EXPLANATORY MEMORANDUM TO

THE CONTAMINANTS IN FOOD (AMENDMENT) (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 Currently, the contaminants in food legislation is set by the EU and is implemented in the UK by statutory instruments.

2.2 *The Contaminants in Food (Amendment) (EU Exit) Regulations 2019* (the instrument) fixes inoperabilities in the retained EU legislation on contaminants in food (as listed in para 6.2) so that it will continue to be applicable as domestic law and ensure continued safety of food after the UK has left the EU.

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 Contaminants in Food policy and legislation.

Explanations

What did any relevant EU law do before exit day?

2.4 The aim of the contaminants legislation is to ensure food is safe to eat with regards to chemical contamination, whether naturally occurring or manmade. The legislation establishes general rules and principles relating to chemical contaminants which Food Business Operators (FBOs) must work to. More explicitly, the legislation establishes maximum levels for various contaminants in different foods in the annexes to the regulations. Rules on sampling and analysis are also set out for chemical contaminants in foods. These are designed to ensure that sampling is representative and provides assurance that methods of analysis have comparable levels of performance. Such rules are primarily directed towards enforcement officers for official food and feed controls but can also be used by food manufacturers to help them ensure compliance with the legislation. Changes to the annexes are adapted on a regular basis (several times a year) taking into account new scientific evaluations to include for instance, new maximum levels for an individual contaminant in a food or to lower existing levels.

Why is it being changed?

2.5 The changes introduced come as a result of EU exit. The 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 rules”, and “Member states”. Where necessary, functions currently undertaken by for instance the European Commission or the European Food Safety Authority (EFSA) will be replaced by references to domestic risk management and risk assessment authorities.

Additionally, the requirement for the UK to submit data to EFSA is no longer necessary. Further details can be found in section 6 below.

What will it now do?

2.6 The new instrument will ensure that appropriate legislation remains in place on chemical contaminants in food after exit. The changes introduced do not affect the essence of the legislation but ensure that the contaminants legislation remains operable after exit. The maximum levels for contaminants in food will remain as they are 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 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 The territorial application of this instrument is 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 has made the following statement regarding Human Rights:

"In my view the provisions of the Contaminants in Food (Amendment) (EU Exit) Regulations 2019 are compatible with the Convention rights."

6. Legislative Context

6.1 The European Union (Withdrawal) Act 2018 (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) 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 EU contaminants legislation is made up of a framework Regulation setting out the general rules for contaminants under which sit two Regulations establishing maximum levels for contaminants in various foods. This is further supplemented by five detailed Regulations setting out the methods of sampling and analysis for official controls. These Regulations are listed below:

Framework regulation for contaminants

- Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food

Maximum legal levels

- Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
- Commission Regulation (EC) No 124/2009 of February 2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed

Sampling and analysis

- Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs
- Commission Regulation (EC) 1882/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of the levels of nitrates in certain foodstuffs
- Commission Regulation (EC) No 333/2007 of March 2007 laying down methods of sampling and analysis for the control of the levels of trace elements and processing contaminants in foodstuffs
- Commission Regulation (EU) 2015/705 of 30 April 2015 laying down methods of sampling and performance criteria for the methods of analysis for the official control of the levels of erucic acid in foodstuffs and repealing Commission Directive 80/891/EEC
- Commission Regulation (EU) No 2017/644 of 5 April 2017 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 589/2014

The Contaminants in Food (England) Regulations 2013 No 2196 provides powers to enforcement officers to implement the EU regulations. Equivalent legislation exists in Scotland, Wales and Northern Ireland.

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 to this.

7. Policy background

What is being done and why?

7.1 Chemical contamination in food can be natural or manmade. Legislation on maximum permitted levels of certain contaminants in food is developed as a risk management measure. It is the responsibility of FBOs to ensure the food they sell is safe and is compliant with the legislation. Relevant competent authorities will undertake controls to check compliance and take enforcement action as necessary.

7.2 The contaminants covered include agricultural contaminants and plant toxins such as mycotoxins produced by fungi, environmental contaminants such as heavy metals present in the soil, contaminants formed during processing of foods such as polycyclic aromatic hydrocarbons (PAHs) which can be formed when food is smoked and also contaminants which may persist in the environment and find their way into food from historical industrial use. Controls are also set on unavoidable carryover of some veterinary residues from animal feed. When maximum levels are set, they focus on the food commodities that constitute the highest risk for consumers.

7.3 The EU rules on contaminants in food contained in the contaminants regulations mentioned in para 6.2 need to be maintained in UK law in order to ensure food in the UK is safe to eat for consumers. The changes introduced in this instrument and listed below will ensure that the legislation remains operable.

- The European Food Safety Authority is currently consulted for the assessment of risk to health posed by chemical contaminants in food. The instrument will provide that in the future this role will be undertaken by 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).
- Where necessary to the effective functioning of the retained EU law, these functions are assigned to appropriate UK entities via the Secretary of State for Health and Social Care as the risk manager.
- The requirements to inform the European Commission of new evidence or data will be removed. In the future this would remain the responsibility of the Food Safety Authority to consider and where necessary recommend action to be taken on any such evidence.
- EU legislation currently allows other European Member States to benefit from derogations to the legislation for foods marketed only on their territories. As foods benefitting from these derogations do not leave the respective countries, these provisions are no longer relevant after exit.
- Currently EU Member States are required to report national monitoring of nitrates in leafy vegetables to the European Food Safety Authority. The requirement to report back to the European Food Safety Authority will not be necessary after exit. Similarly, the requirement for data submitted to the European Food Safety Authority to be in a particular format is no longer needed in UK law.
- References to “Member States”, “Community” or ‘national’ at various places will be replaced with UK relevant references, e.g. “sampling to be done according to the rules of the MS” will become “sampling to be done according to United Kingdom rules”.

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 Contaminants in Food (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

[1] Please note the familiarisation time has been amended from less than 30 to less than 60 minutes following consultation feedback.

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 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.

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 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 (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 legislation applies to activities that are undertaken by small businesses.

13.2 Over 90% of the UK food industry sector comprises small and micro businesses and EU legislation generally applies to food and feed businesses regardless of size, as requirements are intended to be risk based to reflect the activities undertaken by business. Due to the high ratio of small and micro food businesses in the UK, it is often not feasible to exempt smaller businesses from new food measures, as this would fail to achieve the intended effect of reducing risks to public health. The FSA makes every effort to identify the impacts and minimise burdens on small and micro businesses where possible.

13.3 The changes made to the legislation will provide continuity for business and should not impact on the day-to-day workload of small and micro businesses as all food and feed safety standards and legal definitions are maintained.

[2] Wage rate taken from the ONS' 2017 Annual Survey of Hours and Earnings (ASHE), table 14.6a.

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 Mark Willis at the Food Standards Agency can be contacted with any queries regarding the instrument. Telephone: 0207 276 8559 or email: Mark.Willis@food.gov.uk.

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

15.3 Steve Brine, Parliamentary Under Secretary of State for Public Health and Primary Care at the Department for Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

Annex

Statements under the European Union (Withdrawal) Act 2018

Part 1

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA SIs	Explain the instrument, identify the relevant law before exit day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.
Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9, and	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.

		23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising sections 10(1), 12 and part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 4 or 14, Schedule 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 13, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA, identifying the relevant law before exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 16, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority's response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and, c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.

Part 2

Statements required when using enabling powers under the European Union (Withdrawal) 2018 Act

1. Appropriateness statement

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

"In my view the Contaminants in Food (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 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 chemical contaminants in foods 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.".

4. Explanations

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