EXPLANATORY MEMORANDUM TO

THE FOOD AND FEED SAFETY (MISCELLANEOUS AMENDMENTS AND TRANSITIONAL PROVISIONS) REGULATIONS 2021

2021 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 Safety (Miscellaneous Amendments and Transitional Provisions) Regulations 2021 are made under powers in the Food Safety Act 1990 and the European Union (Withdrawal) Act 2018.

2.2 The purpose of this instrument is to:

- amend Article 53 of the retained General Food Law to correct a deficiency that has arisen as a result of the Northern Ireland Protocol. The amendment will ensure that the emergency measures that may be applied where a serious risk to health is identified can be applied to all goods entering into GB;
- amend the authorisation provisions for feed additives and GM food/feed, so that the decisions made by Ministers will be enacted through legislation making these consistent with other retained EU food and feed law; and
- provide a time limited period of adjustment, up until 30 September 2022, for businesses to meet new UK address labelling requirements for certain food products. This would allow businesses to use up old labelling stocks, without facing enforcement action for failure to label affected products with a UK address during this time.

Explanations

What did relevant EU food and feed law do before exit day and during the Transition Period?

2.3 Relevant EU food and feed law provided a high level of consumer protection with regard to food and feed hygiene and safety. In particular, relevant EU food and feed law set out the general principles for the safe and hygienic production of food and feed. They also prescribed 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 Transition Period.

Why is it being changed?

2.4 The changes introduced by this instrument are being made to-

- correct an operability issue under retained EU law (REUL). The correction will enable Ministers to take action to address third country goods coming into

GB via Northern Ireland where a serious risk to human health has been identified with those goods;

- clarify that any Government decision to authorise feed additives and GM food/feed will be issued through legislation; and
- provide a time limited period of adjustment for businesses to move from EU to UK address labels for quick-frozen foods and extraction solvents when these are traded between businesses. Up until 30 September 2022, businesses will not face enforcement action if products are labelled with old EU addresses. This will allow businesses to use up stocks of old address labels on these products whilst adjusting to the new requirements.

What will it now do?

2.5 The amendments to Article 53 do not change the purpose or function of the provision. The amendments ensure that emergency measures for the control of food and feed may be applied in all circumstances where a serious risk to health has been identified.

2.6 The changes will also ensure that appropriate legislative provision is in place to enable the authorisation of GM food/feed and feed additives and provide a smooth transition for businesses adjusting to new labelling requirements.

2.7 The changes are detailed in paragraph 7.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 Regulations 2 and 3 come into force on the day after the day on which these Regulations are made, and so breach the 21-day rule. They provide for a transitional period of adjustment for products with labels that complied with the requirements before IP completion day. Accordingly, they do not impose a duty on people that is more onerous than before.

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 Part 3 of this instrument applies and extends to the law of England and Wales, and Scotland.

5. European Convention on Human Rights

5.1 The Parliamentary Under-Secretary of State for Prevention, Public Health and Primary Care at the Department of Health and Social Care Jo Churchill has made the following statement regarding Human Rights:

"In my view the provisions of the Food and Feed Safety (Miscellaneous Amendments and Transitional Provisions) Regulations 2021 are compatible with the Convention rights."

6. Legislative Context

6.1 Sections 16(1)(a), (c) and (e), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990 enable UK Ministers to make transitional provisions (regulations 2 and 3).

6.2 Section 8(1)(b) of, and paragraph 21 of Schedule 7, to the European Union (Withdrawal) Act 2018 enables UK Ministers to fix deficiencies in REUL enabling retained legislation and the safeguards it provides to operate effectively following the end of the Implementation Period (regulations 5 and 6). Section 8C(1) of that Act enables UK Ministers to make regulations for the purposes of dealing with matters arising out of, or related to, the Northern Ireland Protocol (regulation 4).

7. Policy background

What is being done and why?

7.1 This instrument makes necessary amendments to Article 53 of retained EU law Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, to address an operability issue that inhibited the application of emergency measures in all circumstances. The amendment means that, where food or feed entering GB through any route, including Northern Ireland, is identified as likely to constitute a serious risk to human health, emergency measures may be taken to control the entry of those goods (regulation 4).

7.2 It amends the REUL concerning feed additives (Regulation (EC) No. 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition) and concerning GM food/feed (Regulation (EC) No. 1829/2003 of the European Parliament and of the Council on genetically modified food and feed), to clarify that any decision to authorise these products will be enacted through legislation (regulations 5 and 6).

7.3 It also provides periods of adjustment for businesses to meet new UK address labelling requirements by amending the relevant legislation for quick frozen foods (The Quick-frozen Foodstuffs (England) Regulations 2007) and for extraction solvents placed on the market in England (The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013) (regulations 2 and 3). Provision for these periods of adjustment have been made in Scotland and will shortly also be provided in Wales.

7.4 This instrument makes the following notable changes to retained EU law:

Emergency powers for the control of food and feed identified as likely to constitute a serious risk to health:

7.5 An analysis of the emergency powers for the control of food and feed identified an operability issue that inhibited a GB Minister from introducing emergency controls on goods identified as presenting a serious threat to human health, from entering GB in every circumstance. The operability issue prevented exercise of those emergency control powers where third country goods, identified as presenting a serious threat to human health, entered GB via NI.

7.6 The amendment to Article 53 of the retained EU Regulation No. 178/2002 corrects this operability issue by permitting GB Ministers to access, in all circumstances, the emergency powers available in REUL. The Article 53 amendment ensures uniform application of emergency measures for food and feed and that NI is treated on par with other parts of the UK. It means that GB Ministers may apply the food and feed safety controls equally across all parts of the UK in the event that emergency measures are required.

Authorisation of feed additives and of GM food and feed:

7.7 The intention for all regulated food and feed products is that authorisations for each product will be enacted through a statutory instrument. A recent FSA review of the REUL identified that the texts within the legislation governing the use of feed additives and GM food/feed lacks sufficient clarity and does not expressly state that authorisation decisions will be given effect in legislation. As a consequence, it will be difficult for competent authorities to enforce any conditions that are put in place to regulate the use of the products concerned without the statutory basis for that authorisation decision and the conditions attached to it. An amendment is needed so that Ministers have the express authority to prescribe their decisions through legislation, ensuring they are legally enforceable.

7.8 As these changes necessitate GB wide amendment of the REUL, consent of the devolved administrations has been acquired.

Periods of adjustment for food labelling changes:

7.9 In preparation for the end of the Implementation period, legislation governing the use of extraction solvents and quick-frozen foods was updated to change the territorial scope of address requirements from the EU to the UK. When these products are traded between businesses in England, the labels or documents that accompany them must now provide the name and UK address of the legal person responsible for them. Failure to meet this requirement can result in enforcement action being taken against the food business. The FSA considers it is appropriate to provide affected businesses with a period of adjustment, up until 30 September 2022, to meet the changed labelling requirement through this instrument. This would provide businesses with ample time to adjust and use up existing stocks of labels and packaging and would be consistent with approaches for wider food labelling changes being taken—maintaining a consistent approach across GB.

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(1) and 8C of the European Union (Withdrawal) Act 2018. Section 8(1) 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. Section 8C(1) of that Act enables UK Ministers to make regulations for the purposes of dealing with matters arising out of, or related to, the Northern Ireland Protocol 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.

10.2 A full public consultation was carried out from 4 September until 14 October 2018 on the proposed approach to REUL for food and feed safety and hygiene. The consultation received 50 responses. Of these, 82% supported or did not disagree with the proposed approach being outlined by the Food Standards Agency and 16% contained mixed comments.

10.3 The main concerns raised were relating to the communication of change and ensuring sufficient lead time is given. The consultation and 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

10.4 A further public consultation was carried out from 20 August until 16 September 2020 on further amendments to UK food and feed regulations, including those necessitated by the application of the Withdrawal Agreement and the Northern Ireland Protocol. The consultation received 7 responses from interested parties. A significant proportion (71%) supported the proposed approach being outlined within the consultation whilst 29% of replies had mixed comments. The consultation and responses can be found 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

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 **Emergency powers for the control of food and feed identified as likely to constitute a serious risk to health**: A public consultation was carried out in August 2020 on amendments to REUL including those necessitated by the application of the Withdrawal Agreement and the Northern Ireland Protocol as detailed above.

10.7 **Authorisation of feed additives and of GM food and feed:** A public consultation was carried out in September 2018 on the proposed approach to REUL for food and feed safety and hygiene as detailed above. The amendments included within this instrument will affect a further necessary technical amendment that falls within the scope of the earlier 2018 consultation, as they are required to ensure that the statute book remains operable and public health is protected.

10.8 **Periods of adjustment for food labelling changes:** The FSA has considered information gathered by Defra in its public consultation on the same change to food labelling requirements for pre-packed foods, and responses to two FSA public consultations in 2018 on health and ID marks across England, Wales and Northern Ireland. Defra's public consultation on food labelling was carried out over the 4 weeks up to the 4th December 2018. A Government response was issued on the 5th February 2019. The two FSA consultations took place in the two weeks up to 7 Aug 2018 and

then in the four weeks up to 8 Oct 2018. A combined response to both was issued on 27 November 2018.

10.9 A wider public consultation was not conducted as it would be unlikely to provide further insight in addition to the information already gathered as the UK address labelling changes do not affect information provided to the public.

10.10 Feedback from the FSA consultations on Health and ID marks was extensive with a key issue for industry being whether a transitional period would be provided for using up stock of old packaging still bearing the old 'EC' identification mark as any non-compliant packaging would need to be destroyed bringing a high disposal cost and potential environmental impact. A period of 12-24 months was indicated as sufficient time to use up stocks of packaging. Specific responses indicated that frozen produce could have a shelf life of at least two years. There may, therefore, already be a large volume of produce already manufactured pending dispatch as businesses plan frozen stock years in advance. The Defra consultation evidenced broad consensus for periods of adjustment of between 6 -24 months so that businesses can manage smooth transition to the necessary changes to labelling information brought on by EU Exit.

10.11 The information gathered indicates that the average costs of mandatory labelling changes per stock-keeping unit for a food business can range from £2000 - £2945, and that food businesses generally hold between 3 and 9 months of packaging/labelling in stock. Overall, whilst a formal assessment of impact was not carried out, the FSA considers there is sufficient evidence to support the need for periods of adjustment.

10.12 In light of this, the FSA considers it appropriate to provide a 21 month 'grace period' for businesses placing affected goods on the market in England. This aligns to the approach being taken in other parts of GB for these products as well as that being taken by Defra for the same change to address label requirements for pre-packed foods.

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. The FSA intends to issue targeted messaging to enforcement officers in local authorities and port health authorities, so they are promptly made aware of the Government's intentions on the periods of adjustment.

12. Impact

12.1 According to the ONS Inter Departmental Business Register (IDBR), there are about 220,000 businesses active in the agri-food sector. The Food Standards Agency envisages negligible one-off familiarisation costs for businesses when being notified about the extension of the period to meet labelling requirements. The amendments related to the exercise of Ministerial empowerments are not foreseen to present a direct impact on businesses.

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 Transition Period. The Food Standards Agency envisages minimal one-off familiarisation costs to LAs and PHAs, where we estimate that it will take authorities an hour to familiarise themselves with the amendments being made to REUL and

domestic enforcement legislation, 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 The 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 these Regulations which the Food Standards Agency has certified as being below the *de minimis* threshold of +/- £5m equivalent annual net direct cost to business. The Regulations are designed only to amend elements of retained EU legislation (detailed in Section 7) that relate to the exercise of Ministerial empowerments and provide a 'grace period' for business thereby supporting the continued supply of food on the market in England. The Regulations provide continuity for stakeholders and the FSA has not identified any significant impact on stakeholders as a consequence of this legislation 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 Food Standards Agency 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. On the contrary, the provision of periods of adjustment should help to support small businesses and ease cost burdens that would otherwise immediately arise on them.

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 No review clause is required for those parts of this instrument made under the EU (Withdrawal) Act 2018.

14.2 For those amendments being made under the Food Safety Act 1990, to the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013, and the Quick-frozen Foodstuffs (England) Regulations 2007, these will be considered under the post implementation reviews of those instruments. The reviews will assess whether the implementation of the Regulations fulfilled the intended objectives, and whether they continue to be effective and necessary after they were enacted.

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 Jo Churchill, Parliamentary Under-Secretary of State for Prevention, Public Health and Primary Care at the Department of Health and Social Care.

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 the end of the Transition 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 2(2) ECA 1972	Paragraph 13, Schedule 8	Anybody making an SI after the end of the Transition Period 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 the end of the Transition 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 Transition Period, 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) Act 2018

1. Appropriateness statement

1.1 Jo Churchill (Parliamentary Under-Secretary (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 Safety (Miscellaneous Amendments and Transitional Provisions) Regulations 2021 do no more than is appropriate in respect of amendments made under the European Union (Withdrawal) Act 2018".

1.2 This is the case because: the instrument, insofar as it uses the powers in the European Union (Withdrawal) Act 2018, only addresses deficiencies arising out of the withdrawal of the United Kingdom from the European Union and matters arising out of, or related to, the Northern Ireland Protocol. It adds no additional legislative measures.

2. Good reasons

2.1 Jo Churchill (Parliamentary Under-Secretary (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".

3. Equalities

3.1 Jo Churchill (Parliamentary Under-Secretary (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 Jo Churchill (Parliamentary Under-Secretary (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, Jo Churchill, 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.