EXPLANATORY MEMORANDUM TO

THE FOOD AND FEED (MAXIMUM PERMITTED LEVELS OF RADIOACTIVE CONTAMINATION) (AMENDMENT) (EU EXIT) REGULATIONS 2019

2019 No. [XXXX]

1. Introduction

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

2. Purpose of the instrument

2.1 *The Food and Feed (Maximum Permitted Levels of Radioactive Contamination) (Amendment) (EU Exit) Regulations 2019* ("the instrument") are being made to fix inoperabilities in the retained EU legislation, Council Regulation (Euratom) 2016/52 laying down maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency, that will arise as a consequence of the UK's exit from the European Union.

2.2 This instrument is a legislative consequence of the UK's decision to leave the European Union, which will also result in our departure from the European Atomic Energy Community ("the Euratom Treaty"). The Euratom Treaty covers civil nuclear policy and legislation across the EU including emergency response to nuclear incidents.

2.3 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 the Food and Feed (maximum permitted levels of radioactive contamination) policy and legislation.

Explanations

What did any relevant EU law do before exit day?

2.4 The EU law established maximum permitted levels of radioactive contamination in food and feed which would come into effect following a nuclear accident or any other case of radiological emergency. This council Regulation acts as a framework Regulation that can be enacted to promptly set emergency levels of radioactive contamination in food and feed to protect consumers. These levels, if exceeded, would have a detrimental effect on human health from the consumption of food that has been contaminated by radioactivity and would assist the policy response to a radiological incident. Further details can be found in section 6 below.

Why is it being changed?

2.5 The changes introduced come as a result of EU exit. Retained EU law will need to be adapted in order for it to be operable in the UK after exit. All rules will remain the same. What will change is references to terms such as "Community", and "Member states". Where necessary, functions currently undertaken by for instance the European Commission or the Group of Experts established under Article 31 of the Euratom

Treaty will be replaced by references to domestic risk management and risk assessment authorities.

What will it now do?

2.6 The instrument will ensure that appropriate legislation remains in place after exit. The changes introduced do not affect the essence of the legislation but ensures that the legislation remains operable after exit. The maximum levels for radioactive contaminants in food will remain as they are now and the same will be true for sampling and analysis rules.

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 section 8 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 whole of the United Kingdom.

4.2 The territorial application of this instrument is the whole of the United Kingdom.

5. European Convention on Human Rights

5.1 The Parliamentary Under Secretary of State for Public Health and Primary Care, Steve Brine has made the following statement regarding Human Rights:

"In my view the provisions of the Food and Feed (Maximum Permitted Levels of Radioactive Contamination) (Amendment) (EU Exit) Regulations 2019 are compatible with the Convention rights."

6. Legislative Context

6.1 The Act repeals the European Communities Act 1972 on EU exit day. It maintains all domestic law and retains previously directly applicable EU 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 EU law and the safeguards it provides to operate effectively following the UK's exit from the EU.

6.2 This instrument is being made to apply fixes to retained Council Regulation (Euratom) 2016/52 laying down maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other case of radiological emergency.

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 Radioactivity in food can be natural or manmade. Manmade radioactive contaminants can enter food as a result of routine operations or following a nuclear accident or other radiological emergency. For routine operations, exposure to radioactive contaminants is regulated by measures including the Ionising Radiation Regulations 2017 and the Environmental Permitting (England and Wales) Regulations 2016. In the event of a nuclear accident or other radiological emergency, additional measures may be required to protect the public which includes preventing contaminated food and feed from being placed on the market.

7.2 This SI will fix the inoperabilities in retained direct EU legislation which established maximum permitted levels of radioactive contamination in food and feed following a nuclear accident or other radiological emergency. These levels, if exceeded, would have a detrimental effect on human health from the consumption of food that has been contaminated by radioactivity and having pre-set levels allows for a prompt policy response to the incident.

7.3 The pre-set levels in this legislation can also be used to ensure that, for an overseas incident, imports from the affected country are only imported when below the levels and that suitable checks are carried out.

7.4 The legislation provides for deviations from the maximum permitted levels in specific circumstances and where scientifically justified.

7.5 The EU legislation to be retained has not been used but its predecessor, which was fundamentally the same, was enacted in relation to food imported from Japan following the Fukushima nuclear accident. Similar controls were also applied following the Chernobyl nuclear accident, however this accident preceded (and was the initiator to) the establishment of pre-set maximum permitted levels.

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

- Functions currently undertaken by the European Commission in adopting an implementing regulation rendering applicable the maximum permitted levels will in the future be the responsibility of the 'appropriate authority' who must prescribe measures which apply the applicable maximum permitted levels;
- "appropriate authority" means:

  (a) in relation to England, the Secretary of 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

- The Group of Experts established under Article 31 of the Euratom Treaty are currently consulted for the assessment of risk to health when reviewing the maximum permitted levels of radioactive contamination and their implementation. The instrument will provide that in the future this role will be undertaken by the appropriate authority.
- Retained EU legislation currently allows other European Member States to derogate temporarily from the maximum permitted levels for foods consumed only on their territories. As foods benefitting from these derogations do not leave the respective countries, these provisions are no longer relevant after exit.
- References to "Member States" or "Community" at various places will be replaced with UK relevant references, e.g. "Member States may make recommendations concerning the diluting conditions in order to ensure that the maximum permitted levels laid down in this Regulation are observed" will become "The Food Safety Authority may make recommendations concerning the diluting conditions in order to ensure that the maximum permitted levels laid down in this instrument are observed".
- 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 (FSS).

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 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 Food and Feed (Maximum Permitted Levels of Radioactive Contamination) (Amendment) (EU Exit) Regulations 2019, using powers under the European Union Withdrawal Act. It was proposed in our approach that the corrections would be made by way of statutory instruments of which 15 had been prepared. Key corrections would provide a suitable replacement for the risk management function currently undertaken by the European Commission and for the risk assessment function currently undertaken by the European Food Safety Authority (EFSA),

amongst other minor, non-controversial amendments. The corrections would not result in any material change in the level of protection to human or animal health, or to the high standard of domestic or imported food and feed which consumers expect. The statutory instruments which would make the corrections will be subject to review and approval by Parliament.

10.2 The consultation covered the proposed approach used for all of the FSA's Statutory Instruments in relation to EU Exit. It received 50 responses of which 82% supported or did not disagree with the proposed approach being outlined by the Food Standards Agency. 16% of replies contain mixed comments. The main concerns regarding the FSA approach in general were related to the communication of change and ensuring sufficient lead time is given. A more detailed analysis of the responses can be seen at the published link below.

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

10.4 The consultation and its responses can be viewed at:

https://www.food.gov.uk/news-alerts/consultations/proposed-approach-to-retained-eu-law-for-food-and-feed-safety-and-hygiene

11. Guidance

11.1 It is considered that guidance is not required for this instrument as it generally maintains existing regulations and does not introduce new requirements.

12. Impact

12.1 The impact on business, charities or voluntary bodies is minimal. According to the ONS Inter Departmental Business Register (IDBR) there were 214,175 businesses active in the agri-food sector in 2017. The FSA envisages minimal one-off familiarisation costs to businesses, charities and voluntary bodies; where we estimate that it will take each organisation less than 60 minutes[1] to read and understand the proposed regulations and then disseminate the information to key staff within their organisation. However, it is unlikely that the envisaged changes will present any other impact on businesses', charities or voluntary bodies' day to day operations as the rules are not changing as a result of this instrument. The associated direct cost for businesses has been calculated by applying the 2017 median annual wage for "production managers and directors" of £22.05 and uprating it by 20% to account for overheads[2]. Multiplying this wage rate with the expected familiarisation time gives an estimated total one-off cost to businesses of £5.7m. After adjusting for inflation and applying a discount rate of 3.5% as per HMT Green Book guidance, this translates to an Equivalent Annual Net Direct Cost to Business (EANDCB) of approximately £600,000.

12.2 In terms of the impact on the public sector, there are approximately 419 Local Authorities (LAs) and 35 Port Health Authorities (PHAs) in the UK, which enforce existing food and feed law and will continue to enforce the retained EU law after the UK's EU Exit. The FSA envisages minimal one-off familiarisation time costs to LAs and PHAs; where we estimated that it will take authorities less than 60 minutes 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.

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.

12.3 An impact assessment has not been produced for this instrument which the FSA has certified as being below the *de minimis* threshold of +/- £5m equivalent annual net direct cost to business. The instrument is designed only to fix the inoperability of retained EU legislation (detailed in Section 6) 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 maximum permitted levels in this legislation would only come into effect in the event of a nuclear accident or other radiological emergency. However, in this event. the legislation would apply 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 As this instrument is made under the EU Withdrawal Act 2018, no review clause is required.

15. Contact

15.1 Christopher Thomas at the Food Standards Agency can be contacted with any queries regarding the instrument. Telephone: 020 7276 8728 or email: christopher.thomas@food.gov.uk

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

"In my view the Food and Feed (Maximum Permitted Levels of Radioactive Contamination) (Amendment) (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 Steve Brine Parliamentary Under Secretary of State for Public Health and Primary Care 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 radioactive contaminants in foods preventing UK businesses from being placed in a disadvantageous position when trading overseas.

3. Equalities

3.1 Steve Brine Parliamentary Under Secretary of State for Public Health and Primary Care 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 Steve Brine Parliamentary Under Secretary of State for Public Health and Primary Care 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.