EXPLANATORY MEMORANDUM TO

THE SPECIFIC FOOD HYGIENE (REGULATION (EC) NO. 853/2004) (AMENDMENT) (EU EXIT) REGULATIONS 2019

2019 No. 1247

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 (Regulation (EC) No. 853/2004) (Amendment) (EU Exit) Regulations 2019* ("the instrument") is being made to refine an amendment to retained EU law made by the Specific Food Hygiene (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019 No. 640)

2.2 The refinement concerns the process for approval of substances which may be used to remove surface contamination from products of animal origin. The process is presently set out in EU law as part of Regulation (EC) No. 853/2004 laying down specific hygiene rules for food of animal origin.

Explanations

What did any relevant EU law do before exit day?

Regulation (EC) No. 853/2004

2.3 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 has already been debated in Parliament).

2.4 Article 3(2) of Regulation 853/2004 provides that FBOs are not permitted to use any substance other than potable water, or where permitted clean water to remove surface contamination from POAO unless this has been approved by the European Commission.

2.5 Following EU Exit, the existing ban on use of chemical decontaminants and washes on animal products other than those already approved by the European Commission, will be brought onto the UK statute book by the European Union (Withdrawal) Act 2018 and amended (without change to policy) so that it functions properly by the FSA's SI the Specific Food Hygiene (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019 No. 640).

2.6 Following technical discussions, a refinement to the amendment set out in the Specific Food Hygiene (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019 No. 640) is proposed to be made by way of this instrument.

Why is it being changed?

2.7 Unless this instrument comes into force, the amendment already made to Regulation No 853/2004 by virtue of the Specific Food Hygiene (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019 No. 640) will apply. Following further policy deliberations, a revised approach to describing the process for approval of substances which may be used to remove surface contamination from products of animal origin is felt to be desirable. As with the earlier instrument, no substantive policy change is made by this instrument. Its purpose is simply to ensure that, in a sensitive area of food regulation, retained EU law operates clearly and effectively.

What will it now do?

2.8 The drafting in this instrument, while improving clarity, continues to follow closely the drafting of the provision in the EU Regulation to make clear that no policy changes are being made to the text of the EU Regulation. The FSA was clear on its approach to fixing inoperabilities in the EU legislation and the public consultation it issued in October 2018 assured that only the most essential changes had been made to provide operability of retained EU legislation on EU exit.

2.9 Regulation 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 most businesses, ensuring the continued safety of POAO and protecting public health. Following EU exit FBOs are not permitted to use any substance other than potable water, or where permitted clean water to remove surface contamination from POAO unless this has been approved by ministers. This has been expanded upon in paragraph 7.2.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This instrument is made subject to the urgent 'made affirmative' procedure. The Ministerial statement in Part 2 of the Annex sets out the reasons for this decision.

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 Parliamentary Under Secretary of State for Prevention, Primary Care and Public Health, Jo Churchill, has made the following statement regarding Human Rights:

"In my view the provisions of the Specific Food Hygiene (Regulation (EC) No. 853/2004) (Amendment) (EU Exit) Regulations 2019 are compatible with the Convention rights."

6. Legislative Context

6.1 The Act extinguished 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) of the Act enables 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.

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 for a single aspect of Regulation (EC) No. 853/2004.

7.2 Article 3(2) of Regulation (EC) 853/2004 provides that FBOs are not permitted to use any substance other than potable water, or where permitted clean water to remove surface contamination from POAO unless this has been approved. Currently this is done by the European Commission, following EU exit, this function will be carried out by ministers. The amendment made to Article 3(2) by the Specific Food Hygiene (Amendment etc.) (EU Exit) Regulations 2019 (SI 2019 No. 640) is being further refined by this instrument to make clearer that ministers will hold responsibility for authorising the use of any additional substances to remove surface contamination from POAO.

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.

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(1) of the Act 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 the 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 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.

10.2 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 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.

10.3 The consultation 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 raised were relating to the communication of change and ensuring sufficient lead time is given. A more detailed analysis will be undertaken to ensure this is addressed.

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

10.5 Additionally, a range of generic comments were received which were not within the scope of the consultation, these will be analysed and referred to the relevant teams for further scrutiny.

10.6 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 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. 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 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 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 The UK food industry sector is comprised of mainly small and micro businesses (generally greater than 90%) 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. Approved establishments can vary in size, but it is likely that there will be a higher proportion of larger businesses overall. 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 No specific action is proposed to minimise regulatory burdens on small businesses from this legislation, which should not have any disproportionate negative impact on small businesses.

13.4 The changes made to the legislation will provide continuity for business and should not impact on the day-to-day workload of small businesses as all food and feed safety standards and legal definitions are to be 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 Alistair Edwards at the Food Standards Agency can be contacted with any queries regarding the instrument. Telephone: 020 7276 8459

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

15.3 Parliamentary Under Secretary of State for Prevention, Primary Care and Public Health, Jo Churchill, 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 Parliamentary Under Secretary of State for Prevention, Primary Care and Public Health, Jo Churchill, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view the Specific Food Hygiene (Regulation (EC) No. 853/2004) (Amendment) (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 and hygiene practices. There are no changes in policy compared to the original EU regulations.

2. Good reasons

2.1 Parliamentary Under Secretary of State for Prevention, Primary Care and Public Health, Jo Churchill, 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 Parliamentary Under Secretary of State for Prevention, Primary Care and Public Health, Jo Churchill, 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 Parliamentary Under Secretary of State for Prevention, Primary Care and Public Health, Jo Churchill, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the instrument, I, Jo Churchill, 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.

5. Urgency

5.1 Parliamentary Under Secretary of State for Prevention, Primary Care and Public Health, Jo Churchill, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view by reason of urgency, it is necessary to make The Specific Food Hygiene (Regulation (EC) No. 853/2004) (Amendment) (EU Exit) Regulations 2019, without a draft of the instrument containing the regulations being laid before, and approved by a resolution of, each House of Parliament."

5.2 The urgency procedure is required for this instrument to ensure that these changes can be made to Regulation (EC) No. 853/2004 before exit day and by the 11 October 2019. Due to the prorogation of Parliament, we are required to use the urgent, made-affirmative procedure for this SI to ensure that is made by 11 October, which is when we understand the EU Commission will take a vote on whether the UK can be listed as a Third Country for exporting products of Animal Origin. This export market is worth approx. £5 billion per year to the UK, and the EU have stated that all necessary legislation implementing current regulations must be made by the date of the vote.