the UK and EU, in terms of continued sharing of this vital food safety data.

7.9 The FSA is retaining its existing processes for incident response with current provisions for risk assessment and risk management advice during incidents being maintained. Building upon this proven approach, we are further developing our incident handling and communication procedures to meet future needs. This will

provide us with the capability that is required for incident response post EU Exit and counter any loss of full access to RASFF that we might incur. These improvements fall into two principal areas namely enhanced stakeholder engagement and improved receipt and management capability.

7.10 In terms of stakeholder engagement, the FSA is working to foster strong relationships with the competent food safety authorities across Europe and worldwide to develop a mutually supportive approach to information sharing. We are implementing an enhanced programme of bilateral engagement and surveillance which focuses upon exchange of information on risks to the food chain. This targeted engagement is actively progressing and is focused upon strengthening relationships with the main trading partners of the UK. We have increased our level of engagement with INFOSAN (the International Food Safety Authorities Network), managed jointly by the FAO and the WHO of the United Nations. This provides the UK with extensive 'reach' and a framework for communicating food safety issues with countries across the world.

7.11 The FSA has also developed a receipt and management processes so that we can improve our detection capability for potential incidents. This enables us to monitor selected data sources to identify signals indicative of potential food safety risks to the UK which may require mitigation. The enhanced process includes the introduction of an IT based information handling system which enables us to validate, triage and prioritise potential incidents that might affect the UK. Going forward we anticipate that this will be further supported by the FSA's ongoing surveillance programme.

7.12 *Regulation (EU) 931/2011*, which sets out specific traceability requirements for food of animal products under *Regulation (EC) 178/2002*, has been absorbed into the instrument and amendments made to ensure its effective function as retained EU law.

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* in order to address failures in 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 The instrument does not consolidate existing law, EU or UK.

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 General Food Law (Amendment etc.) (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 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 exit from the EU. The FSA envisages minimal one-off familiarisation costs to

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

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

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.

12.3 The instrument is not considered to add additional or new burdens on enforcement bodies, other than those identified here. The FSA is engaging with LAs and PHAs through the Food Standards and Labelling Focus Group and the Food Hygiene Focus Group to explain the corrections and amendments being made through this instrument. Both groups are made up of trading standards and environmental health officers responsible for enforcing food legislation.

12.4 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 legislation (*Regulation (EC) No. 178/2002*) 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 The approach to monitoring of this legislation will depend on what deal is reached between the United Kingdom and the European Union.

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

15. Contact

15.1 Fiona MacConnacher at the Food Standards Agency can be contacted with any queries regarding the instrument. Telephone: 0207 276 8362 or email: fiona.macconnacher@food.gov.uk. If not available contact David Gray at the Food Standards Agency. Telephone 0207 276 8940 or email: david.gray@food.gov.uk

15.2 Michael Wight, 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 Social 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 General Food Law (Amendment etc.) (EU Exit) Regulations 2019 does no more than is appropriate".

1.2 This is the case because there is a need for continuation of food safety in the UK post EU Exit.

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 This is the case because the instrument makes only minor and technical amendments to the retained EU legislation to ensure that it remains operable following the United Kingdom's withdrawal from the European Union.

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 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.