

Explanatory Memorandum to the Food and Feed Regulated Products (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019

This Explanatory Memorandum has been prepared by Food Standards Agency and is laid before the National Assembly for Wales 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 Regulated Products (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019.

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.

Vaughan Gething AM
Minister for Health and Social Services
5 March 2019

PART 1

1. Description

- 1.1 The Food and Feed Regulated Products (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 (“this Instrument”) amend the Statutory Instruments listed below relating to EU-derived domestic regulations applying in Wales on: a) genetically modified food; b) materials and articles in contact with food; c) food additives, flavourings and enzymes. These amendments are required to address deficiencies in the relevant domestic legislation arising from EU Exit and ensure that the statute book remains operable following the UK’s exit from the EU
- The Genetically Modified Food (Wales) Regulations 2004
 - Materials and Articles in Contact with Food (Wales) Regulations 2012
 - The Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013
- 1.2 The instrument comes into force on “exit day”, which section 20(1) of the European Union (Withdrawal) Act 2018 (“the 2018 Act”) defines as 29 March 2019 at 11.00 pm.

2. Matters of special interest to the Constitutional and Legislative Affairs Committee

- 2.1 This Instrument is being made using the powers conferred by paragraph 1(1) of the 2018 Act. Regulation 3(6) is being made in exercise of powers under section 16(2) of the Food Safety Act 1990.
- 2.2 As set out in the Ministerial statement in Part 2 of the Annex to this Explanatory Memorandum it is proposed that the instrument be subject to negative procedure.
- 2.3 The instrument makes minor and technical changes so it is considered appropriate to make this Instrument subject to annulment in pursuance of a resolution of the National Assembly for Wales.
- 2.4 The Constitutional and Legislative Affairs Committee considered the Food and Feed Regulated Products (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 on 11 February 2019 and agreed that the appropriate procedure for these Regulations is the negative resolution procedure. A copy of the published report can be found at <http://www.assembly.wales/laid%20documents/cr-ld12150/cr-ld12150-e.pdf>
- 2.5 Regulation 3(6), made in exercise of powers under the Food Safety Act 1990, amends the Materials and Articles in Contact with Food (Wales) Regulations 2012 to make provision about the criteria applicable to the method for determining the level of vinyl chloride in materials and articles

in contact with food and of determining the level of vinyl chloride released by those materials and articles.

3. Legislative background

- 3.1 This Instrument is being made partly using the power in Part 1 of Schedule 2 to the European Union (Withdrawal) 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.
- 3.2 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.

4. Purpose and intended effect of the legislation

What did any relevant EU law do before exit day?

The Genetically Modified Food (Wales) Regulations 2004

- 4.1 The Genetically Modified Food (Wales) Regulations 2004 make 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.
- 4.2 The authorisation process involves a risk assessment based on rigorous scrutiny of scientific data by the European Food Safety Authority (EFSA) in line with international guidelines. GM for food/feed use is authorised by means of EU Decisions by the European Commission. These risk assessment and risk management functions are, respectively, being transferred to Food Standards Agency and 'appropriate authority' post-EU exit by the Genetically Modified Food and Feed (Amendment etc.) (EU Exit) Regulations 2019¹. Authorisations are granted for a period of 10 years and the EU law sets down a process and requirements for renewal of authorisations for further 10-year periods, and provides for the withdrawal of authorisations in appropriate circumstances.
- 4.3 EU law requires that all authorised GM food and feed must have a method of detection scientifically assessed and validated by the European Union Reference Laboratory (EU-RL). The EU law also sets down labelling and traceability requirements for authorised GM food and feed placed on the market. This is to ensure that consumers and food/feed businesses operators are clear that they are handling or using GM food/feed.

¹ SI 2019/XX.

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

- 4.4 These Regulations implement the following EU Regulations in relation to Wales.
- Regulation (EU) No 10/2011 provides rules on plastic materials and articles intended to come into contact with food
 - Regulation (EC) No 1935/2004 provides 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 provides 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 establishes good manufacturing practices for materials and articles intended to come into contact with food.
 - Regulation (EC) No 450/2009 provides rules on active and intelligent materials and articles intended to come into contact with food.
- 4.5 The EU Regulations, as implemented by these Regulations, provide for the protection of food from hazards that may arise from materials and articles into which they may come into contact throughout the food chain.

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

- 4.6 The Food Additives, Flavourings, Enzymes and Extraction Solvents (Wales) Regulations 2013 make provision for the execution of Commission Regulations 2065/2003 (smoke flavourings), 1332/2008 (food enzymes), 1333/2008 (food additives), 231/2012 (specifications for food additives approved under 1333/2008) and 1334/2008 (flavourings). It also partially transposes Directive 2009/32 on extraction solvents.
- 4.6 Food improvement agents are used in or on food for a technological purpose during its production or storage. They are also used to improve the taste, texture, and appearance of food. In general, the harmonised EU legislation governing these substances requires a pre-market risk assessment and authorisation before being placed on the market. The legislation provides lists of permitted substances, applicable specifications, conditions of use, as well as categories of foods in which they may be used. The legislation also provides specific labelling requirements for certain food products sold to consumers. This includes a mandatory warning on products containing aspartame as it is a source of phenylalanine, which could be detrimental to those suffering from Phenylketonuria.

Why is it being changed?

- 4.6 The minor and technical changes made by this Instrument are necessary to ensure that the domestic legislation enforcing the retained EU law continues to operate effectively.
- 4.7 The specific changes being proposed to the Regulations detailed at 1.1 above are as follows:

The Genetically Modified Food (Wales) Regulations 2004

- Instrument makes a consequential amendment caused by the revocation of an Article in the relevant EU Regulation which is enforced by the above domestic Regulations.

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

- Removing redundant references to EU Directives where other amendments mean that there is no longer a need to refer to them
- Replacement of requirements on Lead and Cadmium
- Replacement of requirements on Vinyl Chloride

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

- Amends references to the “EU” and the “territory of the EU”.

What will it now do?

- 4.9 This instrument will ensure the Welsh regulations, which provide enforcement powers for the retained EU law relating to genetically modified food, materials and articles in contact with food, food additives, flavourings and enzymes will continue to be operable and enforceable in Wales after the UK leaves the EU. The instrument does not make any change to the way the Welsh regulations operate. The changes make only minor, technical amendments to ensure the Welsh regulations are operable after the UK leaves the EU.

5. Consultation

- 5.1 A four-week consultation was undertaken in Wales on the principle of the proposed amendments. No responses were received in relation to the amendments made by these Regulations and no changes have been made as a result of consultation. Parallel consultation was undertaken in England, Scotland and Northern Ireland.

6. Regulatory Impact Assessment (RIA)

- 6.1 A Regulatory Impact Assessment has not been prepared to accompany these Regulations as there are no changes to the current controls and

therefore no identified costs to consumers, businesses or enforcement authorities associated with implementation of these Regulations.

- 6.2 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 1

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 <i>Paragraph 3(7) (anticipated to be a requirement on Welsh Ministers in Standing Orders)</i>	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 CLA Committee (as sifting committee)
Appropriateness	Sub-paragraph (2) of paragraph 28, Schedule 7	Applies to Ministers of the Crown exercising	A statement that the SI does no more than is appropriate.

		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	
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 committed to make the same statement when exercising powers in Schedule 2	A statement to 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	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 what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. A statement 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	Applies to Ministers of the Crown exercising powers in sections 8(1), 9 and 23(1) or jointly exercising powers in	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

		Schedule 2. Welsh Ministers have committed to make the same statement when exercising powers in Schedule 2	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. 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	A statement to explain why it is appropriate to create such a sub-delegated power.

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.
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Part 2

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

1. Sifting statement(s)

The Minister for Health and Social Services has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

“In my view the Food and Feed Regulated Products (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 should be subject to annulment in pursuance of a resolution of the National Assembly for Wales (i.e. the negative procedure).”

This is the case because the amendments being made are minor and technical in nature. There is no change to policy.

Appropriateness statement

The Minister for Health and Social Services has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

“In my view the Food and Feed Regulated Products (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 do no more than is appropriate.”

This is the case because the minor and technical changes are necessary to ensure the accuracy and operability of the statute book on exit day. There is no change in policy.

2. Good reasons

The Minister for Health and Social Services 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 genetically modified food, food additives, enzymes and flavourings and novel foods failing to operate effectively after the UK leaves the EU.

3. Equalities

The Minister for Health and Social Services 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 Health and Social Services has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

“In relation to the instrument, I, Vaughan Gething, The Minister for Health and Social Services, 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

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

5. Criminal offences

Not applicable/required.

6. Legislative sub-delegation

Not applicable/required.

7. Urgency

Not applicable/required.