

EXPLANATORY MEMORANDUM TO
THE GENERAL 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 Act.

2. Purpose of the instrument

2.1 *The General Food Hygiene (Amendment etc.) (EU Exit) Regulations 2019* (“the instrument”) are being made principally to fix inoperabilities in *Regulation (EC) No. 852/2004* that will arise as a consequence of the UK’s exit from the European Union.

2.2 The fixes being made to *Regulation (EC) No. 852/2004* by way of this instrument will help to maintain the continued safety of food through the maintenance of requirements for hygienic practices from primary production through all stages of food production to the final consumer.

2.3 This instrument also fixes the inoperability of certain other retained, related EU Regulations. These are *Regulation (EU) No. 579/2014*, *Regulation (EC) No. 2073/2005* and *Regulation (EU) No. 2017/2158*.

2.4 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 Hygiene policy and legislation.

Explanations

What did any relevant EU law do before exit day?

2.5 *Regulation (EC) No. 852/2004* set out the general principles for the hygienic production of foodstuffs by food business operators (“FBOs”) and effective and proportionate controls which must be applied by FBOs throughout the food chain from primary production through to the sale or supply to the final consumer.

2.6 It also:

- established that primary responsibility for food safety lies with FBOs;
- laid down that food safety must be protected throughout the food chain, starting with primary production;
- required the registration of approval of food business establishments;
- required the application of basic common hygiene requirements including for premises, transport, equipment, waste, water supply, personal hygiene of food handlers, wrapping and packaging and general requirements for food itself;
- required that food businesses’ safety procedures (except primary producers) are based on hazard analysis and critical control point (“HACCP”) approaches, together with the application of good hygiene practice;

- required microbiological criteria and temperature control requirements based on scientific risk; and,
 - ensured that imported foods meet at least the same or equivalent hygiene standards as those set down in the retained EU law.
- 2.7 Regulation (EU) No. 579/2014 granted derogation from certain provisions under Annex II of Regulation (EC) No. 852/2004 regarding the transportation of liquid oils and fats by sea.
- 2.8 Regulation (EC) No. 2073/2005 set out microbiological criteria which are required under Regulation (EC) No. 852/2004. Regulation (EU) No. 2017/2158 established mitigation measures and benchmark levels for the reduction of acrylamide. Although acrylamide is a chemical, process contaminant, this legislation is linked to Regulation (EC) No 852/2004 as it relates to HACCP and hygiene practices (see paragraph 2.5 and 2.6).

Why is it being changed?

- 2.9 The existing EU regulations are being retained in UK law after EU Exit. Unless this instrument comes into force, certain elements of Regulation (EC) No. 852/2004 will be inoperable after the UK's exit from the European Union. The minor and technical changes introduced by this instrument will enable the retained law to operate effectively within the UK after Exit allowing for a smooth transition for businesses, the voluntary sector and consumers.
- 2.10 The following changes have been made:
- references to the European Union have been replaced with the UK;
 - references to European institutions have been replaced with UK equivalents entities;
 - the text has been amended to reflect its place in UK legislation and not that of the European Union
 - the incorporation of regulations (see paragraph 2.2) which are linked to *Regulation (EC) No. 852/2004*.

What will it now do?

Regulation (EC) No. 852/2004 and its related Regulations are being retained in UK law and amendments to them introduced by this instrument will mean there will be no change to the day-to-day legal requirements and obligations that apply to FBOs. No substantive policy changes are being introduced by this instrument. The policy objective is to maintain existing laws at EU 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 to 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 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 *General Food Hygiene (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 retained legislation and the safeguards it provides to operate effectively following the UK’s exit from the EU.
- 6.2 This statutory instrument is being made to apply fixes to retained Regulation (EC) No. 852/2004, Regulation (EU) No 579/2014, Regulation (EC) No 2073/2005 and Regulation (EU) No. 2017/2158.
- 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; this will be retained after EU Exit. 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 **Purpose:** For food safety controls to be maintained seamlessly after EU Exit, it is necessary that existing EU Regulations are retained in an operable form in UK law. This instrument delivers this and helps to ensure continued safety for consumers and continuity for businesses.
- 7.2 **Context:** The retained legislation amended by this instrument relates to food hygiene requirements for businesses at all stages of the food chain. The importance of food safety is paramount, and the wording of this instrument ensures this is maintained in the event of a ‘no-deal’ scenario. There are no changes to policy from the original regulations as outlined in Paragraphs 2.5 – 2.8.

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 Hygiene (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 minutes¹ 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 overheads². 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 LAs and PHAs based on estimates 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. 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.

12.3 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 (*Regulation (EC) No. 852/2004*) and ensure the continued hygiene controls and practices of food business operators. This instrument provides 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.

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.

- 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 Hygiene (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 and hygiene controls and practices.

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.