

## EXPLANATORY MEMORANDUM TO

### THE NOVEL FOOD (AMENDMENT) (EU EXIT) REGULATIONS

2019 No. 702

#### 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 Novel Food (Amendment) (EU Exit) Regulations 2019* (the instrument) fixes inoperabilities in the retained EU legislation on novel foods so that it will continue to operate as domestic law after the UK has left the EU.
- 2.2 The instrument amends the Novel Foods Regulations (EU) 2015/2283 (“the EU Regulation”) together with its associated implementing acts as listed in para 6.2.
- 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 Novel Food policy and legislation.

#### *Explanations*

##### What did any relevant EU law do before exit day?

- 2.4 Novel Foods are foods or food ingredients that do not have a significant history of consumption within the EU before 15 May 1997. The EU legislation on Novel Foods is harmonised across the EU. Foods which are new to the market are not assumed to be safe. In the interests of safeguarding public health, they are required to have a premarket safety assessment before being placed on the market, a recent example of this is chia seeds. The premarket safety assessment examines a range of issues to establish whether consumers would be at risk if they consumed the novel food, how high the level of risk is likely to be and how, if a risk is established, that risk would be managed. The EU Regulations governing novel foods are enforced in England through The Novel Foods (England) Regulations 2018 with similar legislation enacted across Wales, Scotland, and Northern Ireland.

##### Why is it being changed?

The minor and technical amendments being made through this instrument will rectify deficiencies in the retained EU Regulation that arise as 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. The instrument designates responsibilities incumbent on the European Commission to Ministers in the four UK countries and designates responsibilities currently incumbent on the European Food Safety Authority (EFSA) to the "Food Safety Authority", the Food Standards Agency (FSA) in England, Wales, Northern Ireland, and Food Standards Scotland (FSS) or other

devolved administration organisations able to take up this role subject to further agreement).

This instrument also removes references to the “EU”, “Union”, and “Single Market”, and replaces these as appropriate with “UK”, “appropriate authority” etc). The SI will also delete text which has become redundant for example deleting references to consulting Member States of the EU on the novel food status of a food and minor changes such as fixing references to other legislation. These changes will ensure that the retained law 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.

What will it do now?

- 2.5 The amended Regulations will remain operable and enforceable after EU exit so that existing levels of public health protection and food safety are maintained in this area. The geographical scope of the Regulations is being maintained so that food which had a history of consumption in Member States of the EU and so could continue to be marketed within the EU without requiring to be authorised, would not become novel and require authorisation to be sold in the UK when the UK exits the EU.
- 2.6 The authorisations will continue to be generic with data protection being available when the associated criteria are met. Maintaining the equivalent processes to those of the EU, will allow businesses to be able to produce one set of data which can be used for both the UK and the EU novel food processes reducing the burden on businesses seeking to market novel foods in the UK.

### **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 The European Union (Withdrawal) Act 2018 (‘the Act’).) The instrument is being enacted under powers afforded by section 8 of the Act to correct deficiencies in the retained legislation and the territorial application of this instrument is not limited either by the Act or by the instrument.

### **4. Extent and Territorial Application**

- 4.1 The territorial extent of this instrument covers the entire United Kingdom
- 4.2 With the exception of regulations 2 and 3, which concern the Novel Foods (England) Regulations 2018, and which apply in England only, the territorial application of this instrument covers the entire United Kingdom.

## **5. European Convention on Human Rights**

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

“In my view the provisions of The Novel Food (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 exit day. 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 the retained legislation and the safeguards it provides to operate effectively following the UK’s exit from the EU.

6.2 This instrument amends the EU Regulation which came into force on 1 January 2018. The EU Regulation set down the legal requirements that apply to novel foods placed on the market in the UK. Under the EU Regulation a novel food is a food which hadn’t been placed on the market in the UK or the EU prior to 15 May 1997. The EU Regulation has four associated implementing acts which are retained EU legislation with that Regulation. They are:

- Regulation (EU) 2017/2469 laying down administrative and scientific requirements for applications;
- Regulation 2017/2468 laying down administrative and scientific requirements concerning traditional foods from third countries;
- Regulation (EU) 2017/2470 establishing a Union list of novel foods; and
- Regulation (EU) 2018/456 on the procedural steps of the consultation process for the determination of novel food status.

6.3 The implementation acts establish the list of novel foods and outline processes provided for in the EU Regulation such as the authorisation of novel foods and the assessment of whether a food is subject to the Regulation.

6.4 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**

7.1 Novel foods are foods which have no significant history of consumption in the European Union prior to 15 May 1997. The EU Regulations requires novel foods to undergo a safety assessment as part of the authorisation process before they are permitted to be placed on the market anywhere within the EU. This supports access to safe food innovation and maintaining consumer confidence in food innovations entering the market.

7.2 The EU Regulation is implemented by four acts listed in Section 6.2, which; legislate for the administrative procedure and scientific data required in applications for novel food authorisations and authorisations for traditional foods from outside Europe; establish a list of novel foods which have been authorised and can be placed on the

UK market; and to legislate for a consultation process to enable businesses and others to confirm whether their product requires authorisation, through a process to produce a definite ruling as to whether a food is novel or not.

- 7.3 The Instrument is legally important as it provides the basis for managing new foods and ensuring new foods entering the market are safe. The EU Regulation will be retained in UK law when the UK exits the EU. As the EU legislation refers to procedures involving EU institutions, geographical area and Member States the EU Legislation will become inoperable when the UK exits the EU. This SI fixes these deficiencies so that the EU Regulation remains effective and enforceable; maintaining the definition of a novel food and that novel foods have a safety assessment before they are allowed onto the UK market.
- 7.4 The reason for including the ‘EU’ in the definition of novel foods is to maintain the status quo. If the EU was not in the definition existing foods with a history of consumption prior to May 1997 in the EU, but which didn’t have a history of consumption in the UK (e.g. Kiwi berries where the history of consumption is based solely on consumption in Poland) would become novel overnight when the UK leaves the EU and the foods would have to be withdrawn from the UK market until they were authorised as novel foods. It is important for the maintenance of trade relationships both with Europe and with the rest of the world that food/food ingredients, which are not considered unsafe, are not withdrawn and important to UK consumers that consumer choice is maintained.

## **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 Novel 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<sup>1</sup> 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<sup>2</sup>. 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

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<sup>1</sup> Please note the familiarisation time has been amended from less than 30 to less than 60 minutes following consultation feedback.

<sup>2</sup> Wage rate taken from the ONS' 2017 Annual Survey of Hours and Earnings (ASHE), table 14.6a.

Food 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.

### **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 Alison Asquith at the Food Standards Agency. Telephone: 0207 276 8596 or email: Alison.Asquith@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 Novel 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 novel 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.