EXPLANATORY MEMORANDUM TO

THE FOOD AND FEED (MISCELLANEOUS AMENDMENTS) REGULATIONS 2022

2022 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 His Majesty.

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

2. Purpose of the instrument

2.1 This instrument, The Food and Feed (Miscellaneous Amendments) Regulations 2022, is made under powers in the European Union (Withdrawal) Act 2018 ("EUWA 2018").

2.2 The purpose of this instrument is to:

- amend national (England) Regulations in the fields of articles in contact with food, extraction solvents and animal feed to remove cross references to European Union ("EU") Directives and correct other EU Exit related inoperabilities;
- address a range of remaining deficiencies in retained direct EU law in the field of food and feed safety and hygiene to ensure the continued operability of this legislation after exiting the EU;
- address issues that have arisen as a consequence of previous deficiency amendments made pursuant to section 8 of EUWA 2018;
- extend the tolerance period of three withdrawn Genetically Modified Organisms ("GMOs") for a further three years, until 31 December 2025, to align with the correction of a deficiency in retained Regulation (EC) 619/2011 in relation to these withdrawn GMOs; and
- provide for a time-limited transitional period for edible insects, specific to Great Britain (GB). This will permit qualifying edible insects to remain on the market in GB after 31 December 2023 while applications for novel food authorisation are considered by the appropriate authority.

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 None.

4. Extent and Territorial Application

4.1 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) and its application (that is, where the instrument produces a practical effect) varies between the provisions of the instrument.

4.2 Part 2 (regulations 2 to 6) extends to England and Wales but applies to England only.

4.3 Parts 1 and 3 (regulations 1 and 7 to 20) extend (and apply) to England and Wales and Scotland.

5. European Convention on Human Rights

5.1 The Secretary of State for Health and Social Care, the Rt Hon Dr Thérèse Coffey MP, and the Parliamentary Under-Secretary of State at the Department of Health and Social Care, Dr Caroline Johnson MP, have made the following statement regarding Human Rights:

"In our view the provisions of the Food and Feed (Miscellaneous Amendments) Regulations 2022 are compatible with the Convention rights."

6. Legislative Context

6.1 This instrument is being made pursuant to powers in EUWA 2018.

6.2 Much of food and feed law is now retained EU Law ("REUL"). The law relating to food and feed safety in the UK is contained in REUL, statutory instruments and the Food Safety Act 1990. The Food Safety Act 1990 has been the main source of domestic food law since it was enacted and provides wide-ranging powers to regulate matters relating to food safety and consumer protection in relation to food throughout the UK. Up until the UK's exit from the EU, the powers in the Food Safety Act 1990 have been used in conjunction with those under section 2(2) of the European Communities Act 1972 to implement and enforce food and feed law in the UK.

6.3 Part 2 of this instrument contains amendments to the national (England) Regulations for the following three distinct areas: materials and articles in contact with food (regulation 2), extraction solvents (regulation 3) and animal feed (regulations 4, 5 and 6). These Regulations contain cross-references to their corresponding Directives— in particular, to the lists and tables in the respective Annexes to those Directives. These lists and tables are being into copied into the corresponding national Regulations and cross-references to the Directives are being removed. The amendments also remove the obligation to consider the implementation of EU law by Member States when conducting legislative reviews.

6.4 The amendments in Part 3 of this instrument rectify deficiencies in certain retained direct EU legislation that have arisen because of the UK's exit from the EU. Minor deficiencies are addressed in retained direct EU legislation covering feed additives (regulations 8, 10, 14 and 16), food of animal origin (regulation 9), the common authorisation procedure for food additives, food enzymes and food flavourings (regulation 15), active and intelligent materials and articles intended to come into contact with food (regulation 17), animal feed (regulation 18) and genetically modified food and feed (regulations 7, 11 to 13 and 19). The amendments in regulations 11 to 13 extend the tolerance periods of three withdrawn GMOs until 31 December 2025 to align with the correction made by regulation 19 to the legislation laying down the methods of sampling and analysis for the official control of feed. Finally, for novel foods, the instrument provides for a time-limited transitional period for edible insects, specific to GB, by correcting an inoperable transitional provision which related to EU procedures (regulation 20).

7. Policy background

What is being done and why?

Amendment of national Regulations on materials in contact with food, extraction solvents and animal feed

7.1 This instrument makes necessary amendments to the relative national (England) legislation for articles in contact with food (the Materials and Articles in Contact with Food (England) Regulations 2012 (S.I. 2012/2619)), extraction solvents (the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013 (S.I. 2013/2210)) and animal feed (the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015 (S.I. 2015/255); the Animal Feed (Hygiene, Sampling etc and Enforcement) (England) Regulations 2015 (S.I. 2015/454); and the Animal Feed (Basic Safety Standards) (England) Regulations 2019 (S.I. 2019/683)). These amendments copy over the lists and tables of substances from the Annexes within the Directives concerned (as those lists had effect in the EU immediately before the UK exited the EU) into new schedules within the corresponding Regulations, as follows:

(a) Annexes 1 and 2 from Commission Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs (OJ L 172, 30.6.2007, p. 71–82) are inserted as Schedule 5 to the Materials and Articles in Contact with Food (England) Regulations 2012;

(b) Annex 1 from Directive 2009/32/EC of the European Parliament and of the Council on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (OJ L 141, 6.6.2009, p. 3–11) is inserted as Schedule 6 to the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013; and

(c) the Annex to Commission Directive 82/475/EEC laying down the categories of ingredients which may be used for the purposes of labelling compound feeding stuffs for pet animals (OJ L 213, 21.7.1982, p. 27–28) is inserted as Schedule 3 to the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015 and Annexes 1 and 2 from Directive 2002/32/EC of the European Parliament and of the Council on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10–22) are inserted as Schedules 4 and 5 to those Regulations.

7.2 As a result, any cross references within those Regulations need to be replaced with a reference to the new Schedule(s). This will allow for any future amendments to the lists to be made to the national legislation and will also avoid duplicate lists appearing if new products are added or removed domestically. In addition, these amendments remove cross-references within the Regulations to requirements within their relevant Directives as well as obligations within the national Regulations themselves that are now obsolete and no longer applicable or enforceable now the UK is not a Member State (regulations 2, 3, 4, 5 and 6). This instrument also corrects incorrect cross-references in the Animal Feed (Hygiene, Sampling etc. and Enforcement) (England) Regulations 2015 to provisions that have previously been removed. Similar provisions are being made in Wales and Scotland.

Feed Additives

7.3 This instrument makes minor amendments to the legislation concerning procedures for the submission and analytical method evaluation of feed additive applications

(Regulation (EC) No. 1831/2003 on additives for use in animal nutrition, Regulation (EC) No. 378/2005 on detailed rules for the implementation of Regulation (EC) No. 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives, Regulation (EC) No. 429/2008 on detailed rules for the implementation of Regulation (EC) No. 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives and Regulation (EC) No. 152/2009 laying down the methods of sampling and analysis for the official control of feed) to align with processes adopted for GB applications for feed additive authorisation, most notably where the Reference Laboratory in GB has taken on responsibility of analytical evaluations, which was previously undertaken by the European Reference Laboratory (EURL). The FSA and FSS have developed a more streamlined approach in receiving feed additive applications and the approach for analytical method evaluations. In addition, this instrument corrects an error in Article 16(1) of Regulation (EC) No. 1831/2003 on additives for use in animal nutrition by correcting a reference to "Great Britain" to a reference to "the British Islands", in order to harmonise labelling and packaging requirements for feed additives and premixtures across the UK, the Channel Islands and the Isle of Man (regulations 8, 10, 14 and 16).

Amendments to correct inconsistency and correctly retain food hygiene legislation

7.4 This instrument amends REUL concerning hygiene rules for food of animal origin (Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin) by omitting Article 1(4) to remove an inconsistency, principally with Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs, in how the legislation was retained. The instrument also amends Article 10 of Regulation (EC) No 853/2004 so that it reflects the amendments made to it by prior to exiting the EU (regulation 9).

Common authorisation procedure for food additives, food enzymes and food flavourings

7.5 This instrument amends the REUL concerning the common authorisation procedure for food additives, food enzymes and food flavourings (Regulation (EC) No. 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings), to remove the remaining reference in Article 7(4) to 'Community list' and replace it with 'domestic list' (regulation 15).

Active and Intelligent Materials and Articles in Contact with Food – Do Not Eat pictograph

7.6 This instrument makes a minor amendment to the existing legislative requirements for active and intelligent materials and articles intended to come into contact with food (Regulation (EC) No. 450/2009 on active and intelligent materials and articles intended to come into contact with food). It removes the requirement to use the Do Not Eat pictograph on such products given that the EU, or similar entity, holds the intellectual property rights of the pictograph. The pictograph will be removed from Annex 1 as a result. The requirement to apply the wording of 'DO NOT EAT' on active and intelligent food contact materials will continue to remain mandatory (regulation 17).

Animal Feed

7.7 This instrument corrects a numbering reference and reinstates the use of the term 'pet food' into REUL concerning animal feed (Regulation (EC) No. 767/2009 on the placing on the market and use of feed) which was inadvertently deleted by the Animal Feed (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/654) (regulation 18).

Reinstating of powers to extend the transitional period for the trace presence of withdrawn GMOs in food and feed:

7.8 This instrument makes the necessary reinstating of powers into REUL on genetically modified food and feed (retained Regulation (EC) No. 1829/2003 of the European Parliament and of the Council on genetically modified food and feed) provided by Articles 8(6) and 20(6) that make provisions to set limited periods of time for a tolerance in the traces of GMOs for which the authorisation has expired, to assist with the withdrawal from the market. In addition, the instrument corrects an ongoing failure of REUL to operate effectively due to an inconsistency between the transitional period in Article 2(b) of retained Regulation (EC) 619/2011 and the tolerance periods for three withdrawn GMO products, Ms1×Rf1, Ms1×Rf2 and Topas 19/2 oilseed rape, set out in retained Decisions 2007/305/EC, 2007/306/EC and 2007/307/EC. It is necessary to correct this inconsistency and amend these periods so that they align. Therefore, amendments are made to the transitional period in Article 2(b) of retained Regulation (EC) 619/2011 and the expiration dates in the trace presence tolerance period for the three withdrawn GMOs, to align and extend these dates to 31 December 2025 (regulations 7, 11, 12, 13 and 19).

Novel foods – transitional measures for edible insects

7.9 This instrument makes necessary amendments to the transitional provision in REUL concerning novel foods (Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, etc). This will fix inoperabilities in the application of Article 35 as it applies to GB to provide for a time-limited transitional period for edible insects, specific to GB and omit inoperable and redundant sections relating to functions and requirements placed on the European Commission (regulation 20).

Explanations

What did any law do before the changes to be made by this instrument?

7.10 Before Implementation Period completion day, 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 Implementation Period.

Why is it being changed?

7.11 The principal changes introduced by this instrument will ensue that national and GB wide Legislation continues to operate effectively following the UK's exit from the EU.

What will it now do?

7.12 This instrument will make the following notable changes to REUL

Amendment of national Regulations on materials in contact with food, extraction solvents and animal feed.

7.13 The national Regulations governing materials in contact with food, extraction solvents and animal feed, respectively, all make cross references to associated European Directives. These cross references are to both Articles that assign specific duties to Member States and to lists and tables in the Annexes to those Directives. This meant that the Regulations referred to the most current version of the Directive- removing the need to update the national Regulations when any changes were made. Whilst these cross-references provided a practical work around whilst the UK was an EU Member State, and despite the current references to the Directives being 'frozen' as they were on EU exit (31 December 2020 23:00), retaining them would present certain difficulties, especially in relation to the approval of new, or amendment of currently authorised, substances. If any modifications or new approvals were to occur, a separate list would be created in national Regulations alongside the existing Annex in the Directive. This would mean that industry would have to refer to two separate lists in separate legislation, which is both burdensome and increases the potential for error of understanding. We are now moving the lists into new Schedules within the relevant national legislation and replacing cross-references to the Annexes with a reference to the new Schedule (please also see the summary in paragraph 7.1 above). The national Regulations also include review clauses which placed a duty on the FSA to review the execution and enforcement of the legislation within a set period, but with regard to how the Directives and instruments are being enforced in other Member States. As the UK is no longer a Member State, this requirement is obsolete and is being removed. This does not affect or remove the FSA's requirement to review the operation and effect of the Regulations.

7.14 The Materials and Articles in Contact with Food (England) Regulations 2012 ("2012 Regulations") sets out manufacturing requirements and conditions of use for regenerated cellulose film in contact with foodstuffs. The cross-references to Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs within the 2012 Regulations are no longer operable. This includes the reference to Annex 2 of Directive 2007/42/EC that lists the substances that are authorised in the manufacture of regenerated cellulose film. The 2012 Regulations will be amended to include a new Schedule that lists the substances that are authorised in the manufacture of regenerated cellulose film. It will also be possible to update the newly created schedule with new substance authorisations and any modifications to existing authorisations as a result of new scientific evidence. This will provide clarity to enforcement authorities and business operators. Accordingly, references to Directive 2007/42/EC, and provisions of it, will be omitted from the 2012 Regulations. Furthermore, unnecessary references to other Directives within the 2012 Regulations will also be removed.

7.15 The Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013 ("2013 Regulations") sets out controls on the use of extraction solvents. The 2013 Regulations contain cross-references to Directive 2009/32/EC on extraction solvents used in the production of foodstuffs and food ingredients, in particular to Annex 1 where permitted extraction solvents, their usage levels and maximum residue levels are set; and to Article 3(c) of that Directive, which serves as

a place holder to allow future amendments to be made to purity criteria. The cross-reference to Annex 1 of the Directive is unsuitable since any future proposals that affect permissions for existing extraction solvents, or the authorisation of new extraction solvents would need to be provided as standalone national legislation, i.e., a separate list in addition to the list in Annex 1 of the Directive. To provide greater clarity and ease of reference for enforcement authorities and industry in the future, the information contained in Annex 1 of Directive 2009/32/EC will be copied over into a new schedule within the 2013 Regulations. Accordingly, references to Directive 2009/32 and provisions of it will be removed from the 2013 Regulations. Regulation 11(a) (v) of the 2013 Regulations will now be removed as any future amendments to purity criteria will be made under powers in the Food Safety Act 1990. In addition, the 2013 Regulations contain a review clause that outlines that the FSA must, when undertaking a review in accordance with regulation 22 of the 2013 Regulations, have regard as to how Directive 2009/32 is implemented and EU Regulations executed and enforced, in other Member States. As the UK is no longer a Member State, this requirement is obsolete and regulation 22(2) will be removed. This does not affect or remove the FSA's requirement to review the operation and effect of the regulations.

7.16 The Animal Feed (Composition, Marketing and Use) (England) Regulations 2015 ("2015 Regulations") make provision for the enforcement of retained Regulation (EU) No. 767/2009 on the placing on the market and use of feed. The legislation stipulates in the case of compound feed intended for non-food producing animals, the indication of the specific name of a feed material may be replaced by the name of the category to which the feed materials belong and that only the categories listed in the Annex to Directive 82/475/EEC may be indicated. Similarly, undesirable substances may be present in products intended for animal feed only in accordance with the conditions laid down in the 2015 Regulations, which cross-references to lists in the Annex of Directive 2002/32/EC. The lists in these Directives remain as they were on EU exit (31 December 2020 23:00). If changes were made to amend the permitted feed material categories, or adjust the existing level, introduce a new level, or prohibit the presence of an undesirable substance in animal feed based on scientific and technical developments, this would result in the creation of separate lists in addition to those contained within the Directives that are cross-referenced. Therefore, to provide greater clarity and ease of reference for enforcement authorities and industry in the future, the lists contained in Directive 82/475/EEC and Directive 2002/32/EC will be incorporated into new schedules in the 2015 Regulations and cross-references within those Regulations to the Directives will be amended accordingly. Outstanding references to other Directives that are no longer applicable or relevant, including the reference to Directive 2013/59/Euratom, in the Animal Feed (Basic Safety Standards) (England) Regulations 2019 will also be omitted. Furthermore, as the UK is no longer a Member State, national feed regulations are being amended to remove the obligation to consider the implementation of EU Law by Member States when conducting legislative reviews. This instrument will also correct the Animal Feed (Hygiene, Sampling etc. and Enforcement) (England) Regulations 2015 by removing incorrect cross-references to Article 20(2) & 22(2)(b) of retained Regulation (EU) No. 183/2005 that have been omitted from that retained Regulation.

Feed Additives

7.17 Minor amendments of retained Regulations (EU) No. 1831/2003, 378/2005 and 429/2008 concerning feed additives will provide clarity to applicants on requirements

of the GB streamlined process for feed additive authorisations and analytical method evaluations. In addition, correcting Article 16 (1) of retained EU Regulation No. 1831/2003 will provide harmonisation on labelling requirements across the UK, the Channel Islands and the Isle of Man.

7.18 Further amendments of retained EU Regulations No. 1831/2003, 378/2005, 429/2008 and 152/2009 will be made to update cross-references to current legislation with no change in regulatory function.

Amendments to correct inconsistency and correctly retain food hygiene legislation

7.19 The instrument omits Article 1(4) of retained EU Regulation No 853/2004 laying down specific hygiene rules for food of animal origin. This will align how this Regulation is retained with an equivalent provision in retained Regulation (EU) No. 852/2004 on the hygiene of foodstuffs. Article 1(4) provides for the provision of national rules on the direct supply by the producer of small quantities of primary food products to the consumer or to retailers for direct supply to consumers. Following the UK's exit from the EU, Article 1(4) is not required for the making of national rules.

7.20 The instrument also amends Articles 10 and 11 of retained Regulation (EU) No. 853/2004. This reflects the amendments made to those Articles prior to exiting the EU and which are not currently reflected in the retained legislation. This will ensure that the correct provisions of Articles 10 and 11 are in place and allow for the appropriate authority to prescribe amendments or implementing measures to retained Regulation (EU) No. 853/2004 for certain specified purposes, for example identification marking measures and hygiene measures for the production of food products of animal origin under Annexes 2 and 3 of the Regulation.

Common authorisation procedure for food additives, food enzymes and food flavourings

7.21 In preparation for EU exit, legislation governing regulated products was updated to remove terminology which related to the European Union and replace it with terms that reflected the new ways of working in the UK. Lists which were previously referred to as 'Community lists' were changed to 'domestic lists'. These changes were made through a series of Statutory Instruments. Under the Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 , multiple references to 'Community lists' were replaced with 'domestic lists' within the legislation governing the common authorisation procedure for food additives, food enzymes and food flavourings (retained Regulation (EC) No. 1331/2008). Unfortunately, a single reference was overlooked in drafting. Correcting this reference will bring Article 7(4) of retained Regulation (EC) No. 1331/2008 in line with the rest of the regulation and other REUL.

Active and Intelligent Materials and Articles in Contact with Food – Do Not Eat pictograph

7.22 Following the UK's exit from the European Union, it is no longer appropriate to continue to apply, where technically possible, the Do Not Eat pictograph (as prescribed in Annex 1 of retained EU Regulation No. 450/2009) to active and intelligent materials and articles when placing these onto the GB market. This is because there is uncertainty as to the ownership of intellectual property rights with respect to the pictograph The requirement to apply the wording 'DO NOT EAT' to active and intelligent materials and articles will continue to remain mandatory.

Animal Feed

7.23 The amendments to retained Regulation (EU) No.767/2009 reinstate permission for the term 'pet food' to be allowed in the designation of feed for pets (which was inadvertently deleted in the Animal Feed (Amendment) (EU Exit) Regulations 2019). This will allow manufacturers to continue to label products as 'pet food'. Furthermore, Article 24(5) in retained Regulation (EU) No. 767/2009 was renumbered by the Animal Feed (Amendment) (EU Exit) Regulations 2019 as Article 24(2). Therefore, this instrument corrects an incorrect cross-reference to Article 24(5) in Article 16 of Regulation 767/2009, which will allow the legislation to operate effectively.

Reinstating of powers to extend the transitional period for the trace presence of withdrawn GMOs in food and feed:

7.24 The instrument corrects a deficiency by reinstating powers in retained Regulation (EU) 1829/2003. These powers will enable regulations to be made in the future that will make the process of granting of an extension to the tolerance period of trace levels of the three withdrawn GMO products, Ms1×Rf1, Ms1×Rf2 and Topas 19/2 oilseed rape simpler and easier. These GMOs are currently under a transitional tolerance arrangement that permits a trace presence set at no higher than 0.1% which is due to expire at the end of 2022. Once the tolerance arrangement expires, this would require all GM oilseed rape consignments to have an absolute zero detectable presence for the three withdrawn GMOs upon sampling and detection control measures. These powers relate to provisions that allow the use of existing stocks of GM food and feed products, that may be applied for a limited period of time, upon having withdrawn the product from the market.

7.25 In addition, the instrument corrects an ongoing failure of REUL to operate effectively due to an inconsistency between the transitional period in Article 2(b) of retained Regulation (EC) 619/2011 and the tolerance periods for the three withdrawn GMO products, Ms1×Rf1, Ms1×Rf2 and Topas 19/2 oilseed rape, set out in retained Decisions 2007/305/EC, 2007/306/EC and 2007/307/EC. The instrument corrects this inconsistency and amends the dates of the respective periods so that they align.

Novel foods – transitional measures for edible insects

7.26 In 2018, prior to the UK leaving the EU, the EU replaced its existing novel foods legislation with Regulation (EU) 2015/2283 ("Regulation 2015/2283"). The update captured whole edible insects within the framework for the first time. Thereafter, all insects are considered to be novel— unless they are one of a very limited number of species that were commonly consumed within the EU or the UK prior to 15 May 1997.

7.27 To provide industry time to move to compliance, transitional measures were included in Article 35(2) of 2015/2283. These allowed certain edible insects to continue to be placed on the market until the European Commission made a decision regarding authorisation. This was under the provision that the product had been lawfully placed on the market by 1 January 2018, did not fall within the scope of EU Regulation No. 258/97 (the precursor framework to the subsequent novel foods legislation) and was subject to an application having been submitted to the EU by 1 January 2019 (this was originally 2 January 2020 but was varied to 1 January 2019 by Article 8 of Commission Implementing Regulation (EU) 2017/2469).

7.28 While Article 35(2) was retained in UK novel food legislation (retained Regulation (EU) No. 2015/2283), it was retained without being adapted to the market or regulatory context in GB. Accordingly, this instrument corrects this by providing for a transitional period in GB, which eligible edible insect businesses can use and which will facilitate authorisation applications in GB for the GB market.

7.29 This legislation makes provision that insects may remain on the market where they are the subject of an application made to GB authorities before 31 December 2023 in addition to meeting the pre-exiting criteria for the transitional measures in Article 35(2) of retained Regulation 2015/2283.

7.30 The transitional measures apply until an application concludes and Article 35(2A) has been inserted to provide the conditions under which an application concludes. This clarifies that food businesses supplying edible insects must pass through the GB authorisation process if they are to remain on the market.

7.31 Article 35(1) is to be omitted as it is inoperable. It refers to the functions of the European Commission in the handling of requests for edible insects to be authorised as novel foods made prior to 1 January 2018. This is incompatible with the principle that applications for novel food authorisations should be considered by the appropriate authorities in England, Wales and Scotland following the UK's exit from the EU.

7.32 Article 35(3) is to be omitted as it is redundant. It relates to requirements on the European Commission to adopt implementing acts in relation to these transitional measures using powers that expired before Implementation Period (IP) Completion Day and which were omitted by The Novel Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/702).

8. European Union Withdrawal and Future Relationship

8.1 This instrument is being made using the power in section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018 in order to address failures of retained EU law to operate effectively or other deficiencies arising from the withdrawal of the United Kingdom from the European Union. 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.

Previous consultations on general amendments to Retained EU Law

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 FSA 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 significant support for the FSA's proposed approach to amendments to Retained EU Law for Food and Feed Safety and Hygiene.

These consultations were used to inform the following changes:

10.6 **Changes to retained Regulations (EU) No. 1831/2003, 378/2005, 429/2008 and 152/2009/ Alignment of the submission and analytical method processes for GB authorisation and updates on cross-reference to legislation:** Minor technical amendments for the legislation to function post-EU exit and are covered by the above consultations for Regulation No. 1831/2003 and harmonising these amendments with Regulations No. 378/2005 and 429/2008. Other amendments concern updating cross-references to current legislation.

10.7 **Amendments to EU food hygiene retained Regulation (EU) No. 853/2004**: the amendments detailed will correct oversights in the retained EU food hygiene Regulation to bring it into line with the hygiene measures in place before the UK exited the EU and fall within the approach and scope set out in the earlier 2018 consultation.

10.8 **Changes to retained Regulation (EC) No. 1331/2008 Correction of reference to "Community List":** This consultation was used to inform the changes from 'Community' to 'domestic' in the previous Statutory Instrument, the Food Additives, Flavourings, Enzymes and Extraction Solvents (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/860). As detailed, the amendment included within this instrument corrects a minor, continuing inoperability. Correcting this will bring Article 7(4) in line with the rest of the Regulation and, therefore, will affect a further necessary technical amendment that falls within the scope of the earlier 2018 consultation.

10.9 **Changes to retained Regulation (EU) No. 767/2009/ Correction of a numbering reference and reinstating the term "Pet food":** the amendment of Article 16 and Annex 2 detailed within this instrument corrects a drafting oversight which falls within the scope of the earlier 2018 consultation.

10.10 **Changes to retained Regulation (EU) No. 1831/2003 Correction of reference to "United Kingdom":** the amendment of Article 16(1) detailed above within this instrument corrects a drafting oversight which falls within the scope of the earlier 2018 consultation.

Consultations undertaken for this SI

10.11 **Amendment of national Regulations on materials in contact with food, extraction solvents and animal feed:** A joint consultation covering the proposed changes in England was launched on 13 July 2022 and ran for 4-weeks. The consultation and responses can be found here https://www.food.gov.uk/news-alerts/consultations/consultation-on-proposed-changes-to-national-england-only-law-in-relation-to-eu-directives-on-animal-feed-food-contact-materials . The consultation was published on the FSA website, shared with Local Authorities ("LA") and Enforcement Authorities using the FSA's Smarter Communications platform and directly circulated with relevant stakeholders, as identified in Annex A of the consultation. Twelve responses were received split across the 3 regimes. The FSA issued a response on 6 September 2022. Feedback was positive, with all respondents indicating support for the proposed amendments. Points were raised in relation to the usability of legislaton.gov which the FSA agreed to take back to the National Archives. As these are England-specific changes, FSA Wales and FSS undertook their own separate consultations.

10.12 **Active and intelligent materials and articles in contact with food – Do Not Eat pictograph:** A GB wide public consultation was carried out from 13 July to 10 August 2022 on the proposed approach to remove the requirement to use the Do Not Eat pictograph on active and intelligent materials and articles as detailed above. The consultation and responses can be found here https://www.food.gov.uk/news-alerts/consultations/consultation-on-removal-of-the-requirement-to-use-the-do-not-eat-pictograph-on-active-and-intelligent-food-contact-materials .The consultation received 3 responses, which included a trading standards department, a business operator and a member of the public. Two responders agreed with the proposed approached to remove the requirement to apply the Do Not Eat pictograph, on the condition that applying the wording of DO NOT EAT continues to remain a mandatory requirement. They accepted that this was necessary as a result of the UK's exit from the European Union. One responder said they thought that the current pictograph was not particularly understandable, but they believed it was important that organisations and charities that represented individuals with learning difficulties had the opportunity to view the proposals. The consultation was circulated to several organisations directly, including those representing individuals with visual impairment, Alzheimer's disease and learning difficulties. We did not receive responses from any of these organisations

10.13 **Genetically Modified Food and Feed – Amendments to retained EU law and the extension to the tolerance period for traces of withdrawn GM oilseed rape products:** A UK wide public consultation was carried out between 20 September and 4 October 2022 on the proposed amendments to retained Regulations (EC) 1829/2003 and 619/2011 and extensions to the transitional tolerance levels in traces of Ms1×Rf1, Ms1×Rf2 and Topas 19/2 oilseed rape. The consultation and a full summary of responses have been published on the FSA website: https://www.food.gov.uk/news-alerts/consultations/consultation-on-amendments-to-retained-eu-law-18292003-and-6192011-and-extension-to-the-tolerance-period-for-traces-of-withdrawn. The consultation received three responses, including two responses from industry associations and one response from an enforcement officer representing a Local Authority. The three respondents were in favour of the proposed plans to reinstate the appropriate powers in retained Regulation 1829/2003, correct the ongoing inoperability in retained Regulation 619/2011 and to extend the tolerance period for

the affected withdrawn GM oilseed rape products. The extension of the transitional tolerance measures for the three withdrawn GM oilseed rape products was supported by respondents to provide the certainty of its continued legal status to those commercial operators. The two industry association respondents acknowledged that residual trace presence of less than 0.1% with the three withdrawn GM oilseed rape commodities were still unintentionally circulating in the food supply chain and could be expected after 31 December 2022. One respondent had concluded that such permittance of a continued trace level tolerance was unlikely to present a safety risk and would be to only create unnecessary non-compliance. Without the extension being applied, one respondent noted that the impact would result in imports being affected if detected as non-compliant to these tolerances which would result of the bulk shipment being rejected and loss of use to the food industry and supply chains.

10.14 **Novel foods – transitional measures for edible insects:** A GB-wide public consultation was carried out between 13 July and 10 August 2022 on the proposed changes to provide for a time-limited transitional period for edible insects, specific to GB. The consultation and a full summary of responses has been published on the FSA website: https://www.food.gov.uk/news-alerts/consultations/consultation-on-transitional-arrangements-for-edible-insects-in-great-britain. A total of 315 responses were received, of which 64 provided substantive comments which have been considered. These included seven food businesses and two organisations representing the edible insect and alternative protein industry, two LAs, two other organisations and 51 members of the public or unrelated businesses.

10.15 The industry expressed a range of views, with the majority supportive of the provision of a GB-specific transitional measure to enable them to maintain products on the market while their applications for novel foods are considered. Some expressed views over the cost and time required to prepare a novel food application and the burden on small and medium businesses. This is beyond the scope of the proposed amendment to the transitional measures, but we welcome these views in informing the FSA's upcoming overarching review on novel food regulation.

10.16 Other businesses, organisations and members of the public expressed safety concerns (including toxicity, bacterial and parasite contamination and potential allergen risks) and clear labelling for consumer choice and potential allergens. These are factors which will be considered as part of the process for considering applications for novel food authorisation which is necessary for these products to remain on the market beyond the transitional period. FSA and FSS have undertaken a rapid risk assessment which considers potential food safety concerns during the transition period which has been published on the FSA website: https://www.food.gov.uk/research/novel-and-non-traditional-foods-additives-and-processes/rapid-risk-assessment-what-is-the-risk-to-consumers-from-consumption-of-the-seven-edible-insects-products-currently-available-in.

10.17 Twenty members of the public expressed support for measures that would increase the availability and range of edible insect products as an alternative source of protein for their diets.

10.18 The remaining 251 comments were from members who did not provide comments of substance relevant to the proposals in the consultation. They either expressed a negative view or disgust on the principle of edible insects, interpreted the consultation as an intention to mislead consumers into unknowingly buying insect products and / or linked this policy to global conspiracy theories.

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 There is no, or no significant, impact on charities and voluntary bodies. The impacts of the miscellaneous regulations on business are expected to be minimal. In line with the consultations listed in Section 10, the FSA envisages minimal one-off familiarisation costs for food and feed businesses affected by each of the amendments discussed. The changes are minor technical amendments. The FSA does not foresee any impact on the day-to-day running of operations. Details of the familiarisation costs provided in the various consultations are summarised below, evidencing the impact of below £5m:

General amendments to Retained EU Law. According to the ONS Inter Departmental Business Register (IDBR) there were approximately 220,000 businesses active in the agri-food sector in 2019. We estimate that it will take each business one hour to read and understand the miscellaneous regulations and then disseminate the information to key staff in their firm.

Amendment of national Regulations on materials in contact with food, extraction solvents and animal feed. Using the IDBR and internal registers, we estimate that around 13,750 English food and feed businesses will be affected. We estimate that it will take one manager per business one hour to read and understand the legislative changes and then disseminate the information to key staff within their firms, leading to a total cost to businesses in England of £318,000.

Active and intelligent materials and articles in contact with food – Do Not Eat pictograph. Based on the number of known GB-based business operators that produce active and intelligent materials and articles, we have estimated that it will take up to two hours for business operators to read the legislation and any accompanying guidance and two hours to disseminate this information to key staff. The total familiarisation cost is estimated to be £1,700 across England, Wales and Scotland.

Novel foods – transitional measures for edible insects. Using available market intelligence, it is estimated at least 30 firms in the Great Britain produce edible insect products and could be impacted. We estimate that it will take one manager per business one hour to understand the legislative changes and disseminate the information to key staff within their firms, leading to a cost of less than £1,000 for Great Britain.

Genetically Modified Food and Feed – Amendments to retained regulations 1829/2003 and 619/2011, and extension of tolerance period for traces of withdrawn GM oilseed rape products: Given that these oilseed rape products are already withdrawn from the market and that the proposed measures will extend tolerance periods that are already in force, there is not seen to be any change introduced or new impact presented onto businesses. It would be reasonable to have assessed that there would not present any requirement to have to disseminate information of this legislative change to businesses and therefore for there not to be any associated costs.

12.2 The impact on the public sector is expected to be minimal. The FSA envisage minimal one-off familiarisation costs to Local Authorities (LAs)s and Port Health Authorities (PHAs) and the other government departments, but no impact on the day-to-day operations of LAs. There are approximately 419 LAs and 22 Port Health Authorities PHAs in the UK, together with FSA, FSS and the Department of Agriculture, Environment and Rural Affairs in NI (DAERA), who undertake official controls relating to food and animal feed safety and hygiene. Each regulation set out in this instrument may only impact a proportion of total LAs, as outlined below:

General amendments to Retained EU Law. We expect all food and feed safety and hygiene authorities to familiarise themselves with the changes. We estimated that it will take authorities 1 hour to read and familiarise themselves with the retained EU Regulations and then disseminate to staff and key stakeholders. It is estimated that one officer in each of these authorities (e.g., one Food/Feed Officer from each local authority; and one 'Port Health Officer' from each PHA) will need to undertake this task.

Amendment of national Regulations on materials in contact with food, extraction solvents and animal feed. We expect all LAs responsible for food standards in England to familiarise themselves with the legislative changes and that this takes one hour across all three of the regulations being incorporated, leading to a one-off familiarisation cost of £6,900.

Active and intelligent materials and articles in contact with food – Do Not Eat pictograph. We expect all LAs in Great Britain to familiarise themselves with the legislative changes. We have estimated that it will take up to two hours for enforcement bodies to familiarise themselves with the new requirements and two hours to disseminate this information to interested staff. The total familiarisation costs to enforcement bodies across England, Wales and Scotland is £53,217.

Genetically Modified Food and Feed - extension of tolerance period for traces of withdrawn GM oilseed rape products: The impact of this legislative change will place a requirement for the Food Safety Authority to update the GMO food and feed register, to have the tolerance period end date reflect a period beyond the currently stated expiry date of 31 December 2022 to have updated to 31 December 2025.

The policy primarily relates to enforcement measures that could be carried out during the sampling and detection strategies as part of official control measures taken for the presence of genetically modified organisms in food and feed products. Provided that this legislative change is made prior to the currently stated expiry date, enforcement of official control measures on the detection of genetically modified organisms in food and feed will be unaffected, since the current tolerance levels will remain unchanged. It is therefore considered that there would be no familiarisation costs involved to LAs and PHAs, should this legislative change be in force prior to the current set of transitional measures expiring.

Novel foods – transitional measures for edible insects. We expect all food and feed safety and hygiene authorities across Great Britain to familiarise themselves with these changes. We estimate that this takes one hour, leading to a £9,800 one-off familiarisation cost to Local Authorities responsible for food standards in Great Britain.

12.3 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. The instrument is not considered to add additional or new burdens on food and feed businesses or enforcement bodies, other than those identified above. This instrument provides 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 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 instrument, which should not have any disproportionate negative impact on small businesses.

13.4 The changes made to legislation by this instrument 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.

14.2 For the amendments to the Materials and Articles in Contact with Food (England) Regulations 2012, the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013, the Animal Feed (Composition, Marketing and Use) (England) Regulations 2015, the Animal Feed (Hygiene, Sampling etc and Enforcement) (England) Regulations 2015 and the Animal Feed (Basic Safety Standards) (England) Regulations 2019), these will be considered under the post implementation reviews of those instruments. The reviews will assess whether the implementation of this instrument fulfilled the intended objectives and whether they continue to be effective and necessary after they were enacted.

15. Contact

15.1 The Food Standards Agency, helpline@food.gov.uk, can be contacted with any queries regarding the instrument.

15.2 The Food Standards Agency can confirm that this Explanatory Memorandum meets the required standard.

15.3 Dr Caroline Johnson, Parliamentary Under-Secretary of State for Public Health and Mental Health 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 and the European Union (Future Relationship) Act 2020

Part 1A

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) or 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) or 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) or 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) or 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) or 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 IP completion 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) or	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 section 8 or 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 5 or 19, Schedule 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 14, Schedule 8	Anybody making an SI after IP completion day under powers conferred before the start of the 2017-19 session of Parliament 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.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 15, Schedule 8	Anybody making an SI after IP completion 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 IP completion day, and explaining the instrument's effect on retained EU law.

Part 1B

Table of Statements under the 2020 Act

This table sets out the statements that may be required under the 2020 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraph 8 Schedule 5	Ministers of the Crown exercising section 31 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

Part 2

Statements required under the European Union (Withdrawal) 2018 Act or the European Union (Future Relationship) Act 2020

1. Appropriateness statement

1.1 The Secretary of State for Health and Social Care, the Rt Hon Dr Thérèse Coffey MP, and the Parliamentary Under-Secretary of State at the Department of Health and Social Care, Dr Caroline Johnson MP have made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In our view the Food and Feed (Miscellaneous Amendments) Regulations 2022 does no more than is appropriate".

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. It adds no additional legislative measures.

2. Good reasons

2.1 The Secretary of State for Health and Social Care, the Rt Hon Dr Thérèse Coffey MP, and the Parliamentary Under-Secretary of State at the Department of Health and Social Care, Dr Caroline Johnson MP have made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In our 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: to ensure national Regulations are operable, remove remaining inoperabilities in retained EU law, remedy previous amendments made to retained EU law, extend the tolerance period for three previously withdrawn GMOs, and provide a time limited transitional period for edible insects specific to GB. Further details can be found in section 7 of the EM.

3. Equalities

3.1 The Secretary of State for Health and Social Care, the Rt Hon Dr Thérèse Coffey MP, and the Parliamentary Under-Secretary of State at the Department of Health and Social Care, Dr Caroline Johnson MP have 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 Secretary of State for Health and Social Care, the Rt Hon Dr Thérèse Coffey MP, and the Parliamentary Under-Secretary of State at the Department of Health and Social Care, Dr Caroline Johnson MP have made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

"In relation to the draft instrument, we, Dr Thérèse Coffey MP and Dr Caroline Johnson MP, 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 7 of the main body of this explanatory memorandum.