

Explanatory Memorandum to the Food and Feed Hygiene and Safety (Miscellaneous Amendments and Saving Provision) (Wales) (EU Exit) Regulations 2020

This Explanatory Memorandum has been prepared by the Food Standards Agency and is laid before the Senedd Cymru in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

Minister/Deputy Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Food and Feed Hygiene and Safety (Miscellaneous Amendments and Saving Provision) (Wales) (EU Exit) Regulations 2020.

I have made the statements required by the European Union (Withdrawal) Act 2018. These statements can be found in Part 2 of the Annex to this Memorandum.

Eluned Morgan

Minister for Mental Health, Wellbeing and Welsh Language

24 November 2020

PART 1

1. Description

The Food and Feed Hygiene and Safety (Miscellaneous Amendments and Saving Provision) (Wales) (EU Exit) Regulations 2020 ('the 2020 Regulations') make amendments, which apply in relation to Wales only, to subordinate legislation in the fields of food and feed safety and hygiene, and food compositional standards.

The purpose of the 2020 Regulations is to:

- implement the Protocol on Ireland/Northern Ireland ('NIP') by making necessary amendments to a number of provisions in three EU-Exit statutory instruments ('the 2019 SIs') and other domestic legislation applying in relation to Wales in the fields of food and feed safety and hygiene, and food compositional standards;
- address deficiencies in Welsh domestic legislation arising from EU-Exit also in the fields of food and feed safety and hygiene, and food compositional standards to ensure that the statute book continues to operate effectively at the end of the implementation period ('IP'); and
- ensure that any amendments in the fields of food and feed safety and hygiene, and food compositional standards introduced by EU-Exit SIs made after the 2019 SIs are being accounted for.

The 2020 Regulations amend the following instruments:

- The Food and Feed Regulated Products (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019, and in particular to regulation 3, which amends:
 - The Materials and Articles in Contact with Food (Wales) Regulations 2012;
- The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019, and in particular to regulations 4 and 7, which respectively amend:
 - The Quick-frozen Foodstuffs (Wales) Regulations 2007; and
 - The Plastic Kitchenware (Conditions on Imports from China) (Wales) Regulations 2011;
- The Food (Miscellaneous Amendments) (Wales) (EU Exit) (No. 2) Regulations 2019, and in particular to regulation 8, which amends:

- The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015;
- The Genetically Modified Food (Wales) Regulations 2004;
- The General Food Regulations 2004;
- The Fishery Products (Official Controls Charges) (Wales) Regulations 2007;
- The Food Irradiation (Wales) Regulations 2009;
- The Meat (Official Controls Charges) (Wales) Regulations 2009;
- The Official Feed and Food Controls (Wales) Regulations 2009;
- The Food Safety (Sampling and Qualifications) (Wales) Regulations 2013;
- The Contaminants in Food (Wales) Regulations 2013;
- The Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013;
- The Honey (Wales) Regulations 2015; and
- The Caseins and Caseinates (Wales) Regulations 2016.

2. Matters of special interest to the Legislation, Justice and Constitution Committee

The 2020 Regulations are subject to the affirmative procedure under paragraph 1(8) of Schedule 7 to the European Union (Withdrawal Agreement) Act 2018 ('2018 Act').

3. Legislative background

The 2020 Regulations are being made using the power in Part 1 of Schedule 2 to the 2018 Act 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. The instrument is also made under paragraph 11M(1) of Schedule 2 as well as under paragraph 7 of Schedule 4 and paragraph 21(b) of Schedule 7 to the 2018 Act.

In accordance with the requirements of the 2018 Act, the Minister for Mental Health, Wellbeing and Welsh Language has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

4. Purpose and intended effect of the legislation

Following the end of the IP, without amendment, certain provisions will be inoperable and as a result existing law will either be unclear or will not function effectively.

The 2020 Regulations, therefore, use powers under the 2018 Act to make technical changes to the below legislation to ensure that it remains coherent and it continues to function correctly after the end of the IP.

What did any relevant EU law do before exit day?

The Food and Feed Regulated Products (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019

This instrument makes amendments to subordinate legislation applying in Wales in the fields of genetically modified food and feed, materials and articles in contact with food, and food additives, flavourings, enzymes and extraction solvents. The amendments made by this instrument come into force at the end of the IP.

The 2020 Regulations are particularly concerned with regulation 3 of this instrument, which contains amendments to the Materials and Articles in Contact with Food (Wales) Regulations 2012.

The Materials and Articles in Contact with Food (Wales) Regulations 2012

This instrument implements the following EU Regulations in relation to Wales:

- Regulation (EU) No 10/2011 providing rules on plastic materials and articles intended to come into contact with food;
- Regulation (EC) No 1935/2004 providing rules on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC;
- Regulation (EC) No 1895/2005 providing rules on restrictions of use of certain epoxy derivatives in materials and articles intended to come into contact with food;

- Regulation (EC) No 2023/2006 establishing good manufacturing practices for materials and articles intended to come into contact with food;
- Regulation (EC) No 450/2009 providing rules on active and intelligent materials and articles intended to come into contact with food;
- Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food.

The EU Regulations, as implemented by the 2012 Regulations, provide for the protection of food from hazards that may arise from materials and articles with which they may come into contact throughout the food chain.

The Food and Feed Hygiene and Safety (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019

This instrument makes amendments to subordinate legislation applying in Wales in the fields of food and feed hygiene and safety to address failures of retained EU law to operate effectively and other deficiencies arising from the withdrawal of the UK from the EU. The amendments made by this instrument come into force at the end of the IP.

The 2020 Regulations are particularly concerned with regulations 4 and 7 of this instrument, which respectively contain amendments to the Quick-frozen Foodstuffs (Wales) Regulations 2007 and the Plastic Kitchenware (Conditions on Imports from China) (Wales) Regulations 2011.

The Quick-frozen Foodstuffs (Wales) Regulations 2007

This instrument implements Regulation (EC) No. 37/2005 in relation to Wales.

That EU Regulation, as implemented in Wales by these Regulations, provides rules for monitoring of temperature in the means of transport, warehousing and storage of quick-frozen foodstuffs intended for human consumption.

This instrument revokes and re-enacts in relation to Wales the Quick-frozen Foodstuffs Regulations 1990, which extend to the whole of Great Britain.

The Directives implemented by the Quick-frozen Foodstuffs Regulations 1990 that this instrument continues to implement are:

- Directive 89/108/EEC on the approximation of the laws of Member States relating to quick-frozen foodstuffs for human consumption; and

- Directive 92/2/EEC laying down the sampling procedure and the Community method of analysis for the official control of the temperatures of quick-frozen foods intended for human consumption.

The Plastic Kitchenware (Conditions on Imports from China) (Wales) Regulations 2011

This instrument implements Regulation (EU) No 284/2011 in relation to Wales.

That EU Regulation, as implemented in Wales by these Regulations, provides specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region, China.

The Food (Miscellaneous Amendments) (Wales) (EU Exit) (No. 2) Regulations 2019

This instrument makes amendments to subordinate legislation applying in Wales in the fields of food and feed hygiene and safety, food and feed regulated products, and food standards and labelling to address failures of retained EU law to operate effectively and other deficiencies arising from the withdrawal of the UK from the EU. The amendments made by this instrument come into force at the end of the IP.

The 2020 Regulations are particularly concerned with regulation 8 of this instrument, which contains amendments to the Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015.

The Natural Mineral Water, Spring Water and Bottled Drinking Water (Wales) Regulations 2015

This instrument transposes the following EU Directives in relation to Wales:

- Directive 98/83/EC on the quality of water intended for human consumption;
- Directive 2003/40/EC establishing the list, concentration limits and labelling requirements for the constituents of natural mineral waters and the conditions for using ozone-enriched air for the treatment of natural mineral waters and spring waters;

- Directive 2009/54/EC of the European Parliament and of the Council on the exploitation and marketing of natural mineral waters;
- Directive 2013/51/EURATOM laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption.

This instrument also implements the following EU Regulation in relation to Wales:

- Regulation (EU) No 115/2010 laying down the conditions for use of activated alumina for the removal of fluoride from natural mineral waters and spring waters.

The Genetically Modified Food (Wales) Regulations 2004

This instrument makes provision for the execution and enforcement of Commission Regulation 1829/2003. This Commission Regulation provides a regulatory framework for the pre-market scientific assessment and authorisation of Genetically Modified Organisms (GMOs) for use in food and feed.

The General Food Regulations 2004

This instrument provides for the enforcement of Regulation (EC) No 178/2002 in relation to Wales. This instrument originally applied in relation to England, Scotland and Wales but has largely been superseded in relation to England.

Regulation (EC) No 178/2002, as implemented in Wales by these Regulations, establishes the responsibility of Food Business Operators (FBOs) to produce food with a high level of protection of human life and health and establishes principles of traceability through the food chain. Together, they provide the high-level principles underpinning the placing of safe food and feed on the market in the EU.

The Fishery Products (Official Controls Charges) (Wales) Regulations 2007

This instrument sets out the charges required to be levied for official controls undertaken on fishery products as specified in Regulation (EU) 2017/625.

Regulation (EU) 2017/625 lays down specific rules on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products.

The Food Irradiation (Wales) Regulations 2009

This instrument transposes, in relation to Wales:

- Directive 1999/2/EC, which provides the framework for the manufacture, marketing and importation of foods and food ingredients treated with ionising radiation. The Directive sets out the purpose, conditions and the approved sources for authorising the treatment of food with radiation;
- Directive 1999/3/EC, which establishes a list of foods and food ingredients treated with ionising radiation. The Commission List sets out the list of approved facilities for the treatment of foods and food ingredients with ionising radiation in Member States, and the Commission Decisions provide a similar list of approved facilities in third countries.

The Meat (Official Controls Charges) (Wales) Regulations 2009

This instrument sets out the rules and mechanisms for the collection of certain charges for the delivery of official controls as set out in Regulation (EU) 2017/625 and in any Implementing and Delegated Regulations made under it, as laid out in the Meat (Official Controls Charges) (Wales) (Amendment) Regulations 2019.

The Official Feed and Food Controls (Wales) Regulations 2009

This instrument provides for the execution and enforcement, in Wales, of Regulation (EU) 2017/625 and such implementing regulations made under it, as laid out in the Official Feed and Food Controls (Wales) (Miscellaneous Amendments) Regulations 2019, setting out official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products;

This instrument sets out the competent authorities for the enforcement of feed and food law, the control mechanisms by which enforcement authorities may monitor the production and supply of food and feed in order to ensure a high level of protection for human life and health, as well as the powers to deal with any non-compliance with the relevant rules.

The Food Safety (Sampling and Qualifications) (Wales) Regulations 2013

This instrument:

- specifies the qualifications necessary to be a public analyst, food analyst or food examiner for the purposes of the Food Safety Act 1990;
- prohibits specified persons from carrying out analyses or examinations;
- specifies the procedures to be followed when a sample has been procured under the Food Safety Act 1990 for analysis or examination;
- excludes from these procedures samples taken under Regulations which have their own procedures; and
- prescribes the form of certificate to be used by analysts and examiners in making their reports.

The Contaminants in Food (Wales) Regulations 2013

This instrument revokes and re-enacts with changes the Contaminants in Food (Wales) Regulations 2010, making provision for:

- the continuing implementation of Regulation (EU) 2015/2284 relating to the fixing of the maximum level of erucic acid in oils and fats intended as such for human consumption; and
- the continuing execution and enforcement of Commission Regulation (EC) No. 1881/2006 setting maximum levels for certain contaminants in foodstuffs

This instrument also provides for the execution and enforcement of Commission Regulation (EC) No. 124/2009, which concerns maximum permitted levels for certain feed additives that may, in specified circumstances, occur in food.

The Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013

This instrument implements the following EU Regulations in relation to Wales:

- Regulation (EC) No. 2065/2003 on smoke flavouring used or intended for use in or on foods;

- Regulation (EC) No. 1332/2008 on food enzymes;
- Regulation (EC) No. 1333/2008 on food additives;
- Commission Regulation EU No. 231/2012 laying down specifications for food additives approved under 1333/2008;
- Regulation (EC) No. 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods flavourings.

This instrument also transposes Directive 2009/32/EC on extraction solvents used in the production of foodstuffs and food ingredients.

The Honey (Wales) Regulations 2015

This instrument transposes Council Directive 2001/110/EC relating to honey. The Directive lays down compositional requirements and reserved names by which honey can be called.

Caseins and Caseinates (Wales) Regulations 2016

This instrument transposes Directive (EU) 2015/2203 relating to caseins and caseinates intended for human consumption in relation to Wales.

Directive (EU) 2015/2203 on caseins and caseinates intended for human consumption lays down specifications for use of reserved descriptions, manufacturing specifications and labelling of casein products so as to ensure their free movement within the European Union. It also aligns composition requirements with the international standard set by the Codex Alimentarius for the sake of consistency and to avoid trade distortions.

Why is it being changed?

Corrections are necessary to the text of the legislation to ensure that a range of provisions in Welsh domestic legislation reflect the application of the NIP. In addition to this, there is a need to account for any legislative developments made since the introduction of the 2019 SIs as well as to ensure that amendments to retained direct EU law introduced by other EU-Exit SIs have been reflected in the associated amendments made to the domestic legislation.

The 2020 Regulations provide the necessary amendments to Welsh domestic legislation by amending a number of provisions in three Wales specific EU-Exit instruments and in other domestic legislation that apply in relation to Wales, to

ensure that these fully implement the NIP in the fields of food and feed safety and hygiene, and compositional standards. It also includes updated technical amendments to Welsh instruments to account for deficiencies arising from the withdrawal of the UK from the EU and accounts for any recent changes to other retained EU law made after the implementation of the three EU-Exit SIs listed in the Description section at page 2 of this Explanatory Memorandum.

The proposed amendments in the 2020 Regulations are technical in nature and cover a range of issues such as:

- Updating references to retained EU law;
- Amending the definitions of third country;
- replacing references to 'EU' with 'UK' or 'GB' as appropriate to reflect the application of the NIP post IP; and
- removing or replacing references to EU-specific terminology.

These amendments are necessary to ensure that Wales' obligations under the NIP are met as well as to ensure the accuracy and efficiency of the statute book in Wales after the end of the IP.

Where appropriate, existing EU-Exit changes are omitted and the provisions remade (with relevant updates, amendments and consolidation) within this instrument to ensure that EU-Exit amendments are as clear and accessible as possible.

What will it now do?

The 2020 Regulations will ensure the proper application of the NIP in relation to, and will address technical deficiencies in, the Welsh legislation affected by this instrument and arising from EU-Exit at the end of the IP. The 2020 Regulations will also ensure that any amendments to relevant retained EU law in the fields of food and feed safety and hygiene, and food compositional standards, including those introduced by other EU-Exit SIs made after the 2019 SIs, are reflected in the current drafting.

The amendments ensure that the legislation is operable at the end of the IP and provides a smooth transition for businesses.

5. Consultation

Duty to consult with the Secretary of State

In accordance with paragraph 4 of Schedule 2 to the 2018 Act there has been consultation with the Secretary of State for Environment, Food and Rural Affairs and the Secretary of State for Health and Social Care on 11 November 2020 regarding the need for Part 2 of this instrument to be brought into force before IP completion day.

General consultation

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.

The FSA undertook a UK-wide consultation between the 20 August 2020 and 16 September 2020 in relation to “Amendments to Retained EU Law for Food and Feed Safety and Hygiene for the end of the Transition Period”, specifically in relation to changes needed in relation to the Withdrawal agreement and NIP. The consultation received 7 responses from interested parties. A significant proportion (71%) supported the proposed approach being outlined within the consultation. The remaining replies (29%) had mixed comments, however, no concerns were raised in relation to the proposed fixes.

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>.

The FSA in Wales also undertook consultation between 7 January 2019 and 4 February 2019 in relation to “The proposed approach to amendments to Welsh domestic legislation for food and feed safety and hygiene, food compositional standards, labelling”.

This consultation concerned the technical amendments detailed by the three Wales specific EU-Exit SIs the 2020 Regulations are amending.

The purpose of this FSA consultation was to provide stakeholders with the opportunity to comment on the FSA’s proposals to make technical fixes to the relevant domestic legislation, and on the FSA’s options for the more

substantive corrections that were required in relation to food compositional standards and labelling.

A copy of the consultation is available here:

<https://www.food.gov.uk/news-alerts/consultations/the-proposed-approach-to-amendments-to-welsh-domestic-legislation-for-food-and-feed-safety-and-hygiene-food-compositional>.

6. Regulatory Impact Assessment (RIA)

No impact assessment has been produced in relation to these Regulations as no impact on the private, voluntary or public sectors is foreseen.

This legislation has no impact on the statutory duties (sections 77-79 of the Government of Wales Act 2006) or statutory partners (sections 72-75 of the Government of Wales Act 2006).

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 of the Welsh Ministers under the 2018 Act. The table also sets out those statements that may be required of Ministers of the Crown under the 2018 Act, which the Welsh Ministers have committed to also provide when required. The required statements can be found in Part 2 of this annex.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(7) and 4(3), Schedule 7 Standing Order 27.1A	The Welsh Ministers exercising powers in Part 1 of Schedule 2 to make a Negative SI Paragraph 3(7) applies to Ministers of the Crown, but Welsh Ministers have committed to make the same statement	A statement to explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation of the LJC Committee (as sifting committee)
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Applies to Ministers of the Crown exercising powers in sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2. Welsh Ministers have committed to make the same statement when 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	Applies to Ministers of the Crown exercising powers in sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2. Welsh Ministers have	A statement to explain the good reasons for making the instrument and that what is being done is a reasonable course of action.

		committed to make the same statement when exercising powers in Schedule 2	
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Applies to Ministers of the Crown exercising powers in sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2. Welsh Ministers have committed to make the same statement when exercising powers in Schedule 2	<p>A statement to explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them.</p> <p>A statement that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.</p>
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 7	Applies to Ministers of the Crown exercising powers in sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2. Welsh Ministers have committed to make the same statement when exercising powers in Schedule 2	A statement to explain the instrument, identify the relevant law before exit day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g. whether minor or technical changes only are intended to the EU retained law.
Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Applies to Ministers of the Crown exercising powers in sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2. Welsh Ministers have committed to make the same statement when exercising powers in Schedule 2	A statement setting out the 'good reasons' for creating a criminal offence, and the penalty attached.
Sub-delegation	Paragraph 30, Schedule 7	Applies to Ministers of the Crown exercising powers in sections 8(1), 9 and paragraph 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority.	A statement to explain why it is appropriate to create such a sub-delegated power.

		Welsh Ministers have committed to make the same statement when exercising powers in Schedule 2 or paragraph 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority	
Urgency	Sub-paragraph (2) and (8) of paragraph 7, Schedule 7	Welsh Ministers exercising powers in Part 1 of Schedule 2 but using the urgent procedure in paragraph 7 of Schedule 7	A statement that the Welsh Ministers are of the opinion that it is necessary to make the SI using the urgent procedure and the reasons for that opinion.

Part 2

Statements required when using enabling powers under the European Union (Withdrawal) 2018 Act

1. Sifting statement(s)

Not applicable/required.

2. Appropriateness statement

The Minister for Mental Health, Wellbeing and Welsh Language, Eluned Morgan, 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 and Saving Provision) (Wales) (EU Exit) Regulations 2020 do no more than is appropriate.”

This is the case because the Instrument predominantly corrects technical deficiencies arising from EU-Exit and ensures the proper application of the NIP.

3. Good reasons

The Minister for Mental Health, Wellbeing and Welsh Language, Eluned Morgan, 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.”

These are that failure to make this legislation would result in Welsh legislation relating to feed and food safety and hygiene failing to operate effectively after IP completion day.

4. Equalities

The Minister for Mental Health, Wellbeing and Welsh Language, Eluned Morgan, has made the following statement

“The 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.”

The Minister for Mental Health, Wellbeing and Welsh Language, Eluned Morgan, has made the following statement regarding the use of legislative powers in the European Union (Withdrawal) Act 2018:

“In relation to the [draft] instrument, I, Eluned Morgan 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.”.

5. Explanations

The explanations statement has been made in paragraph 4 (Purpose & intended effect of the legislation) of the main body of this explanatory memorandum.

6. Criminal offences

Not applicable/required.

7. Legislative sub-delegation

Not applicable/required.

8. Urgency

Not applicable/required.