EXPLANATORY MEMORANDUM TO

THE SPECIFIC FOOD HYGIENE (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 Specific Food Hygiene (EU Exit) Regulations 2019* ("the instrument") is being made to fix the inoperabilities of retained EU legislation which arise as a consequence of the UK's exit from the European Union.

2.2 The instrument fixes the inoperabilities of *Regulation (EC) No. 853/2004* that lays down specific hygiene measures for the production and processing of certain food products of animal origin and *Regulation (EC) No. 854/2004* that lays down the corresponding official controls.

2.3 The instrument also fixes the inoperabilities of *Regulation (EU) No. 101/2013*, *Regulation (EU) No. 2015/1474*, and *Regulation (EU) No. 2017/1978*, which either provide additional requirements for specific hygiene purposes or amend existing requirements.

2.4 This instrument revokes *Regulation (EU) No. 636/2014* concerning unskinned large wild game.

2.5 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 Specific Food Hygiene policy and legislation.

Explanations

What did any relevant EU law do before exit day?

Regulation (EC) No. 853/2004

2.6 *Regulation (EC) No. 853/2004* laid down specific hygiene requirements for food business operators ("FBOs") manufacturing and handling certain products of animal origin ("POAO") such as meat, eggs, fish and dairy and which did not carry out retail activities (i.e. they do not supply consumers directly) or where retail activities were only a small part of the business. It built on and complemented the general hygiene requirements laid down in *Regulation (EC) No. 852/2004* which is also being retained in UK law (the fixing instrument for which is accompanied by a separate explanatory memorandum).

2.7 Examples of the sorts of FBO establishments which were subject to *Regulation (EC) No. 853/2004* requirements included abattoirs, meat cutting plants, fish wholesalers, egg grading establishments and cheese makers.

2.8 To operate, such FBOs had to be approved by the competent authority ("CA") and as part of this, each establishment was provided with a unique number. This number along with a two letter designation of the country in which the establishment stands and a two letter designation of the European Union (i.e. 'UK' and 'EC' respectively for establishments in England, Scotland, Wales and Northern Ireland) had to be applied either as part of a health mark (for carcases of cattle, pigs, sheep and game) or an identification ("ID") mark (for other POAO such as yoghurt, fish, cheese or bacon).

Regulations relating to Regulation (EC) 853/2004

2.9 *Regulation (EU) No. 101/2013* concerned the use of lactic acid to reduce microbiological surface contamination on bovine carcases and *Regulation (EU) No. 2015/1474* concerned the use of recycled hot water to remove such contamination from carcases. *Regulation (EU) No. 2017/1978* amended existing requirements as regard the harvesting of echinoderms (e.g. sea urchins) outside classified production areas.

2.10 This instrument revokes *Regulation (EU) No. 636/2014* concerning unskinned large wild game, as it concerned only intra-EU arrangements and will no longer be relevant to the UK after exiting the EU.

Regulation (EC) 854/2004

2.11 *Regulation (EC) No. 854/2004* laid down the official controls (i.e. the requirements on CAs) verifying compliance with hygiene standards for POAO and for the approval of establishments that produce POAO so that they could operate – it effectively mirrored the controls required by *Regulation (EC) No. 853/2004*; and described the form of the health mark, which denoted that carcases of animals such as cattle, pigs and sheep met hygiene requirements applicable in slaughterhouses.

Why is it being changed?

2.12 Unless the instrument comes into force, *Regulation (EC) No. 853/2004*; *Regulation (EC) No.* 854*/2004*; and those listed in paragraph 2.3, will be inoperable after the UK's exit from the European Union. The changes introduced by this instrument will enable retained law to operate effectively within the UK after exit providing continuity for businesses, CAs, the voluntary sector and will maintain existing levels of food safety protection for consumers.

What will it now do?

2.13 *Regulation (EC) No. 853/2004* is being retained in UK law and amendments to it introduced by this instrument will mean there will be no change to the day-to-day legal requirements for those businesses carrying out activities for which *Regulation (EC) No. 853/2004* lays down requirements, ensuring the continued safety of the manufacture of certain POAO, protecting public health and, potentially, enabling the continued export of those products. *Regulation (EC) No. 854/2004* is also being retained in UK law to maintain a consistent approach after exit to the verification and enforcement of hygiene requirements. This will help to ensure that public health protection is maintained in regard to such food and potentially enable continue export of those products.

2.14 From EU exit, UK FBOs will no longer be allowed to show 'EC' as part of their health mark or identification (ID) mark (see paragraph 2.8). UK FBOs manufacturing

or handling POAO will be required to apply a different form of mark. This is expanded upon in paragraphs 7.4 and 7.5.

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").) The instrument is being enacted under powers afforded by section 8 of the Act to correct deficiencies in the 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 covers the entire United Kingdom.

4.2 The territorial application of this instrument 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, for has made the following statement regarding Human Rights:

"In my view the provisions of the Specific Food Hygiene (EU Exit) (Amendment etc.) 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. 853/2004* lays down specific hygiene requirements for FBOs manufacturing and handling POAO such as meat, eggs, fish and dairy and which do not carry out retail activities.

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 For food safety to be maintained after the UK's exit, it is necessary that existing EU Regulations are retained in an operable form in UK law. This instrument delivers this principally for *Regulation (EC) No. 853/2004* but also for some related Regulations.

7.2 As already described, *Regulation (EC) No. 853/2004* lays down specific requirements for FBOs manufacturing and handling certain POAO. In order to operate, such FBOs must be approved by the 'competent authority' or CA (this is the FSA in slaughterhouses and cutting plants and local authorities in other establishments) and as part of this, each establishment is provided with a unique number. In the UK, altogether this could impact on the 6,453[1] approved food business establishments.

7.3 The importance of food safety is paramount, and the wording of the retained legislation as amended by this instrument ensures that this is maintained in the event of a "no-deal" scenario. Any agreements reached during exit negotiations that impact the food regulatory regime will be factored in to any future amendments to this instrument.

Health marks and Identification (ID) marks

7.4 As stated earlier, products handled by approved establishments had to be applied either with a health mark (for carcases of cattle, pigs, sheep and game) or an ID mark (for other POAO such as yoghurt, fish, cheese or bacon). The marks had to include the unique number of the establishment along with a two-letter designation of the country in which the establishment stands and a two-letter designation of the European Union (i.e. 'UK' and 'EC' respectively for establishments in England, Scotland, Wales and Northern Ireland) had to be applied.

7.5 When the UK exits the EU, UK food business establishments exporting foods of animal origin to EU Member States and to other third countries will no longer be allowed to include the abbreviation 'EC' as part of their ID marks or health marks. However, UK food businesses will be able to keep their existing ID numbers and, subject to the outcome of technical discussions with the EU, to continue to use the abbreviation "UK" or to use the words "United Kingdom" within their marks. The relevant SI is presented to Parliament on the basis that the use of the abbreviation "UK" or the words "United Kingdom" is the outcome of those technical discussions. However, should changes prove necessary, ministers will seek to bring forward later, amending legislation for future Parliamentary scrutiny and consideration.

7.6 In terms of food traded within the UK, on the advice of colleagues in Defra a twenty-one month transition period is proposed in order that UK food businesses can make the necessary changes to all labelling, including ID marks / health marks. Ministers will seek to make provision for this transitional period in a separate Statutory Instrument, The Food [and Feed] Hygiene and Safety (Miscellaneous Amendments) (EU Exit) Regulations 2019 which will be brought forward for Parliamentary scrutiny and consideration as soon as possible.

[1] At 01.10.2018. Listed for England, Scotland, Wales and Northern Ireland on the Food Standards Agency web site: https://data.food.gov.uk/catalog/datasets/1e61736a-2a1a-4c6a-b8b1-e45912ebc8e3

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

8.1 The instrument is being made using the powers 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 retained 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 existing law, EU or UK.

10. Consultation outcome

10.1 The FSA and Food Standards Scotland (FSS) undertook a consultation from 11 September to 8 October 2018 on proposed changes to health and ID marks for certain food products of animal origin, which will be necessary when the UK exits the EU.

10.2 Approximately 140 businesses and individuals responded to the consultation. Responses were received from a good cross-section of key stakeholders: including food businesses (dairy, fish, meat, cheese makers) of different sizes, small independents and large UK businesses as well as local authorities and organisations representing industry.

10.3 As well as having to prepare for the change to the marks, a key issue for industry was whether a transitional period be provided for the using up of old packaging still bearing the identification mark carrying the 'EC'.

10.4 There is a wide variation in costs associated with changing the design of packaging labels and/or re-ordering packaging with the new identification mark. Typically, a small or medium sized business will hold a stock of packaging of up to 36 months, while for a larger business this may be 6 months.

10.5 There was overwhelming support for keeping the changes as simple as possible, dropping the 'EC' abbreviation and retaining the current form and dimensions of the health and ID mark. The majority of respondents expressed a preference for 12 months or over to use up old packing and of this group a majority suggested between 12 and 24 months would provide sufficient time to use stocks of old packing.

10.6 The consultation and the summary of responses can be viewed at: https://www.food.gov.uk/news-alerts/consultations/proposed-changes-to-the-uk-health-and-identification-marking

10.7 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 Specific Food Hygiene (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.

10.8 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.

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

10.10 This 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[2] 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[3]. 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 law and will continue to enforce the retained EU law after the UK's EU

[2] Please note the familiarisation time has been amended from less than 30 to less than 60 minutes following consultation feedback.
[3] Wage rate taken from the ONS' 2017 Annual Survey of Hours and Earnings (ASHE), table 14.6a.

Exit. The FSA envisages minimal one-off familiarisation 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 Officer from each local authority; and one 'Port Health Officer' from each PHA) will need to undertake this task.

12.3 Other Government Departments such as the Animal and Plant Health Agency (APHA) will need to ensure that Official Veterinarians are familiar with the new form of the health and identification marks and that Export Health Certificates and supporting documentation is updated. The FSA is working with APHA on this issue. In addition, the Department for Environment, Food and Rural Affairs (Defra) who hold policy responsibility for international trade and market access for food and feed, will have to notify non-EU countries that the UK exports to, of the new form of the health and identification mark. Again, the FSA is working with Defra on this issue.

12.4 The instrument is not considered to add additional burdens on enforcement bodies, other than those identified here. Recognition of the new health mark or ID mark should be simple for enforcers.

12.5 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 and ensure the continued safety of food after the UK leaves the EU. The instruments 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 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 Specific Food Hygiene (EU Exit) (Amendment etc.) Regulations 2019 does no more than is appropriate".

1.2 This is the case because there is a need for continuation of food safety and hygiene practices. There are no changes in policy compared to the original EU regulations.

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 necessary 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.