EXPLANATORY MEMORANDUM TO

THE FOOD ADDITIVES, FLAVOURINGS, ENZYMES AND EXTRACTION SOLVENTS (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019

2019 No. 860

1. Introduction

1.1 This explanatory memorandum has been prepared by the Food Standards Agency 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 Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (hereon after referred to as 'this instrument') fixes inoperabilities in the retained EU legislation on food additives, flavourings, enzymes, extraction solvents and processing aids which are collectively referred to as food improvement agents. The amendments in this instrument are made in exercise of the powers conferred by section 8(1) of the European Union (Withdrawal) Act 2018 to enable the regulatory requirements applicable to these substances to operate effectively as domestic legislation after the UK has left the EU.

2.2 This instrument amends the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013 which provides for the enforcement in England of the regulatory requirements for food improvement agents, with similar legislation enacted across Wales, Scotland, and Northern Ireland. It will also amend eleven EU Regulations (as listed at para 6.2) that provide the detailed rules for these substances. This instrument will also revoke Regulation (EU) No 257/2010 which provides for the establishment of an ongoing programme of re-evaluation of food additives that were approved prior to 2009.

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 food improvement agents, policy and legislation.

Explanations

What did any relevant EU law do before exit day?

2.4 Food improvement agents are used in or on food for a technological purpose during its production or storage, they are also used to improve the taste, texture, and appearance of food. Common examples of these are artificial sweeteners, preservatives, and flavourings; these are not in the main sold direct to the final consumer but are traded between businesses and used in a very broad range of everyday foods.

2.5 In general, the harmonised EU legislation governing these substances requires a pre-market safety assessment before being placed on the market. The legislation provides lists of permitted substances, applicable specifications, conditions of use, as well as

categories of foods in which they may be used. The legislation also provides specific labelling requirements for certain food products sold to consumers, such as a mandatory warning on products containing aspartame as it is a source of phenylalanine which could be detrimental to those suffering from Phenylketonuria: 'Contains a source of phenylalanine' or if designated only by reference to the E number in the ingredients list, then 'Contains aspartame (a source of phenylalanine)' must appear. This body of legislation helps to ensure a high level of protection for consumers is maintained.

Why is it being changed?

2.6 The minor and technical amendments being made through this instrument will rectify deficiencies in the retained EU legislation that arise as a consequence of the UK's exit from the EU. These deficiencies relate to the conference of functions to EU institutions and processes to which the UK will no longer have access or place reliance on after exit. For example, all tasks and roles assigned to the European Commission and European Food Safety Authority (EFSA) in retained EU law must be assigned to an appropriate UK entity. Certain roles have been assigned to the "appropriate authority" defined as Ministers in England, Wales and Scotland, and the Northern Ireland devolved authority. Whilst others have been assigned to the "food safety authority" which is defined as the Food Standards Agency (FSA) in England, Wales and Northern Ireland, and in Scotland as Food Standards Scotland (FSS).

2.7 This instrument removes references to the "EU", "Union", and replaces these as appropriate with "domestic" or "UK". This instrument also deletes text which has become redundant, for example deleting references to Member States. These changes will ensure that the retained legislation remains operable and enforceable within the UK regulatory framework without compromising existing levels of public health protection and food safety. Not to do so will mean that certain elements of the retained law will not operate effectively in the UK post exit.

2.8 Regulation (EU) No. 257/2010 is being revoked for the entire UK, as it is not appropriate or necessary to retain this legislation. There are other legislative mechanisms by which new and emerging scientific data must be brought to the attention of the UK authorities by applicants, thereby ensuring that the safe use of food additives remains under vigilance. The Food Standards Agency in line with its statutory duty arising from the Food Standards Act 1999, will continue to monitor scientific evaluations and outputs from international assessment bodies such as EFSA and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) to ensure we remain alert to emerging scientific analyses and potential risks.

What will it now do?

2.9 All existing food improvement agents permitted for use within the UK prior to exit day will continue to be permitted after exit and all conditions and requirements attached to their use will be preserved. This will ensure continuity and clarity for UK food businesses, as well as reassurance for consumers that existing levels of public health protection and food safety are being maintained. The amended retained EU legislation will remain operable and enforceable after the UK's exit, so non-compliance can be dealt with as effectively by enforcement authorities as prior to exit.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This instrument corrects errors previously reported by the JCSI at its meeting on 13 March 2019 in its 52 report of the session: https://publications.parliament.uk/pa/jt201719/jtselect/jtstatin/316/31603.htm#_idTextAnchor003

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 instrument includes Scotland and Northern Ireland.

3.3 The powers under which this instrument is made cover the entire United Kingdom (see The European Union (Withdrawal) Act 2018 ('the Act').) This instrument is being enacted under powers afforded by section 8 of the Act to correct deficiencies in the retained legislation and except in relation to amendments to the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013, which applies in England only, 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 United Kingdom.

4.2 The territorial application of this instrument is the entirety of the United Kingdom for those aspects amending deficiencies in retained EU law. The elements of the instrument addressing deficiencies in the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013 will only apply in England and equivalent measures to amend the respective legislation in the devolved administrations will be made there.

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 Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 are compatible with the Convention rights."

6. Legislative Context

6.1 On exit day, the Act will repeal the European Communities Act 1972. It will maintain all domestic law and retain 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 the retained legislation and the safeguards it provides to operate effectively following the UK's exit from the EU.

6.2 Food improvement agents are mainly used by the food industry in or during the food production process. These are regulated by a broad body of EU legislation to which amendments will be made to fix deficiencies in the retained EU law, these being:

- Regulations (EC) No.1331/2008 and No. 234/2011 which provide a common authorisation procedure for food additives, food enzymes and food flavourings;

- Regulation (EC) No. 1332/2008 on food enzymes;
- Regulation (EC) No. 1333/2008 and No 231/2012 on food additives;
- Regulations (EC) No. 1334/2008, No. 872/2012 and No. 873/2012 on flavourings; and
- Regulations (EC) No. 2065/2003 and No. 1321/2011 on smoked flavourings.

This SI will also amend the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013, which provides for the enforcement in England of requirements relating to food improvement agents.

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 Food additives can be added to food for a variety of technological purposes, for example:

- Colours are used to add or restore colour in a food, such as coloured cake frosting;
- Preservatives are added to prolong the shelf-life of foods by protecting them against micro-organisms;
- Antioxidants can also help prolong the shelf-life of foods by protecting them against oxidation (i.e. fat rancidity and colour changes)
- Flour treatment agents are added to flour to improve its baking quality.

7.2 However, the use of additives is strictly controlled, these are subject to a premarket safety evaluation and if authorised, specifications and conditions of use can also be stipulated, as well as the type of food in which any given additive may be used, for example, the food colour Erythrosine (E127) is only permitted in cocktail cherries. In addition to the need for a technological justification for using an additive, and an assessment of its safety, the use of the additive is only permissible if its use does not mislead the consumer. Similarly, flavourings, enzymes and extraction solvents are also subject to strict controls.

7.3 Inoperabilities and deficiencies relating to the conference of functions to EU institutions and processes to which the UK will no longer have access or place reliance on after exit must be corrected. All tasks and roles e.g. administration of the authorisation process or safety evaluation of food improvement agents, previously undertaken by the European Commission and EFSA must be assigned to an appropriate UK entity. Where appropriate, responsibilities executed by EFSA have been assigned to the "Food Safety Authority" (meaning the Food Standards Agency as regards England, Wales and Northern Ireland and Food Standards Scotland as regards Scotland).

7.4 Decision-making on applications or modification/revocation of existing authorisations has been assigned to the "appropriate authority" these being Ministers in England,

Scotland and Wales, and in Northern Ireland the Northern Ireland devolved authority. Scrutiny of these decisions will rightly remain with Parliament through the existing legislative scrutiny processes.

7.5 Other minor changes such as fixing references to other legislation or replacing terms such as 'Union list' with 'domestic list' will also be made to ensure that the law remains operable and enforceable within the UK regulatory framework after exit without compromising existing levels of public health protection and food safety. Not to do so will mean that certain elements of the retained legislation will not operate effectively in the UK post exit and the legislation will be defective.

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 of retained EU law to operate effectively or other deficiencies arising from the withdrawal of the United Kingdom from the European Union. With the exception of amendments being made to the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013, which applies in England only, this instrument is being enacted on a UK wide basis. Only minor and technical amendments are being made to ensure the retained EU law will operate effectively across the UK after exit. 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 Additives, Flavourings, Enzymes and Extraction Solvents (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 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 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 law (detailed in Section 6) and ensure the continued safety of food and

[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.

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.

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 Firth Piracha at the Food Standards Agency Telephone: 020 7276 8126 or email: firth.piracha@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, 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 Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 does no more than is appropriate".

1.2 This is the case because: the instrument only makes minor and technical fixes as explained in section 2 of this Explanatory Memorandum and adds no 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 this legislation will maintain the existing lists of permitted food improvement agents and the requirements that apply to their use, thereby providing continuity and clarity for UK businesses and reassurance for consumers that existing levels of protection of public health and food safety will not be compromised as a consequence of the UK's exit from the EU.

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.