EXPLANATORY MEMORANDUM TO

THE GENETICALLY MODIFIED FOOD AND FEED (AMENDMENT ETC.) (EU EXIT) REGULATIONS 2019

2019 No. 705

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 Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 are being made under Section 8(1) of the European Union (Withdrawal) Act 2018 to ensure the effective functioning of retained EU law concerning genetically modified (GM) food and animal feed ('feed') in the UK after EU Exit.

2.2 The instrument amends the following retained EU law to correct deficiencies that arise as a consequence of the UK's exit from the EU: Regulation (EC) No. 1829/2003 (framework regulation on genetically modified food and feed); Commission Regulation (EC) No 641/2004 (detailed rules on applications for authorisation of new GM food and feed and adventitious or technically unavoidable presence of authorised GM material, and 68 Commission Decisions authorising GM food and/or feed events for placing on the market, or withdrawing such authorisations and providing transitional arrangements which will be extant when the UK exits the EU.

2.3 The instrument also revokes Commission Regulation (EC) No 1981/2006 (detailed rules regarding the Community reference laboratory for GM organisms) which will become redundant when the UK exits the EU.

2.4 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 GM Food and Feed policy and legislation.

Explanations

What did any relevant EU law do before exit day?

2.5 The EU law is part of a regulatory framework which aims to protect human and animal health and the environment. It provides a harmonised regulatory framework including transparent and time-limited procedures for risk assessment and authorisation of GM food and feed. The authorisation process involves a safety evaluation based on rigorous scrutiny of scientific data by the European Food Safety Authority (EFSA) in line with international guidelines. GM events for food/feed use are authorised by means of EU Decisions. Authorisations are granted for a period of 10 years and the EU law sets down a process and requirements for renewal of authorisations for further 10-year periods and provides for the withdrawal of authorisations in appropriate circumstances.

2.6 The EU law requires that all authorised GM food and feed must have a method of detection scientifically assessed and validated by the European Union Reference

Laboratory (EU-RL), also known as the Community Reference Laboratory (CRL), in collaboration with the European Network of GMO Laboratories (ENGL). The EU-RL is also responsible for distributing control samples to Member States' National Reference Laboratories (NRLs). The EU law requires post-market monitoring of the environment in respect of authorised GM food/feed and provisions for action to be taken should any adverse effect be identified.

2.7 The EU law also sets down labelling and traceability requirements for authorised GM food and feed placed on the market. Business-to-business labelling and traceability requirements ensure that food/feed businesses operators are clear that they are handling or using GM food/feed and help them comply with the legislation along the food/feed chain and assist authorised officers in ensuring compliance with the legislation. Product labelling and information at the point of sale provides consumers with information to enable them to make informed choices.

Why is it being changed?

2.8 The minor and technical amendments the instrument makes to retained EU law correct deficiencies that arise as a consequence of the UK exiting the EU. These deficiencies relate to the assignment of functions to EU institutions and processes to which the UK will no longer have access, or can no longer rely on, after UK's exit from the EU.

2.9 The instrument assigns roles and responsibilities currently undertaken by the European Commission, EFSA or EU/Community Reference Laboratories to an appropriate UK entity, i.e. 'the appropriate authority' (defined as ministers in the four countries of the UK), 'the food safety authority" defined as the Food Standards Agency (FSA) in respect of England, Wales and Northern Ireland and Food Standards Scotland (FSS) in respect of Scotland) or the UK reference laboratory. It also replaces references to 'Community' and 'Community law' respectively with references to 'United Kingdom' and 'retained EU law'.

2.10 Not to make these changes would mean that certain elements of the retained EU law will not operate effectively following the UK's exit from the EU.

What will it now do?

2.11 The retained EU law will remain operable and enforceable after EU exit so that existing levels of public and animal health protection and food safety are maintained in this area. Maintaining GM food and feed application processes similar to those of the EU means that supporting scientific data can be utilised for both UK and EU applications, reducing the burden on business.

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 instrument includes Scotland and Northern Ireland.

3.3 The powers under which the instrument is made cover the entire United Kingdom (see section 24 of the European Union (Withdrawal) Act 2018) and the territorial application of the instrument is not limited either by the Act or by the instrument.

4. Extent and Territorial Application

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

4.2 With the exception of regulations 2 and 3, which relate to the Genetically Modified Food (England) Regulations 2004, and apply in England only, the territorial application of this instrument is 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 MP, has made the following statement regarding Human Rights:

"In my view the provisions of The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 are compatible with the Convention rights."

6. Legislative Context

6.1 The European Union (Withdrawal) Act 2018 (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. Sections 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 Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations amend retained EU law detailed in paragraph 2.2 above.

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 No substantive policy changes are being introduced by the instrument; the policy objective is to maintain existing laws. Continued alignment with EU GM standards will ensure that GM food and feed is only authorised for sale if they are judged: (a) not to present a risk to health (b) not to mislead consumers (c) not to have less nutritional value than their non-GM counterpart(s). Regulatory alignment will also help facilitate trade with the EU after Exit by eliminating non-tariff barriers to trade.

7.2 To ensure the seamless continuation of a robust scientific assessment and pre-market authorisation system for GM food and feed after EU Exit, it is necessary that existing EU regulations are retained in an operable form in UK law. The Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 will help to deliver continued protection for human and animal health.

7.3 The following key changes introduced by the instrument will ensure that the legislation remains operable after the UK exits the EU:

- The European Food Safety Authority (EFSA) is currently responsible for undertaking safety evaluations of GM food and feed intended for placing on the market ('risk assessment'). The instrument assigns this responsibility to the 'Food Safety Authority', defined as the Food Standards Agency (FSA) in England, Wales and Northern Ireland and, in Scotland, Food Standards Scotland (FSS).
- The European Commission, assisted by the EU Standing Committee on the Food Chain and Animal Health comprising the Member States, is currently responsible for making legislative changes including authorisations and withdrawal of authorisations. The instrument assigns this responsibility to the 'appropriate authority', defined as the Secretary of State, the Welsh Ministers, the Scottish Ministers and the Northern Ireland devolved authority and provides them with the power to make regulations.
- The instrument assigns functions currently undertaken by the European Commission concerning the administrative work necessary under this regulatory regime to the Food Safety Authority and functions currently undertaken by the EURL/CRL to the UK Reference Laboratory and removes references to ENGL.

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

8.1 The 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 exiting the EU. The instrument is being enacted on a UK wide basis. Amendments made through the 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 The instrument does not consolidate existing law, EU or UK.

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 Genetically Modified Food and Feed (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 the instrument as it generally maintains existing requirements and does not introduce new ones.

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

[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.

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 exits 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 The approach to monitoring of this legislation will depend on what deal is reached between the United Kingdom and the European Union.

14.2 As the instrument is made under the European Union (Withdrawal) Act 2018, no review clause is required.

15. Contact

15.1 Colin Clifford at the Food Standards Agency. Telephone: 020 7276 8584 / E-mail: colin.clifford@food.gov.uk can be contacted with any queries regarding the instrument.

15.2 Michael Wight, Director of 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 of 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 Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019 does no more than is appropriate". The [Title of Minister, name] has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

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 the 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 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.