EXPLANATORY MEMORANDUM TO

THE FOOD AND FEED HYGIENE AND SAFETY (MISCELLANEOUS AMENDMENTS) (EU EXIT) REGULATIONS 2019

2019 No. 1013

1. Introduction

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

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (EU Exit) Regulations 2019 (this instrument) is intended to address a range of remaining deficiencies in retained EU law relating to food and animal feed. These are more minor deficiencies which have not been addressed in the fifteen earlier exit related statutory instruments which have been presented to Parliament by Health and Social Care ministers, and to deal with very recent changes which have been made to EU law, and which could not have been addressed in the earlier instruments. The provisions relate to transitionary elements and clarifications for the policy areas listed in para 6.2. These amendments will facilitate trade and the functioning of retained law after the UK has left the EU.

2.2 Currently, EU law relating to food and feed safety are implemented or enforced in the UK by a number of statutory instruments, covering several policy areas. The aim of this instrument is to complement those provisions through the miscellaneous amendments that are detailed at para 7.3, ensuring their operability and continued safety of food and animal feed after the UK has left the EU.

Explanations

What did any relevant EU law do before exit day?

2.3 Food and feed safety legislation is laid down in directly applicable and other forms of EU law. This provides public health protection and underpins UK businesses' ability to trade domestically and internationally. UK Government intends to bring forward the above-named Regulation under powers in the European Union (Withdrawal) Act 2018.

Why is it being changed?

2.4 The changes introduced by this instrument come as a result of EU exit. The retained EU law will need to be adapted in order for it to be operable within the UK after exit. All rules will remain the same. Since the provisions contained in this instrument cover a wide range of policy areas, they are not, unlike earlier instrument, organised thematically. For example, they are not focussed around amendments to particular EU Regulations and other legislation related to those Regulations.

What will it now do?

2.5 A number of individual changes are made retained EU law. These amendments complete the programme of EU Exit SIs on food and feed safety legislation. The changes are detailed at paragraph 7 and will enable retained EU law to be operable after EU Exit and provide a smooth transition for affected businesses. The changes introduced do not affect the essence of the legislation but ensure that it remains operable after exit.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 A draft of this SI was originally laid on the 18th March. This draft has been revised and re-laid to take account of comments made following informal review of the draft instrument by Counsel for the Committee. These comments included the suggestion that additional footnotes be included in the draft, and other, minor, drafting points relating to the provision of footnotes, and enumeration corrections.

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 section 24 of the European Union (Withdrawal) Act 2018) and the territorial application of this instrument is not limited either by the Act or by the instrument.

4. Extent and Territorial Application

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

4.2 For the purposes of Part 2 of the instrument, the territorial application of this instrument is to England and Northern Ireland.

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 Food and Feed Hygiene and Safety (Miscellaneous Amendments) (EU Exit) Regulations 2019 are compatible with the Convention rights."

6. Legislative Context

6.1 The European Union (Withdrawal) Act 2018 (The Act) will, on Exit day, 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 The contents of this instrument are varied and cover several policy areas as follows:

- Health Mark, Identification Marks and transitional measures;
- Trichinella and Transitional Provisions for Official Laboratories;

- Rules for food businesses and official controls relating to products of animal origin;
- Food Irradiation;
- Official Controls Charges for Fishery Products;
- Food Safety (Sampling and Qualifications);
- EU Decisions relating to Genetically Modified Food and Feed;
- Food Additives; and
- Northern Ireland 'wash up' measures on its behalf.

7. Policy background

What is being done and why?

7.1 This instrument includes necessary amendments to EU food and feed legislation that have either not have been brought forward previously with other EU Exit instruments or have come to light since those instruments were laid. The amendments will correct deficiencies in recently adopted EU Regulations and amend other Regulations to ensure the controls they provide can operate effectively in the event of the UK leaving the EU without a withdrawal agreement in place.

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

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

  "appropriate authority" means –
  (a) in relation to England, the Secretary of the State;
  (b) in relation to Wales, the Welsh Ministers;
  (c) in relation to Scotland, the Scottish Ministers;
  (d) in relation to Northern Ireland, the Northern Ireland devolved authority.
- Under the retained EU law, the "Food Safety Authority" will have a role in providing food safety advice to the appropriate authority. The "Food Safety Authority" means –
  (a) as regards England, Wales and Northern Ireland, the Food Standards Agency (FSA);
  (b) as regards Scotland, Food Standards Scotland.
- The European Food Safety Authority conducts assessment and provides advice in relation to food and feed safety. The instrument designates that role to the Food Safety Authority which will be the Food Standards Agency in England, Wales and Northern Ireland and in Scotland this task will be undertaken by Food Standards Scotland (FSS).

7.3 This instrument in part applies to the Northern Ireland Regulations dealing with food and feed hygiene and safety which is a transferred matter for Northern Ireland under the Northern Ireland Act 1998 and earlier legislation. Although the UK Government remains committed to restoring devolution in Northern Ireland, a functioning statute book is required across the UK, including in Northern Ireland, for exit day. UK Government Ministers have therefore decided that, in the interest of legal certainty in

Northern Ireland, the UK Government will take through the necessary secondary legislation at Westminster for Northern Ireland, in close consultation with the Northern Ireland departments. This is one such instrument.

7.4 Most notably, this instrument makes the following changes:

EC health mark and transition period: This instrument provides legal assurance that products carrying the EC health and identification marks will continue to be acceptable on the UK market for a period of 21 months after exit. This measure reduces the impact of costs to industry in that it allows existing stocks of packaging to be used on the UK market for this time.

As regards the content of the health mark required for carcases of certain animals (such as cattle, pigs, sheep) and identification mark for all foods of animal origin, once the UK has left the EU, the 'EC' abbreviation in these marks for the European Community, will cease to be relevant for UK food businesses. This instrument provides a transitional period of 21 months after exit day during which UK food businesses can apply the 'EC' abbreviation to carcases and foods of animal origin to be placed on the UK domestic market.

This instrument also allows for the abbreviation 'GB' to be used in the health marks as this is the International Organisation for Standardisation (ISO)'s two letter country code for the United Kingdom.

Trichinella (pork nematode worm parasite) provisions and Transitional Provisions for Official Laboratories: The retained EU law regarding specific official controls that apply for Trichinella in meat and Trichinella testing requirements may not be fully enforceable until the specific inoperabilities are addressed.

Rules for businesses and official controls relating to products of animal origin (POAO) under EC Regulation 2074/2005: EC Regulation 2074/2005 is an EU tertiary implementing act that provides certain highly technical and administrative refinements to EU POAO Regulations. It is quite a diverse Regulation; an example of content would be rules relating to fishery products used in the production of fish oil. This instrument will address the inoperabilities and ensure the legislation is fully operational.

Food Irradiation: This instrument makes changes to the Food Irradiation (England) Regulation 2009. An issue of clarity has been identified regarding the use of the term "imports" as defined within legislation. This instrument also clarifies that facilities approved by EU Member States would in future no longer be automatically approved for food imported from the UK and so without this instrument there could be a lack of clarity around the status of newly approved facilities. However, as the market on irradiated foods in the UK is very small, the impact in practice is likely to be very low.

Official Controls for Fishery Products: This instrument includes provisions to set minimum charging rates for hygiene controls for fishery products by amending the Fishery Products (Official Controls Charges) (England) Regulations 2007. These rates are currently set in Euros with an exchange rate to GBP. The exchange rate, from 2008, is now somewhat out of date and would not be in line with Government guidance on amending outstanding references to Euros. However, the current charging mechanism could continue to be used. The Government does not anticipate any increase in the extent to which these charges are levied by local authorities after the UK exists the EU; which is currently reported to be very low.

The Food Safety (Sampling and Qualifications) (England) Regulations: The current national regulations stipulate the necessary qualifications and experience required to be an official control laboratory analyst in England. Only minimal amendments have been proposed to these regulations to correct inoperabilities upon leaving the EU.

Smoke Flavourings: The proposed amendments address a minor error where a quotation mark was left in place at the end of a definition; the second amendment provides for the appropriate authority to provide details of an application to the 'Food Safety Authority' comprised of the Food Standards Agency in England, Wales and Northern Ireland, and Food Standards Scotland in respect of Scotland. This deficiency was identified by the JCSI. The amendments also include naming of the relevant legislature for Northern Ireland where the prescribing powers are provided.

EU Decisions relating to Genetically Modified (GM) Food and Feed: The EU authorisation Decisions which come into force between the laying of the Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 and EU Exit will become retained EU law on exit day. The retained Decisions in their uncorrected form will ensure that GM food/feed authorised in the EU before EU Exit is authorised, and available for use, in the UK after EU Exit. Corrections to the retained Decisions are necessary to make them fully operable with regard to (a) specifying the UK body to which industry must submit annual reports on activities as set out in their mandatory environmental monitoring plans and (b) maintaining the domestic authorised GM food/feed register.

Northern Ireland provisions for the above Regulations/amendments: This instrument makes equivalent changes (to those made to the Regulations relating to England) to the relevant Northern Ireland legislation to ensure that the body of Northern Ireland food law can function properly once the UK leaves the EU. This instrument also inserts a definition of "Northern Ireland devolved authority" or, where appropriate, identifies the department which is the correct "appropriate authority" in various EU Regulations. The amendments also include naming of the relevant legislature for Northern Ireland where the regulation making procedure is provided in various EU Regulations.

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

8.1 This 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 the 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 No consolidation is required.

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 proposed approach to retained EU law for food and feed safety and hygiene. 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.

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

10.4 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.

10.5 A copy of the consultation is attached at Annex II and can also be viewed at: https://www.food.gov.uk/sites/default/files/media/document/euexit-regulations-consultation_0.pdf

11. Guidance

11.1 Guidance to stakeholders on the specific policy areas covered by this SI will be made available or kept updated as required, for instance the advice on health marks, for which guidance was published and circulated to key stakeholders in February 2019: https://www.food.gov.uk/sites/default/files/media/document/update-on-health-and-identification-marks.pdf

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

[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.

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

15. Contact

15.1 Christina Baskaran at the Food Standards Agency email: Christina.Baskaran@food.gov.uk can be contacted with any queries regarding the instrument.

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 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 Food and Feed Hygiene and Safety (Miscellaneous Amendments) (EU Exit) Regulations 2019 does no more than is appropriate".

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

2. Good reasons

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

"In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action".

2.2 These are because the legislation will create a level playing field in the area of food and feed hygiene and safety, preventing UK businesses from being placed in a disadvantageous position when trading overseas.

3. Equalities

3.1 The Parliamentary Under Secretary of State for Public Health and Primary Care, Steve Brine has made the following statement(s):

"The draft instrument does not amend, repeal or revoke a provision or provisions in the Equality Act 2006 or the Equality Act 2010 or subordinate legislation made under those Acts.".

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

"In relation to the draft instrument, I, Steve Brine have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010. This Act does not extend to Northern Ireland; however, I have given equivalent due regard to the implications for equality of opportunity in Northern Ireland."

4. Explanations

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