EXPLANATORY MEMORANDUM TO

THE FOOD AND FEED HYGIENE AND SAFETY (MISCELLANEOUS AMENDMENTS ETC.) (EU EXIT) REGULATIONS 2020

2020 No. [XXXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by the Food Standards Agency (FSA) and is laid before Parliament by Command of Her Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 The Food and Feed Hygiene and Safety (Miscellaneous Amendments etc.) (EU Exit) Regulations 2020 ("the instrument") is made under powers in the European Union (Withdrawal) Act 2018.

2.2 The purpose of this instrument is to:

- implement the Protocol on Ireland/Northern Ireland ("NIP") by amending or revoking the 17 EU Exit instruments in the field of food and food safety to apply to Great Britain only, and additional instruments made in respect of Northern Ireland;
- address a range of remaining deficiencies in retained EU law ("REUL") in the field of food and feed safety and hygiene to ensure the operability of REUL at the end of the Implementation Period, and to take account of EU law that has come into force since the 17 EU Exit instruments were made.

Explanations

What did any EU law do before exit day

2.3 EU food and feed law provided a high level of consumer protection with regard to food and feed hygiene and safety. In particular, EU food and feed law set out the general principles for the hygienic production of food and feed and the effective and proportionate controls which must be applied by food business operators and feed business operators throughout the food chain from primary production through to the sale or supply to the final consumer. It continued to apply unchanged during the Implementation Period.

Why is it being changed?

2.4 The changes introduced by this instrument are primarily being made in order to reflect the NIP in the field of food safety and hygiene. This instrument amends or revokes 16 of 17 EU Exit SIs made in 2019, and also revokes some instruments that were made specifically in relation to Northern Ireland (see regulation 21(a) and (f) of this instrument).

2.5 These amendments and revocations are necessary to ensure that the UK's obligations under the NIP are met and that EU food and feed safety legislation remains directly

applicable in Northern Ireland (NI), as required by Annex 2 of NIP, for as long as the NIP remains in force.

2.6 This instrument also amends relevant retained EU food and feed safety legislation in order to reflect amendments to EU food law during the Implementation Period provided for under the terms of the Withdrawal Agreement, most notably Regulation (EU) 2020/1158 and various EU decisions relating to genetically modified food and feed.

2.7 This instrument will make some revocations and amendments to existing EU Exit regulations in light of Regulation (EU) 2017/625 coming into force and tertiary legislation made under it. The amendments to retained Regulation (EU) 2017/625 and associated tertiary legislation will be taken forward in separate instruments led by Defra.

What will it now do?

2.8 A number of notable changes are made as detailed in section 7 of this explanatory memorandum. The changes do not affect the essence of the legislation but will ensure that it is operable at the end of the Implementation Period to apply in Great Britain and provides a smooth transition for businesses.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This instrument corrects minor errors previously reported by the JCSI in respect of the Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019.

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 varies between the provisions of the instrument.

4. Extent and Territorial Application

4.1 Part 2 of this instrument applies to England but extends to the law of England and Wales.

4.2 Parts 3 and 4 of this instrument apply and extend to the law of England and Wales and Scotland.

4.3 The application and extent of Part 5 is the United Kingdom, except in relation to regulations 21(a) and (f) which apply and extend to Northern Ireland only.

5. European Convention on Human Rights

5.1 The Minister of State for Health, Edward Argar MP has made the following statement regarding Human Rights:

"In my view the provisions of the Food and Feed Hygiene and Safety (Miscellaneous Amendments etc.) (EU Exit) Regulations 2020 are compatible with the Convention rights."

6. Legislative Context

6.1 Sections 8(1) and 8C(1) of, and paragraph 7 of Schedule 4 and paragraph 21 of Schedule 7, to the European Union (Withdrawal) Act 2018 enable UK Ministers to implement the NIP and fix deficiencies in REUL enabling retained legislation and the safeguards it provides to operate effectively following the end of the Implementation Period.

7. Policy background

What is being done and why?

7.1 This instrument provides necessary amendments to EU Exit instruments to ensure they fully implement the NIP. It also includes amendments to take account of recently adopted EU regulations and to amend other regulations that have not been brought forward previously with other EU Exit instruments since those instruments were laid. This instrument amends or revokes 16 out of the 17 food and feed safety EU Exit instruments previously made[1].

7.2 The changes listed below are made frequently throughout the 16 EU Exit instruments being amended:

- Functions currently undertaken by the European Commission in reviewing and making changes to legislation will in the future, be the responsibility of the 'appropriate authority':
- "appropriate authority" means –
  a) in relation to England, the Secretary of the State;
  b) in relation to Wales, the Welsh Ministers;
  c) in relation to Scotland, the Scottish Ministers;
- In Northern Ireland EU law listed in Annex 2 of the NIP will continue to apply. It is therefore appropriate to amend the definition of "appropriate authority" in REUL to remove references to Northern Ireland.
- Under REUL, the "Food Safety Authority" will have a role in providing food and feed safety advice to the appropriate authority. The "Food Safety Authority" means
  a) as regards England and Wales, the FSA
  b) as regards Scotland, Food Standards Scotland.

7.3 The European Food Safety Authority (EFSA) conducts assessments and provides advice in relation to food and feed hygiene and safety. After the end of the Implementation Period, this instrument will designate the role previously undertaken by EFSA to the Food Safety Authority which, in respect of England and Wales, will be the FSA and, in respect of Scotland, will be Food Standards Scotland. It is, therefore, appropriate to amend the definition to remove references to Northern Ireland.

7.4 In addition, this instrument makes the following notable changes to sector specific EU Exit instruments and retained EU law:

[1] See the Annex in the following link for a full list of all 17 EU Exit SIs - https://www.food.gov.uk/news-alerts/consultations/amendments-to-retained-eu-law-for-food-and-feed-safety-and-hygiene-for-the-end-of-the-transition-period .

Northern Ireland Protocol (NIP)

7.5 The NIP forms part of the Withdrawal Agreement and comes into effect at the end of the Implementation Period. One of the requirements of the NIP is that manufactured goods such as food and feed placed on the NI market will need to comply with EU law. The provisions of EU law listed in Annex 2 of the NIP and any legislation made under those provisions will be directly applicable to NI. When the original EU Exit SIs were made, they included provisions to ensure the NI statute book remained operable. This instrument gives effect to the NIP by ensuring retained EU law only applies to Great Britain, by removing reference to NI authorities and revoking corrections previously made to NI domestic legislation in the EU Exit SIs made previously. The Food and Feed Safety and Hygiene (Miscellaneous Amendments) (EU Exit) Regulations 2019 are also being revoked as many of the amendments being made in that SI were made in respect of Northern Ireland.

Official Controls

7.6 Official controls verify compliance with feed and food law and are performed by competent authorities such as the FSA or the Animal and Plant Health Agency (APHA). The new Official Controls Regulation (Regulation (EU) 2017/625) applied from 14 December 2019. It revoked the previous EU official controls legislative framework in Regulation (EC) 882/2004, which was amended by The Official Feed and Food Controls (EU Exit) Regulations 2019 ("the 2019 Regulations"). This instrument will revoke the 2019 Regulations as they are now largely obsolete. As explained above, the amendments to the new official controls Regulation will be dealt with under instruments made by Defra, but this instrument will make amendments to deficiencies contained in England only domestic legislation in the area of official controls (see Part 2 of this instrument).

Contaminants in food

7.7 As well as amendments in respect of the NIP, this instrument fixes additional inoperabilities in light of a recent amendment to the EU law relating to chemical contaminants. The UK was previously included in a list of Member States with a derogation allowing higher levels of polyaromatic hydrocarbons in some traditionally smoked food. Following a review of this issue by the European Commission the UK indicated that the derogation was no longer needed and the provision has been updated in EU law and the UK is no longer listed. The relevant provisions are therefore no longer relevant in the retained EU law at the end the Implementation Period and can be omitted.

Specific Food Hygiene

7.8 This instrument will fix additional inoperabilities in retained direct EU legislation and allow for the words "United Kingdom" or the abbreviation 'UK' to be used on health and identification marks. It also allows for the use of the abbreviation 'GB' as this is the International Organisation for Standardisation (ISO)'s two letter country code for the United Kingdom.

7.9 This amendment maintains the provision that when farmed ratites and certain farmed game ungulates are slaughtered on farm in a region under health restrictions, the carcase is to be accompanied by a certificate signed by an official or approved veterinarian when it is being transported to an approved establishment. The amendment clarifies that a derogation, which allows for information on the slaughter

process to be included in a declaration instead of the certificate, does not apply where restrictions are in place. The definition of 'region' in Directive 64/432/EC, referred to in EU law for this provision, is inserted and updated.

7.10 The amendments made in 2019 to Regulation (EU) 2015/1375 on Trichinella in The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (EU Exit) Regulations 2019 are, as a consequence of revoking those Regulations, brought into this instrument unchanged except for minor amendments to reflect the NIP.

7.11 This instrument fixes inoperabilities relating to certification requirements in Regulation (EU) 2016/759 for the transit through GB of certain raw materials and treated raw materials for the production of gelatine and collagen intended for human consumption bound for a third country and provides for model certificates to be published on a website.

7.12 This instrument also amends Regulation (EU) 2017/185 which provides for transitional measures for the application of certain provisions for the import of products containing both products of plant origin and processed products of animal origin.

General Food Law

7.13 This instrument makes provision for a transitional period in the domestic Food Safety and Hygiene (England) Regulations 2013 allowing for products of animal origin carrying a 'UK/EC' identification mark to continue to be placed on the England market after Implementation Period completion day for a period of up to 21 months, provided the operator is exhausting existing labels and packaging with the UK/EC mark owned by that operator before the end of the Implementation Period. This measure reduces the impact of costs to industry in that it allows pre-printed labels, wrapping or packaging to be used on the market in England. Similar provision is expected to be introduced in Wales and Scotland.

7.14 The amendments to the General Food Law also reinstate the emergency powers under Article 53 of the Regulation (EC) 178/2002 which had been omitted previously.

Animal Feed

7.15 This instrument will allow for the replication of EU interim arrangements for importing animal feed into Great Britain at the end of the Implementation Period. This will include the use of representatives whose role is to provide assurance that a non-UK establishment complies with applicable legislation in Great Britain. In addition, this instrument will reinstate the definitions of 'food producing animal' and 'pet' or 'pet animal' that are currently in EU legislation to ensure they are operable in respect of Great Britain after the end of the Implementation Period.

Food and Feed Imports

7.16 The definition of "third country" (as with other definitions contained in the EU Exit Regulations) is being amended to exclude the Crown Dependencies from being included as a third country for imports and other purposes.

Chernobyl and Fukushima restrictions

7.17 The amendments in Part 4 of this instrument will fix the inoperabilities in retained direct EU legislation relating to controls on the import of food and feed from

countries known to have levels of radioactive contamination that are potentially detrimental to public health. These countries are non-EU and non-EEA countries which were affected by the Chernobyl nuclear accident and regions of Japan which were affected by the Fukushima nuclear accident. Regulation 2019/1787 amended Regulation 2016/6 on special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station. Regulation 2020/1158 replaces Regulation 733/2008 (which expired on the 31 March 2020) and Regulation 1635/2006 on special conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station. As a result of these amendments, the Food and Feed (Chernobyl and Fukushima Restrictions) (Amendment) (EU Exit) Regulations 2019 should now be revoked, and the amendments to the relevant retained EU law will be contained in Part 4 of this instrument.

Food Contact Materials

7.18 There is a minor amendment to Article 15(4) of Regulation (EC) 1935/2004, to reflect the specific labelling requirements of placing or trading a food contact material or article within the UK market. It should no longer be defined as broadly as for placing or trading within the EU market, therefore specific labelling requirements will be made clearer by stipulating that the language is presented in English, or English and Welsh, or similar.

Genetically Modified food and feed Including EU Decisions relating to Genetically Modified (GM) Food and Feed

7.19 The EU authorisation decisions which have come into force between the laying of the Food and Feed Hygiene and Safety (Miscellaneous Amendments) (EU Exit) Regulations 2019 and the end of the Implementation Period will become retained EU law on IP completion day. Such decisions and the inoperabilities in retained EU law, need to be fixed. This instrument will ensure that GM food/feed authorised in the EU before the end of the Implementation Period will be authorised, and available for use, in the UK at the end of the Implementation Period. Corrections to the retained Decisions are necessary to make them fully operable.

7.20 This instrument amends Article 44 of Regulation 1829/2003 to assign administrative responsibilities currently undertaken by the European Commission in relation to obligations under the Cartagena Protocol to the Food Safety Authority. Whilst these amendments are desirable for legislative clarity, they do not have any substantive effect given that the UK is a party to the Protocol in its own right and must, after the end of the Implementation Period, fulfil its obligations under the Protocol regardless.

Smoke flavourings

7.21 EU Regulation 2019/1243 came into force after the laying of the Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 and amended procedures in several pieces of EU legislation including Regulation (EC) 2065/2003 on smoke flavourings to reflect new procedures. This instrument makes necessary amendments to retained EU law to reflect how EU law has changed since the coming into force of Regulation 2019/1243.

8. European Union (Withdrawal) Act 2018/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 EU. This instrument is being enacted on a UK wide basis. Amendments made through this instrument will enable retained EU 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 This instrument does not involve consolidation and there are no plans to consolidate the relevant legislation at this time.

10. Consultation outcome

10.1 Article 9 of Regulation (EC) No. 178/2002 provides that there must 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 in respect of the amendments made in this instrument.

10.2 The FSA consulted on the proposed approach to retained EU law ("REUL") for food and feed safety and hygiene in respect of the UK's exit from the EU between 4 September 2018 and 14 October 2018.

10.3 The consultation received 50 responses from interested parties across a wide range of sectors with an interest in the consultation. A significant proportion 82% supported or did not disagree with the proposed approach being outlined within the consultation

10.4 A further full consultation which provided an update on the approach was carried out form 20 August 2020 to 16 September 2020. The consultation received 7 responses from interested parties, a significant proportion 71% supported the proposed approach being outlined within the consultation. 29% of replies had mixed comments. Further analysis of these will be undertaken.

10.5 The combined consultations demonstrate in significant support for the FSA's proposed approach to amendments to Retained EU Law for Food and Feed Safety and Hygiene.

10.6 A copy of the consultation is available here https://www.food.gov.uk/news-alerts/consultations/amendments-to-retained-eu-law-for-food-and-feed-safety-and-hygiene-for-the-end-of-the-transition-period.

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 According to the ONS Inter Departmental Business Register (IDBR) there were about 220,000 businesses active in the agri-food sector in 2019. The FSA envisages minimal

one-off familiarisation costs to business; where we estimate that it will take each business an hour to read and understand this instrument 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' day to day operations as the rules are not changing as a result of this instrument.

12.2 In terms of the impact on the public sector, there are approximately 419 Local Authorities (LAs) and 22 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 end of the Implementation Period. The FSA envisages minimal one-off familiarisation costs to LAs and PHAs; where we estimated that it will take authorities an hour to familiarise themselves with this instrument 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.

12.3 This instrument is not considered to add additional or new burdens on enforcement bodies, other than those identified here.

12.4 An impact assessment has not been produced for this instrument, which the FSA has certified as being below the *de minimis* threshold of +/- £5m equivalent annual net direct cost to business. This instrument is designed only to fix the inoperability of retained EU legislation (detailed in Section 6) and ensure the continued safety of food and feed at the end of the Implementation Period. This instrument provides 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 The UK food industry sector is comprised of mainly small and micro businesses (generally greater than 90%) 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 No specific action is proposed to minimise regulatory burdens on small businesses from this legislation, which should not have any disproportionate negative impact on small businesses.

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

14. Monitoring & review

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

15. Contact

15.1 Karen Pratt at the Food Standards Agency email: Karen.pratt@food.gov.uk can be contacted with any queries regarding the instrument.

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

15.3 Edward Argar MP, Minister of State for Health 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 Equality 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 2018 SIs.	Explain the instrument, identify the relevant law before the end of the Implementation Period, 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 retained EU 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 s. 2(2) ECA 1972	Paragraph 13, Schedule 8	Anybody making an SI after the end of the Implementation Period under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA 1972.	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA 1972, identifying the relevant law before the end of the Implementation Period, 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 the end of the Implementation Period, under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA 1972.	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 Edward Argar MP (Minister of State for Health, Department of Health and Social Care) has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view the Food and Feed Hygiene and Safety (Miscellaneous Amendments) (EU Exit) Regulations 2020 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 resolves matters regarding the NIP. It adds no additional legislative measures.

2. Good reasons

2.1 Edward Argar MP (Minister of State for Health, Department of Health and Social Care) has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action".

2.2 These are: because the legislation will enable a smooth transition at the end of the Implementation Period for businesses and provide appropriate provision to enable the implementation of the NIP.

3. Equalities

3.1 Edward Argar MP (Minister of State for Health, Department of Health and Social Care) has made the following statement(s):

"The draft instrument does not amend, repeal or revoke a provision or provisions in the Equality Act 2006 or the Equality Act 2010 or subordinate legislation made under those Acts.".

3.2 Edward Argar MP (Minister of State for Health, Department of Health and Social Care) has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the draft instrument, I, Edward Argar, 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.