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W E L S H S T A T U T O R Y  
I N S T R U M E N T S

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**2020 No. 89 (W. 13)**

**FOOD, WALES**

**FOOD SAFETY**

**The Infant Formula and Follow-on  
Formula (Wales) Regulations 2020**

**EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

These Regulations, which apply to Wales, make provision to enforce Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No. 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding (OJ No. L 25, 2.2.2016, p. 1, “the Delegated Regulation”).

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 (c. 68) and references in them to provisions of the Delegated Regulation are to be construed as references to such provisions as they are amended from time to time.

Regulation 3 provides that each food authority must execute and enforce these Regulations within its area. Regulation 2(1) contains a definition of “food authority”.

Regulation 4 and Schedule 2 apply, with modifications, certain provisions of the Food Safety Act 1990 (c. 16) for the purposes of these Regulations.

Regulation 5 and Schedule 3 make provision for revocations and savings as a consequence of these Regulations. The Infant Formula and Follow-on Formula (Wales) Regulations 2007 (S.I. 2007/3573 W. 316) (“the 2007 Regulations”) and the provisions which amend those Regulations are revoked. The 2007 Regulations implement Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive

1999/21/EC (OJ No. L 401, 30.12.2006, p. 1) and Council Directive 95/52/EEC on infant formulae and follow-on formulae intended for export to third countries (OJ No. L 179, 1.7.1992, p. 129). Article 13 of the Delegated Regulation repeals that Directive with effect from 22 February 2020, and from 22 February 2021 in the case of infant formula and follow-on formula manufactured from protein hydrolysates.

Regulation 5 of these Regulations further provides for the revocations to be saved for the purposes of the transitional arrangements in that regulation. Those transitional arrangements provide that where infant formula or follow-on formula has been placed on the market or labelled prior to the date of application of the Delegated Regulation (22 February 2020 or, in the case of infant formula or follow-on formula manufactured from protein hydrolysates, 22 February 2021), it may continue to be marketed until stocks are exhausted, provided that certain requirements are met.

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, it was not considered necessary to carry out a regulatory impact assessment as to the likely costs and benefits of complying with these Regulations.

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W E L S H S T A T U T O R Y  
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**2020 No. 89 (W. 13)**

**FOOD, WALES**

**The Infant Formula and Follow-on  
Formula (Wales) Regulations 2020**

*Made* 30 January 2020

*Laid before the National Assembly for  
Wales* 31 January 2020

*Coming into force in accordance with  
regulation 1*

The Welsh Ministers make the following Regulations in exercise of the powers conferred by sections 6(4), 16(1)(a) and (e) and (2)(b), 17(1) and (2), 26(1) and (3) and 48(1) of the Food Safety Act 1990<sup>(1)</sup> and now vested in them<sup>(2)</sup> and section 2(2) of, and paragraph 1A of Schedule 2 to, the European Communities Act 1972<sup>(3)</sup>.

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- (1) 1990 c. 16. Section 6(4) of the Food Safety Act 1990 (“the 1990 Act”) was amended by paragraph 6 of Schedule 9 to the Deregulation and Contracting Out Act 1994 (c. 40), paragraph 10(1) and (3)(a) of Schedule 5, and Schedule 6 to the Food Standards Act 1999 (c. 28) (“the 1999 Act”) and S.I. 2002/794. Section 16(1) of the 1990 Act was amended by paragraphs 7 and 8 of Schedule 5 to the 1999 Act. Section 17 of the 1990 Act was amended by paragraphs 7, 8 and 12 of Schedule 5 to the 1999 Act and S.I. 2011/1043. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 48(1) was amended by paragraphs 7 and 8 of Schedule 5 to the 1999 Act.
- (2) Those functions formerly exercisable by “the Ministers” (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the 1999 Act. Those functions, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act and thereafter transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (c. 32).
- (3) 1972 c. 68 (“the 1972 Act”). Section 2(2) of the 1972 Act was amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 (c. 51) and by section 3(3) of, and Part 1 of the Schedule to, the European Union (Amendment) Act 2008 (c. 7). Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory

The Welsh Ministers have been designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to measures relating to food (including drink) including the primary production of food<sup>(1)</sup>.

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Welsh Ministers that it is expedient for certain references to provisions of Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No. 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding<sup>(2)</sup> to be construed as references to those provisions as amended from time to time.

The Welsh Ministers have had regard to relevant advice given by the Food Standards Agency in accordance with section 48(4A) of the Food Safety Act 1990<sup>(3)</sup>.

There has been open and transparent public consultation as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>(4)</sup>, during the preparation and evaluation of these Regulations.

### **Title, commencement and application**

**1.**—(1) The title of these Regulations is the Infant Formula and Follow-on Formula (Wales) Regulations 2020.

(2) These Regulations come into force—

(a) except where sub-paragraph (b) applies, on 22 February 2020;

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Reform Act 2006. It was amended by section 3(3) of, and Part 1 of the Schedule to, the European Union (Amendment) Act 2008 and S.I. 2007/1388.

- (1) S.I. 2005/1971, to which there are amendments not relevant to these Regulations.
- (2) OJ No. L 25, 2.2.2016, p. 1, as last amended by Commission Delegated Regulation (EU) 2019/828 (OJ No. L 137, 23.5.2019, p. 12).
- (3) Section 48(4A) was inserted by section 40(1) of, and paragraph 21 of Schedule 5 to, the 1999 Act.
- (4) OJ No. L 31, 1.2.2002, p. 1, as last amended by Regulation (EU) 2019/1243 of the European Parliament and of the Council (OJ No. L 198, 25.7.2019, p. 241).

(b) on 22 February 2021 in respect of infant formula and follow-on formula manufactured from protein hydrolysates.

(3) These Regulations apply in relation to Wales.

## Interpretation

2.—(1) In these Regulations—

“the Act” (“*y Ddeddf*”) means the Food Safety Act 1990;

“the Delegated Regulation” (“*y Rheoliad Dirprwyedig*”) means Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No. 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding<sup>(1)</sup>;

“food authority” (“*awdurdod bwyd*”) has the meaning that it bears by virtue of section 5(1A) of the Act<sup>(2)</sup>;

“specified EU law requirement” (“*gofyniad cyfraith UE penodedig*”) means any provision of the Delegated Regulation specified in column 1 of the table in Schedule 1, as read with any provision specified in the corresponding entry in column 2 of that table.

(2) Any reference to a provision of the Delegated Regulation is a reference to that provision as amended from time to time.

(3) Expressions used both in these Regulations and in the Delegated Regulation have the same meaning in these Regulations as they have in the Delegated Regulation.

## Enforcement

3. Each food authority must execute and enforce these Regulations within its area.

## Application of provisions of the Act

4.—(1) Section 10(1) and (2) of the Act (improvement notices) applies, with the modification (in the case of section 10(1)) specified in Part 1 of Schedule 2, for the purposes of—

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(1) OJ No. L 25, 2.2.2016, p. 1, as last amended by Commission Delegated Regulation (EU) 2019/828 (OJ No. L 137, 23.5.2019, p. 12).

(2) Section 5(1A) was inserted by paragraph 16 of Schedule 9 to the Local Government (Wales) Act 1994 (c. 19).

- (a) enabling an improvement notice to be served on a person requiring that person to secure compliance with any specified EU law requirement; and
- (b) making a failure to comply with a notice referred to in sub-paragraph (a) an offence.

(2) Section 32(1) to (8) of the Act<sup>(1)</sup> (powers of entry) applies, with the modifications (in the case of section 32(1)) specified in Part 2 of Schedule 2, for the purposes of enabling an authorised officer of an enforcement authority—

- (a) to exercise a power of entry to ascertain whether food that does not comply with a specified EU law requirement is, or has been, sold; and
- (b) to exercise a power of entry to ascertain whether there is any evidence of any contravention of a specified EU law requirement.

(3) Section 35 of the Act (punishment of offences) applies, with the modifications specified in Part 3 of Schedule 2, for the purpose of specifying the punishment of an offence committed under section 10(2) as applied by paragraph (1)(b).

(4) Section 37 of the Act (appeals) applies, with the modifications specified in Part 4 of Schedule 2, for the purpose of enabling a person to appeal a decision to serve a notice referred to in paragraph (1)(a).

(5) Section 39 of the Act (appeals against improvement notices) applies, with the modifications (in the case of section 39(1) and (3)) specified in Part 5 of Schedule 2, for the purpose of dealing with appeals against a decision to serve a notice referred to in paragraph (1)(a).

(6) The provisions of the Act specified in paragraph (7) (“the paragraph (7) provisions”) apply, with the modifications specified in Part 6 of Schedule 2, for the purposes of these Regulations insofar as they relate to the provisions of the Act specified in and modified by paragraphs (1) to (5).

(7) The provisions of the Act specified for the purposes of this paragraph are—

- (a) section 3 (presumptions that food intended for human consumption);
- (b) section 20 (offences due to fault of another person);
- (c) section 21<sup>(2)</sup> (defence of due diligence);

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(1) There are amendments to section 32(5) and (6), but none are relevant.

(2) Section 21 was amended by S.I. 2004/3279.

- (d) section 22 (defence of publication in the course of business);
- (e) section 29 (procurement of samples);
- (f) section 30(1) (analysis etc. of samples);
- (g) section 33(2) (obstruction etc. of officers);
- (h) section 36 (offences by bodies corporate);
- (i) section 36A(3) (offences by Scottish partnerships);
- (j) section 44 (protection of officers acting in good faith);
- (k) section 53 (general interpretation);

and any reference in the paragraph (7) provisions to a section of the Act, including a reference to “any of the preceding provisions of this Part”, is to be read as a reference to such sections of the Act that apply by virtue of, and with the modifications made by, these Regulations.

#### **Revocations, savings and transitional provisions**

5.—(1) The instruments specified in column 1 of the table in Schedule 3 are revoked to the extent specified in column 3 of that table, subject to paragraph (2).

(2) The instruments specified in column 1 of the table in Schedule 3 continue to have effect (so far as otherwise revoked to the extent specified in column 3 of that table)—

- (a) until 21 February 2021 in respect of infant formula and follow-on formula manufactured from protein hydrolysates;
- (b) for the purposes of paragraph (3)(b).

(3) Infant formula and follow-on formula which does not comply with a specified EU law requirement may continue to be marketed until stocks of such food are exhausted, provided that—

- (a) it was placed on the market or labelled—
  - (i) before 22 February 2020; or
  - (ii) before 22 February 2021 in the case of infant formula and follow-on formula manufactured from protein hydrolysates; and
- (b) the conditions specified in the following provision of the Infant Formula and Follow-

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(1) Section 30 was amended by paragraphs 7 and 8 of Schedule 5 to the 1999 Act.

(2) Section 33 was amended by paragraph 3(1) and (4) of the Schedule to the Food (Scotland) Act 2015 (asp 1).

(3) Section 36A was inserted by paragraph 16 of Schedule 5 to the 1999 Act.

on Formula (Wales) Regulations 2007<sup>(1)</sup> are met—

- (i) regulation 3(1) (prohibition on the marketing of infant formula unless certain conditions are met) in the case of infant formula;
- (ii) regulation 3(2) (prohibition on the marketing of follow-on formula unless certain conditions are met) in the case of follow-on formula.

*Vaughan Gething*

Minister for Health and Social Services, one of the  
Welsh Ministers  
30 January 2020

## SCHEDULE 1 Regulation 2(1)

### Specified EU law requirements

<b>Column 1</b>	<b>Column 2</b>
<i>Specified provision of the Delegated Regulation</i>	<i>Provision of the Delegated Regulation to be read with the specified provision of the Delegated Regulation</i>
Article 1(2) (placing on the market)	Article 1(1)
Article 2(1) (compositional requirements for infant formula)	Articles 1(1) and 2(3), Annex 1 and Annex 3
Article 2(2) (compositional requirements for follow-on formula)	Articles 1(1) and 2(3), Annex 2 and Annex 3
Article 2(3) (preparation of infant and follow-on formula)	Articles 1(1), 2(1) and (2)
Article 3(1) (suitability of ingredients for infant formula)	Articles 1(1) and 3(3) and paragraph 2 of Annex 1
Article 3(2) (suitability of ingredients for follow-on formula)	Articles 1(1) and 3(3) and paragraph 2 of Annex 2
Article 4(2) (active substance residue threshold)	Articles 1(1) and 4(1), (3) and (5)
Article 4(3) (derogation	Articles 1(1) and 4(1), (2)

(1) S.I. 2007/3573 (W. 316). The relevant amending instrument is S.I. 2008/2602 (W. 228).



from active substance residue threshold)	and (5)
Article 4(4) (requirements on pesticides)	Articles 1(1) and 4(1) and (5)
Article 5(1) (name of food not manufactured entirely from cows' or goats' milk protein)	Article 1(1) and Part A of Annex 6
Article 5(2) (name of food manufactured entirely from cows' or goats' milk protein)	Article 1(1) and Part B of Annex 6
Article 6 (specific requirements on food information)	Articles 1(1) and 7(1), (2), (3), (5), (6), (7) and (8)
Article 7(1) (specific requirements on the nutrition declaration)	Articles 1(1) and 7(4), Annex 1 and Annex 2
Article 7(3) (repetition of information included in mandatory nutrition declaration)	Article 1(1)
Article 7(4) (nutrition declaration mandatory regardless of size of packaging or container)	Articles 1(1) and 7(1), Annex 1 and Annex 2
Article 7(5) (application of Articles 31 to 35 of Regulation (EU) No. 1169/2011 <sup>(1)</sup> )	Articles 1(1) and 7(6), (7) and (8)
Article 7(6) (expression of energy value and amounts of nutrients)	Articles 1(1) and 7(5)
The first sub-paragraph of Article 7(7) (prohibition on expressing energy value and amount of nutrients as a percentage of reference intake)	Articles 1(1) and 7(5)
Article 7(8) (presentation of particulars included in the nutrition declaration)	Article 1(1)
Article 8 (prohibition on making nutrition and health claims on infant formula)	Article 1(1)
Article 9(1) ("lactose only" statement)	Article 1(1)
The first sub-paragraph of Article 9(2) ("lactose free" statement)	Article 1(1)
The second sub-paragraph of Article 9(2) (statement that "lactose free" infant formula and follow-on formula is not suitable for	Article 1(1)

infants with galactosaemia)	
Article 9(3) (prohibition on references to docosahexaenoic acid where infant formula placed on the market on or after 22 February 2025)	Article 1(1)
Article 10(1) (restriction on advertising for infant formula)	Article 1(1)
Article 10(2) (prohibition of promotional devices to induce sales of infant formula)	Article 1(1)
Article 10(3) (prohibition of provision of free or low-priced products, samples or other promotional gifts to the general public, pregnant women, mothers or members of their families)	Article 1(1)
Article 10(4) (requirements for donations or low-priced sales of supplies of infant formula to institutions or organisations)	Article 1(1)
Article 11(2) (requirements on information relating to infant and young child feeding)	Article 1(1)
Article 11(3) (requirements on donations of informational or educational equipment or materials)	
Article 12 (notification requirements)	Article 1(1)

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<sup>(1)</sup> Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, etc (OJ No. L 304, 22.11.2011, p. 18).

SCHEDULE 2 Regulation 4

Modification of provisions of the Act

PART 1

Modification of section 10 of the Act

1. Section 10 of the Act (improvement notices) applies as if, for subsection (1), there were substituted—

“(1) If an authorised officer of an enforcement authority has reasonable grounds for believing that a person is failing to comply with a specified EU law requirement, the authorised officer may, by a notice served on that person (in this Act referred to as an “improvement notice”)—

- (a) state the officer’s grounds for believing that the person is failing to comply or, as the case may be, that the food does not comply with the specified EU law requirement;
- (b) specify the matters which constitute the failure to comply;
- (c) specify the measures which, in the officer’s opinion, the person must take in order to secure compliance; and
- (d) require the person to take those measures, or such measures that are at least equivalent to them, within such period as may be specified in the notice.”

PART 2

Modification of section 32 of the Act

2. Section 32 of the Act(1) (powers of entry) applies as if—

- (a) in subsection (1) for paragraphs (a) to (c) there were substituted—

“(a) to enter any premises within the authority’s area for the purpose of ascertaining whether there has been any contravention of a specified EU law requirement;

- (b) to enter any business premises, whether within or outside the authority’s area,

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(1) Section 32(5) and (6) was amended by section 70 of, and paragraph 18 of Schedule 2 to, the Criminal Justice and Police Act 2001 (c. 16).

for the purpose of ascertaining whether there is on the premises any evidence of any contravention of a specified EU law requirement; and

- (c) when exercising a power of entry under this section, to exercise the associated powers in subsections (5) and (6) relating to records;”;
- (b) subsection (9) were omitted.

### PART 3

#### Modification of section 35 of the Act

3. Section 35 of the Act (punishment of offences) applies as if, before subsection (2), there were inserted—

“(1B) A person guilty of an offence under section 10(2), as applied by regulation 4(1) of the Infant Formula and Follow-on Formula (Wales) Regulations 2020, is liable on summary conviction, to a fine.”

### PART 4

#### Modification of section 37 of the Act

4. Section 37 of the Act (appeals to magistrates’ court or sheriff) applies as if—

- (a) for the heading there were substituted “Appeals”;
- (b) for subsection (1) there were substituted—

“(1) Any person who is aggrieved by a decision of an authorised officer of an enforcement authority to serve an improvement notice under section 10(1), as applied and modified by regulation 4(1) of, and Part 1 of Schedule 2 to, the Infant Formula and Follow-on Formula (Wales) Regulations 2020 may appeal to the magistrates’ court.”;

(c) subsection (2) were omitted;

(d) for subsection (5) there were substituted—

“(5) The period within which such an appeal as is mentioned in subsection (1) above may be brought must be—whichever ends the earlier—

- (a) one month from the date on which notice of the decision was served on the person desiring to appeal; or
- (b) the period specified in the improvement notice

and in the case of such an appeal, the making of the complaint shall be deemed for the purposes

of this subsection to be the bringing of the appeal.”

- (e) in subsection (6)—
  - (i) for “ subsection (3) or (4)” there were substituted “subsection (1)”; and
  - (ii) in paragraph (a), “or to the sheriff” were omitted.

## PART 5

### Modification of section 39 of the Act

**5.** Section 39 of the Act (appeals against improvement notices) applies as if in subsection (3), “for want of prosecution” were omitted.

## PART 6

### Further modifications of provisions of the Act

**6.** Section 3 of the 1990 Act (presumptions that food intended for human consumption) applies as if, in subsection (1), for “this Act” there were substituted “the 2020 Regulations”.

**7.** Section 20 of the Act (offences due to fault of another person) applies as if, for “any of the preceding provisions of this Part”, there were substituted “the 2020 Regulations”.

**8.** Section 21 of the Act (defence of due diligence) applies as if, in subsection (1), for “any of the preceding provisions of this Part”, there were substituted “the 2020 Regulations”.

**9.** Section 22 of the Act (defence of publication in the course of business) applies as if, for “any of the preceding provisions of this Part”, there were substituted “the 2020 Regulations”.

**10.** Section 29 of the Act (procurement of samples) applies as if, in paragraph (b)(ii), after “under section 32 below”, there were inserted “including under section 32 as applied and modified by regulation 4(2) of, and Part 2 of Schedule 2 to, the 2020 Regulations”.

**11.** Section 30 of the Act (analysis etc. of samples) applies as if—

- (a) in subsection (1), after “under section 29 above”, there were inserted “including under section 29 as applied and modified by regulation 4(6) of, and Part 6 of Schedule 2 to, the 2020 Regulations”; and
- (b) in subsection (8), for “this Act” there were substituted “the 2020 Regulations”.

**12.** Section 33 of the Act (obstruction etc. of officers) applies as if, in subsection (1), for “this Act” (in each place where it occurs) there were substituted “the 2020 Regulations”.

**13.** Section 36 of the Act (offences by bodies corporate) applies as if, in subsection (1), for “this Act” there were substituted “the 2020 Regulations”.

**14.** Section 36A of the Act<sup>(1)</sup> (offences by Scottish partnerships) applies as if, for “this Act”, there were substituted “the 2020 Regulations”.

**15.** Section 44 of the Act (protection of officers acting in good faith) applies as if, for “this Act”, in each place where those words appear, there were substituted “the 2020 Regulations”.

**16.** Section 53 (general interpretation) applies as if—

(a) after the definition of “the 1956 Act” there were inserted—

““the 2020 Regulations” means the Infant Formula and Follow-on Formula (Wales) Regulations 2020;”;

(b) after the definition of “slaughterhouse” there were inserted—

““specified EU law requirement” has the meaning given in regulation 2(1) of the 2020 Regulations;”.

### SCHEDULE 3 Regulation 5(1)

#### Revocations relating to Infant Formula and Follow-on Formula

<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>
<i>Instrument</i>	<i>Reference</i>	<i>Extent of revocation</i>
Infant Formula and Follow-on Formula (Wales) Regulations 2007	S.I. 2007/3573 (W. 316)	The whole of the Regulations, except regulation 30
Infant Formula and Follow-on Formula (Amendment) (Wales) Regulations 2008	S.I. 2008/2602 (W. 228)	Regulation 2
Infant Formula	S.I. 2014/123	The whole of

(1) Section 36A was inserted by section 40(1) of, and paragraph 16 of Schedule 5 to, the 1999 Act.

and Follow-on Formula (Wales) (Amendment) Regulations 2014	(W. 13)	the Regulations
Transfer of Functions (Food) (Wales) Regulations 2014	S.I. 2014/1102 (W. 110)	Regulation 5
Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016	S.I. 2016/639 (W. 175)	Schedule 3, paragraph 4

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