

## **Explanatory Memorandum to the Nutrition (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019**

This Explanatory Memorandum has been prepared by the Department of Health and Social Services 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 Nutrition (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019.

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

Vaughan Gething AM  
**Minister for Health and Social Services**  
6 February 2019

## **PART 1**

### **1. Description**

1.1. The Nutrition (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 (“this Instrument”) amends the statutory Instruments listed below relating to nutrition, composition and labelling. These amendments are required to ensure that the statute book remains operable following the UK’s exit from the EU and to address deficiencies in the domestic legislation listed below arising from EU Exit.

- Medical Food (Wales) Regulations 2000
- Food Supplements (Wales) Regulations 2003
- Kava-kava in Food (Wales) Regulations 2006
- Infant Formula and Follow-on Formula (Wales) Regulations 2007
- Addition of Vitamins, Minerals and other Substances (Wales) Regulations 2007
- Food for Particular Nutritional Uses (Addition of Specific Nutritional Purposes) (Wales) Regulations 2009
- Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016 (“the Welsh Regulations”).

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 Schedule 2 and paragraph 21 of Schedule 7 to the European Union (Withdrawal) Act 2018 (“the 2018 Act”).

2.2 As set out in the Ministerial statement in the annex to this Explanatory Memorandum it is proposed that the instrument be subject to negative procedure. As required by the 2018 Act, the instrument was considered for sifting by the CLA Committee on 28 January 2019 and the Committee was satisfied that the Regulations should be subject to the negative procedure. The instrument will therefore be subject to the negative procedure. A link to the CLA Committee’s report can be found at: <http://www.assembly.wales/laid%20documents/cr-ld12093/cr-ld12093-e.pdf>

### **3. Legislative background**

3.1 This instrument is being made 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. The

instrument is also made under paragraph 21 of Schedule 7 to the European Union (Withdrawal) Act 2018. 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?***

###### Commission Directive 1999/21/EC

- 4.1 The Medical Food (Wales) Regulations 2000 make provision for the execution and enforcement of Commission Directive 1999/21/EC on dietary foods for special medical purposes.
- 4.2 The Directive classifies such foods as foods specially processed or formulated for the dietary management, under medical supervision, of patients who require a special diet. The Directive requires Member States to ensure that such food may only be marketed if it complies with the requirements as set out by the Directive. The Directive lays down requirements for formulation, composition and instructions for use of such food, and for its naming and labelling.
- 4.3 The Directive requires notification to competent authorities of the placing on the market of products covered by the Directive whether manufactured within, or imported from outside the European Community. Regulation and prohibits sale of medical foods by manufacturers and importers covered by this notification requirement unless they have complied with it.

###### Directive 2002/46/EC

- 4.4 The Food Supplements (Wales) Regulations 2003 make provision for the execution and enforcement of EC Directive 2002/46/EC on food supplements. This Directive sets out the permitted list of vitamins and minerals used as ingredients of food supplements, their minimum and maximum values, labelling presentation, permitted notification requirements, and safeguarding measures.

###### Commission Directive 2006/141/EC

- 4.5 The Infant Formula and Follow-on Formula (Wales) Regulations 2007 make provision for the execution and enforcement of Commission Directive 2006/141/EC on infant formula and follow-on formula, which consolidated Community legislation on the composition, labelling and marketing of infant formula and follow-on formula. The Directive reflects scientific advice on the essential composition of infant formulae and follow-on formulae and discussions at an international level in the Codex Alimentarius forum. The Directive also gives effect to the principles and aims of the 1981 WHO Code on the Marketing of Breastmilk Substitutes dealing with marketing, information and responsibilities of health authorities. The Directive regulates labelling

and restricts advertising and presentation of infant and follow on formula so as not to discourage breastfeeding.

#### Regulation (EC) No 1925/2006

- 4.6 The Addition of Vitamins Minerals and other Substances (Wales) Regulations 2007 make provision for the execution and enforcement of Regulation (EC) 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods. The Regulation lists the vitamins and minerals that can voluntarily be added to food.
- 4.7 In addition, the Regulation puts in place certain restrictions, most notably prohibiting the addition of vitamins and minerals to non-processed foods and beverages containing more than 1.2% by volume of alcohol. It also sets minimum amounts that must be present following addition and puts in place provisions to set maximum amounts.

#### Commission Delegated Regulation (EC) No.2016/128

- 4.8 The Food for Particular Nutritional Uses (Addition of Specific Nutritional Purposes) (Wales) Regulations 2009 make provision for the execution and enforcement of Commission Delegated Regulation (EU) .2016/125 which supplements Regulation No 609/2013 as regards the specific compositional and information requirements for food for special medical purposes. It applies from 22 February 2010, except in respect of food for special medical purposes developed to satisfy the nutritional requirements of infants, for which it does not apply until 22 February 2020. From 22 February 2019, the Regulation repeals Directive 1999/21/EC on food for special medical purposes, with the exception of food for special medical purposes for infants, for which Directive 1999/21/EC will continue to apply until 22 February 2020.

#### Regulation (EU) No 609/2013

- 4.9 Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016 make provision for the execution and enforcement of Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) 41/2009 and (EC) 953/2009.
- 4.10 The Regulation repeals and replaces a regime regulating (mostly, but not exclusively) compositional and labelling requirements which must be met by certain groups of food before such food may be marketed in Member States.

## **Why is it being changed?**

- 4.11 The minor and technical changes made by the instrument are necessary to ensure that the domestic EU legislation enforcing retained EU legislation (the Welsh Regulations) continues to operate effectively. The changes made to ensure that it operates effectively include the removal of references to “member state” EU law/obligations and definitions of “EEA Agreement”, “EEA State” and “free circulation in member States”. It will also fix references to EU Directives where necessary and replaces references to EU bodies with the names of competent UK authorities. The deficiencies which are subject to correction do not make any substantive change to the way the Welsh Regulations operates. The instrument only makes minor, technical amendments to ensure the Welsh Regulations are operable once the UK leaves the EU.

## **What will it now do?**

- 4.12 The instrument will ensure the Welsh Regulations, which provides enforcement powers for the EU law relating to nutrition, composition and labelling 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 two week consultation was conducted in Wales on the principle of the proposed amendments in December. No responses were received. Parallel consultation on their equivalent domestic regulations were conducted in England (which formed part of the broader consultation on the UK Nutrition (Amendment) (EU Exit Regulations 2019), Scotland and Northern Ireland . All responses received in relation to the domestic fixes were in favour of the approach proposed. No amendments to the domestic SI were made as a consequence of the consultation.

## **6. Regulatory Impact Assessment (RIA)**

- 6.1 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 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 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	A statement to explain the good reasons for making the instrument and that what is being done is a reasonable course of action.

		powers in Schedule 2. Welsh Ministers have 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 18(1), 9 and paragraph 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the	A statement to explain why it is appropriate to create such a sub-delegated power.

		<p>Crown or a Devolved Authority.</p> <p>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</p>	
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)**

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 Nutrition (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 changes being made are minor and technical in nature. There is no change to policy.”

#### **2. 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 Nutrition (Miscellaneous Amendments) (Wales) (EU Exit) Regulations 2019 do no more than is appropriate. This is the case because all the changes being made are solely in order to address inoperabilities arising from EU exit. There is no change to policy.”

#### **3. 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 nutrition, composition and labelling failing to operate effectively after the UK leave the EU.”

#### **4. 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.”

## **5. 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.

## **6. Criminal offences**

Not applicable/required.

## **7. Legislative sub-delegation**

Not applicable/required.

## **8. Urgency**

Not applicable/required.