
WELSH STATUTORY INSTRUMENTS

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^{M1} and now vested in them^{M2} and section 2(2) of, and paragraph 1A of Schedule 2 to, the European Communities Act 1972^{M3}.

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^{M4}.

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^{M5} 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^{M6}.

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^{M7}, during the preparation and evaluation of these Regulations.

Marginal Citations

M1 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.

- M2** 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 \(c. 32\)](#).
- M3** [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 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](#).
- M4** [S.I. 2005/1971](#), to which there are amendments not relevant to these Regulations.
- M5** 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).
- M6** [Section 48\(4A\)](#) was inserted by section 40(1) of, and paragraph 21 of Schedule 5 to, the 1999 Act.
- M7** 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).

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;
- (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.

Commencement Information

- I1** Reg. 1 in force at 22.2.2020 for specified purposes at 22.2.2021 in so far as not already in force, see [reg. 1\(2\)](#)

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 ^{M8};

“food authority” (“*awdurdod bwyd*”) has the meaning that it bears by virtue of section 5(1A) of the Act ^{M9};

“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.

Commencement Information

I2 Reg. 2 in force at 22.2.2020 for specified purpose and at 22.2.2021 in so far as not already in force, see [reg. 1\(2\)](#)

Marginal Citations

M8 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).

M9 [Section 5\(1A\)](#) was inserted by paragraph 16 of Schedule 9 to the [Local Government \(Wales\) Act 1994](#) (c. 19).

Enforcement

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

Commencement Information

I3 Reg. 3 in force at 22.2.2020 for specified purposes and at 22.2.2021 in so far as not already in force, see [reg. 1\(2\)](#)

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—

- (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^{M10} (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 ^{M11} (defence of due diligence);
- (d) section 22 (defence of publication in the course of business);
- (e) section 29 (procurement of samples);
- (f) section 30 ^{M12} (analysis etc. of samples);
- (g) section 33 ^{M13} (obstruction etc. of officers);
- (h) section 36 (offences by bodies corporate);
- (i) section 36A ^{M14} (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.

Commencement Information

- I4** Reg. 4 in force at 22.2.2020 for specified purposes and at 22.2.2021 in so far as not already in force, see [reg. 1\(2\)](#)

Marginal Citations

- M10** There are amendments to section 32(5) and (6), but none are relevant.
- M11** [Section 21](#) was amended by [S.I. 2004/3279](#).
- M12** [Section 30](#) was amended by paragraphs 7 and 8 of Schedule 5 to the 1999 Act.
- M13** [Section 33](#) was amended by paragraph 3(1) and (4) of the Schedule to the [Food \(Scotland\) Act 2015](#) (asp 1).
- M14** [Section 36A](#) was inserted by paragraph 16 of Schedule 5 to the 1999 Act.

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-on Formula (Wales) Regulations 2007 ^{M15} 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.

[^{F1}(4) Regulations 2 to 4 do not apply in respect of infant formula and follow-on formula manufactured from protein hydrolysates until 22 February 2022.

(5) Schedule 4 makes provision in relation to infant formula and follow-on formula manufactured from protein hydrolysates until 22 February 2022.]

Textual Amendments

- F1** Reg. 5(4)(5) inserted (16.9.2021) by [The Infant Formula and Follow-on Formula \(Wales\) \(Amendment\) Regulations 2021 \(S.I. 2021/955\)](#), regs. 1(2), **2(2)**

Commencement Information

- I5** Reg. 5 in force at 22.2.2020 for specified purposes and at 22.2.2021 in so far as not already in force, see [reg. 1\(2\)](#)

Marginal Citations

- M15** [S.I. 2007/3573](#) (W. 316). The relevant amending instrument is [S.I. 2008/2602](#) (W. 228).

Vaughan Gething
Minister for Health and Social Services, one of
the Welsh Ministers

SCHEDULE 1

Regulation 2(1)

Specified EU law requirements

Commencement Information

I6 Sch. 1 in force at 22.2.2020 for specified purposes and at 22.2.2021 in so far as not already in force, see [reg. 1\(2\)](#)

<i>Column 1</i>	<i>Column 2</i>
<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 from active substance residue threshold)	Articles 1(1) and 4(1), (2) 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)

¹ 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).

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. 1169/2011¹) 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 infants with galactosaemia) Article 1(1)

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)

¹ 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).

Article 11(2) (requirements on Article 1(1) information relating to infant and young child feeding)

Article 11(3) (requirements on donations of informational or educational equipment or materials)

Article 12 (notification requirements) Article 1(1)

¹ 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.”

Commencement Information

I7 Sch. 2 para. 1 in force at 22.2.2020 for specified purposes and at 22.2.2021 in so far as not already in force, see [reg. 1\(2\)](#)

PART 2

Modification of section 32 of the Act

2. Section 32 of the Act ^{M16} (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, 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.

Commencement Information

I8 Sch. 2 para. 2 in force at 22.2.2020 for specified purposes and at 22.2.2021 in so far as not already in force, see [reg. 1\(2\)](#)

Marginal Citations

M16 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 \(c. 16\)](#).

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.”

Commencement Information

I9 Sch. 2 para. 3 in force at 22.2.2020 for specified purposes and at 22.2.2021 in so far as not already in force, see [reg. 1\(2\)](#)

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—

Changes to legislation: There are currently no known outstanding effects for the The Infant Formula and Follow-on Formula (Wales) Regulations 2020. (See end of Document for details)

“(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.

Commencement Information

I10 Sch. 2 para. 4 in force at 22.2.2020 for specified purposes and at 22.2.2021 in so far as not already in force, see [reg. 1\(2\)](#)

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.

Commencement Information

I11 Sch. 2 para. 5 in force at 22.2.2020 for specified purposes and at 22.2.2021 in so far as not already in force, see [reg. 1\(2\)](#)

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 ”.

Commencement Information

I12 Sch. 2 para. 6 in force at 22.2.2020 for specified purposes and at 22.2.2021 in so far as not already in force, see [reg. 1\(2\)](#)

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 ”.

Commencement Information

I13 Sch. 2 para. 7 in force at 22.2.2020 for specified purposes and at 22.2.2021 in so far as not already in force, see [reg. 1\(2\)](#)

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 ”.

Commencement Information

I14 Sch. 2 para. 8 in force at 22.2.2020 for specified purposes and at 22.2.2021 in so far as not already in force, see [reg. 1\(2\)](#)

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 ”.

Commencement Information

I15 Sch. 2 para. 9 in force at 22.2.2020 for specified purposes and at 22.2.2021 in so far as not already in force, see [reg. 1\(2\)](#)

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 ”.

Commencement Information

I16 Sch. 2 para. 10 in force at 22.2.2020 for specified purposes and at 22.2.2021 in so far as not already in force, see [reg. 1\(2\)](#)

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 ”.

Commencement Information

I17 Sch. 2 para. 11 in force at 22.2.2020 for specified purposes and at 22.2.2021 in so far as not already in force, see [reg. 1\(2\)](#)

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 ”.

Commencement Information

I18 Sch. 2 para. 12 in force at 22.2.2020 for specified purposes and at 22.2.2021 in so far as not already in force, see [reg. 1\(2\)](#)

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 ”.

Commencement Information

I19 Sch. 2 para. 13 in force at 22.2.2020 for specified purposes and at 22.2.2021 in so far as not already in force, see [reg. 1\(2\)](#)

14. Section 36A of the Act ^{M17} (offences by Scottish partnerships) applies as if, for “this Act”, there were substituted “ the 2020 Regulations ”.

Commencement Information

I20 Sch. 2 para. 14 in force at 22.2.2020 for specified purposes and at 22.2.2021 in so far as not already in force, see [reg. 1\(2\)](#)

Marginal Citations

M17 [Section 36A](#) was inserted by section 40(1) of, and paragraph 16 of Schedule 5 to, the 1999 Act.

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 ”.

Commencement Information

I21 Sch. 2 para. 15 in force at 22.2.2020 for specified purposes and at 22.2.2021 in so far as not already in force, see [reg. 1\(2\)](#)

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;”.

Commencement Information

I22 Sch. 2 para. 16 in force at 22.2.2020 for specified purposes and at 22.2.2021 in so far as not already in force, see [reg. 1\(2\)](#)

SCHEDULE 3

Regulation 5(1)

Revocations relating to Infant Formula and Follow-on Formula

Commencement Information

I23 Sch. 3 in force at 22.2.2020 for specified purposes and at 22.2.2021 in so far as not already in force, see [reg. 1\(2\)](#)

Column 1 Instrument	Column 2 Reference	Column 3 Extent of revocation
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 and Follow-on Formula (Wales) (Amendment) Regulations 2014	S.I. 2014/123 (W. 13)	The whole of 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

[F2] SCHEDULE 4

Regulation 5(5)

Regulation of infant formula and follow-on formula manufactured from protein hydrolysates until 22 February 2022

Textual Amendments

F2 Sch. 4 inserted (16.9.2021) by [The Infant Formula and Follow-on Formula \(Wales\) \(Amendment\) Regulations 2021 \(S.I. 2021/955\)](#), [reg. 1\(2\)](#), [Sch.](#)

Interpretation

1.—(1) In this Schedule—

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

“the Directive” (“*y Gyfarwyddeb*”) means Commission [Directive 2006/141/EC](#) on infant formulae and follow-on formulae and amending [Directive 1999/21/EC](#);

“follow-on formula” (“*fformiwla ddilynoI*”) means foodstuffs intended for particular nutritional use by infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such infants;

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

“health care system” (“*system gofal iechyd*”) means institutions or organisations engaged, directly or indirectly, in health care for mothers, infants and pregnant women, including nurseries or child care institutions and health workers in private practice;

“infant formula” (“*fformiwla fabanod*”) means foodstuffs intended for particular nutritional use by infants during the first months of life and satisfying by themselves the nutritional requirements of such infants until the introduction of appropriate complementary feeding;

“infants” (“*babanod*”) means children under the age of 12 months;

“young children” (“*plant ifanc*”) means children aged between one and three years.

(2) Subject to sub-paragraph (3), any expression other than one defined in sub-paragraph (1) that is used both in this Schedule and in the Act has the meaning it bears in the Act.

(3) Any expression used both in this Schedule and in the Directive has the meaning that it bears in the Directive.

(4) In this Schedule, any reference to a numbered Annex is a reference to the Annex bearing that number in the Directive.

Prohibition on the marketing of infant formula or follow-on formula unless certain conditions are met

2.—(1) No person may market infant formula which contravenes or fails to comply with paragraph 4, 5, 7, 9, 10, 11, 13(1), (2) or (3), 14, 16, 18 or 19(1).

(2) No person may market follow-on formula which contravenes or fails to comply with paragraph 4, 6, 8, 9, 10, 11, 13(1), (2) or (3), 15, 17, 18 or 19(2).

Prohibition on the marketing of products other than infant formula for normal healthy infants

3. No person may market or otherwise represent a product as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life until the introduction of appropriate complementary feeding unless that product is infant formula.

Substances in such quantity as to endanger the health of infants and young children

4. Infant formula and follow-on formula must not contain any substance in such quantity as to endanger the health of infants and young children.

Protein hydrolysates and other food ingredients suitable for infants from birth (infant formula)

5.—(1) Infant formula must be manufactured from—

- (a) protein hydrolysates; and
- (b) other food ingredients the suitability of which for particular nutritional use by infants from birth has been established by generally accepted scientific data and demonstrated in accordance with sub-paragraph (2).

(2) Suitability is to be demonstrated through a systematic review of the available data relating to the expected benefits and to safety considerations as well as, where necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

Protein hydrolysates and other food ingredients suitable for infants aged over 6 months (follow-on formula)

6. Follow-on formula must be manufactured from—
- (a) protein hydrolysates; and
 - (b) other food ingredients the suitability of which for particular nutritional use by infants aged over 6 months has been established by generally accepted scientific data and demonstrated in accordance with paragraph 5(2).

Compositional criteria for infant formula

7.—(1) Subject to sub-paragraph (2), infant formula must comply with the compositional criteria set out in Annex I taking into account the specifications in Annex V.

(2) In the case of infant formula manufactured from protein hydrolysates specified in point 2.2 of Annex I with a protein content between the minimum and 0.56g/100kJ (2.25g/100 kcal)—

- (a) the suitability of the infant formula for the particular nutritional use by infants must be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies; and
- (b) the infant formula must be in accordance with the appropriate specifications set out in Annex VI.

Compositional criteria for follow-on formula

8.—(1) Subject to sub-paragraph (2), follow-on formula must comply with the compositional criteria set out in Annex II taking into account the specifications set out in Annex V.

(2) In the case of follow-on formula manufactured from those protein hydrolysates specified in point 2.2 of Annex II with a protein content between the minimum and 0.56g/100kJ (2.25g/100kcal) —

- (a) the suitability of the follow-on formula for satisfying the nutritional requirements of normal healthy infants in conjunction with complementary feeding must be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies; and
- (b) the follow-on formula must be in accordance with the appropriate specifications set out in Annex VI.

Addition of water (infant formula and follow-on formula)

9. In order to make infant formula or follow-on formula ready for use nothing more must be required than the addition of water.

Prohibitions and limitations on the use of food ingredients (infant formula and follow-on formula)

10. The prohibitions and limitations on the use of food ingredients in infant formula and follow-on formula, set out respectively in Annexes I and II, must be observed.

Listed substances and their purity criteria (infant formula and follow-on formula)

11.—(1) Only the substances listed in Annex III may be used in the manufacture of infant formula and follow-on formula in order to satisfy the requirements of Annexes I and II respectively on—

- (a) mineral substances;
- (b) vitamins;
- (c) amino acids and other nitrogen compounds; and
- (d) other substances having a particular nutritional purpose.

(2) Substances used in the manufacture of infant formula and follow-on formula pursuant to sub-paragraph (1) must meet the relevant purity criteria.

(3) The relevant purity criteria for the purposes of sub-paragraph (2) are—

- (a) the purity criteria for substances, as provided for in [F3assimilated] law concerning the use of substances listed in Annex III, in the manufacture of foodstuffs for purposes other than those covered by the Directive; and
- (b) in the absence of such purity criteria, generally acceptable purity criteria recommended by international bodies.

Textual Amendments

- F3** Word in Sch. 4 para. 11(3)(a) substituted (1.1.2024) by [The Retained EU Law \(Revocation and Reform\) Act 2023 \(Consequential Amendments\) \(Wales\) Regulations 2023 \(S.I. 2023/1332\)](#), regs. 1(2), **23**

Notification of infant formula

12. No food business operator may place an infant formula on the market in Wales that has not yet been placed on the market in the United Kingdom unless the food business operator has given prior notice to the Welsh Ministers by forwarding to them a model of the label used for the product.

Pesticide residues (infant formula and follow-on formula)

13.—(1) Subject to sub-paragraphs (2) and (3), infant formula and follow-on formula must not contain residues of individual pesticides at levels exceeding 0.01 mg/kg.

(2) Infant formula and follow-on formula must not contain any pesticide residue of a pesticide listed in Table 1 or Table 2 of Annex VIII at a level exceeding 0.003 mg/kg.

(3) Infant formula and follow-on formula must not contain any pesticide residue of a pesticide listed in Annex IX at a level exceeding the maximum residue level specified in that Annex.

(4) The levels referred to in sub-paragraphs (1) to (3) apply to the infant formula or follow-on formula—

- (a) manufactured in a form that is ready for consumption; or
- (b) if it is not so manufactured, as reconstituted according to the manufacturers' instructions.

(5) Analytical methods for determining levels of pesticide residues for the purposes of this paragraph must be generally acceptable standardised methods.

Naming of infant formula

14. Infant formula must not be sold unless it is sold under the name “infant formula”.

Naming of follow-on formula

15. Follow-on formula must not be sold unless it is sold under the name “follow-on formula”.

Labelling of infant formula

16.—(1) Infant formula must not be sold unless the labelling bears—

- (a) a statement to the effect that the product is suitable for particular nutritional use by infants from birth when they are not breast fed;
- (b) the available energy value, expressed in kJ and kcal, and the content of proteins, carbohydrates and lipids, expressed in numerical form, per 100ml of the product ready for use;
- (c) the average quantity of each mineral substance and of each vitamin mentioned in Annex I and, where applicable, of choline, inositol and carnitine, expressed in numerical form, per 100ml of the product ready for use;
- (d) instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage; and
- (e) the words “Important Notice” or their equivalent immediately followed by—
 - (i) a statement concerning the superiority of breast feeding; and
 - (ii) a statement recommending that the product be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care.

(2) The labelling of infant formula must—

- (a) be designed to provide the necessary information about the appropriate use of the product so as not to discourage breast feeding; and
- (b) not contain the terms “humanised”, “maternalised”, “adapted” or any similar term.

(3) The labelling of an infant formula must not include—

- (a) any picture of an infant; or
- (b) any other picture or text which may idealise the use of the product,

but may include graphic representations for easy identification of the product or for illustrating methods of preparation.

(4) The labelling of an infant formula may bear nutrition and health claims only when—

- (a) the claim is listed in the first column of Annex IV and is expressed in the terms set out there; and
- (b) the condition specified in the second column of Annex IV in relation to the relevant claim made in the first column is satisfied.

(5) The labelling of an infant formula may bear particulars of the average quantity of nutrients mentioned in Annex III when such information is not covered by sub-paragraph (1)(c) expressed in numerical form, per 100 ml of the product ready for use.

Labelling of follow-on formula

17.—(1) Follow-on formula must not be sold unless the labelling bears—

- (a) a statement to the effect that—
 - (i) the product is suitable only for particular nutritional use by infants over the age of 6 months;
 - (ii) it should form only part of a diversified diet;

- (iii) it is not to be used by infants as a substitute for breast milk during the first 6 months of life; and
 - (iv) the decision to begin complementary feeding, including any decision as to making an exception to the principle of not using follow-on formula before 6 months of age should be made only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal or child care, based on the individual infant's specific growth and development needs;
 - (b) the available energy value, expressed in kJ and kcal, and the content of proteins, carbohydrates and lipids, expressed in numerical form, per 100ml of the product ready for use;
 - (c) the average quantity of each mineral substance and of each vitamin mentioned in Annex II and, where applicable, of choline, inositol and carnitine, expressed in numerical form, per 100ml of the product ready for use;
 - (d) instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage.
- (2) The labelling of follow-on formula must—
- (a) be designed to provide the necessary information about the appropriate use of the product so as not to discourage breast feeding; and
 - (b) not contain the terms “humanised”, “maternalised”, “adapted” or any similar term.
- (3) The labelling of a follow-on formula may bear particulars of—
- (a) the average quantity of nutrients mentioned in Annex III when such information is not covered by sub-paragraph (1)(c) expressed in numerical form, per 100 ml of the product ready for use; and
 - (b) in addition to numerical information, information on vitamins and minerals included in Annex VII, expressed as a percentage of the reference values given in that Annex, per 100ml of the product ready for use.

Avoidance of the risk of confusion between infant formula and follow-on formula

18. Infant formula and follow-on formula must be labelled in such a way that it enables consumers to make a clear distinction between such products so as to avoid any risk of confusion between infant formula and follow-on formula.

Presentation (infant formula and follow-on formula)

19.—(1) The presentation of infant formula must comply with the provisions of paragraphs 16(1)(e), (2), (3) and (4) and 18.

(2) The presentation of follow-on formula must comply with the provisions of paragraphs 17(2) and 18.

(3) For the purposes of this paragraph, “presentation” includes the shape, appearance or packaging of the products concerned, the packaging materials used, the way in which they are arranged and the setting in which they are displayed.

Restrictions on advertising infant formula

20.—(1) No person may advertise infant formula—

- (a) except—
 - (i) in a scientific publication; or

- (ii) for the purposes of trade prior to the retail stage, in a publication of which the intended readership is other than the general public; and
 - (b) unless the advertisement complies with the provisions of paragraphs 16(1)(e), (2), (3) and (4), paragraph 18 and sub-paragraphs (2) and (3).
- (2) Advertisements for infant formula must only contain information of a scientific and factual nature.
- (3) Information in advertisements for infant formula must not imply or create a belief that bottle feeding is equivalent or superior to breast feeding.

Restrictions on advertising follow-on formula

21. No person may advertise follow-on formula where the advertisement contravenes or fails to comply with the provisions set out in paragraphs 17(2) and 18.

Restrictions on promotion of infant formula

- 22.**—(1) No person may, at any place where any infant formula is sold by retail—
- (a) advertise any infant formula;
 - (b) make any special display of an infant formula designed to promote sales;
 - (c) give away—
 - (i) any infant formula as a free sample; or
 - (ii) any coupon which may be used to purchase an infant formula at a discount;
 - (d) promote the sale of an infant formula by means of premiums, special sales, loss-leaders or tie-in sales; or
 - (e) undertake any other promotional activity to induce the sale of an infant formula.
- (2) No manufacturer or distributor of any infant formula may provide for promotional purposes any infant formula free or at a reduced or discounted price, samples or any gift designed to promote the sale of an infant formula, to—
- (a) the general public;
 - (b) pregnant women;
 - (c) mothers; or
 - (d) members of the families of persons mentioned in paragraphs (b) and (c),
- either directly, or indirectly through the health care system or health workers.

Provision of informational and educational material dealing with the feeding of infants

- 23.**—(1) No person may produce or publish any informational or educational material, whether written or audiovisual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, unless that material includes clear information on all the following points—
- (a) the benefits and superiority of breast feeding;
 - (b) maternal nutrition;
 - (c) the preparation for and the maintenance of breast feeding;
 - (d) the possible negative effect on breast feeding of introducing partial bottle feeding;
 - (e) the difficulty of reversing the decision not to breast feed; and
 - (f) where needed, the proper use of an infant formula.

(2) When the material referred to in sub-paragraph (1) contains information about the use of an infant formula it must include information about—

- (a) the social and financial implications of its use;
- (b) the health hazards of inappropriate foods or feeding methods; and
- (c) the health hazards of improper use of infant formula.

(3) When the material referred to in sub-paragraph (1) contains information about the use of an infant formula it must not use any pictures which may idealise the use of infant formula.

(4) No manufacturer or distributor of an infant formula may make a donation of any informational or educational equipment or materials except in accordance with the following conditions—

- (a) the donation must be made following a request by the intended recipient;
- (b) the donation must be made with the written authority of the Welsh Ministers or in accordance with guidelines drawn up by the Welsh Ministers;
- (c) the equipment or materials must not be marked or labelled with the name of a proprietary brand of infant formula; and
- (d) the equipment or materials must be distributed only through the health care system.

Free or reduced rate infant formula

24. An institution or organisation which receives any infant formula free or at a reduced rate must—

- (a) if that infant formula is for use in the institution or organisation, only use it for infants who have to be fed on infant formula and only for as long as required by those infants; or
- (b) if that infant formula is for distribution outside the institution or organisation, only distribute it for infants who have to be fed on infant formula and only for as long as required by those infants.

Offences and enforcement

25.—(1) Any person who contravenes or fails to comply with any of the provisions contained in paragraphs 2, 3, 12, 20(1), 21, 22, 23 and 24, is guilty of an offence and is liable, on summary conviction, to a fine.

(2) Each food authority must enforce and execute this Schedule in its area.

Application of the improvement notice provisions of the Act

26.—(1) Section 10(1) and (2) of the Act (improvement notices) applies, with the modification (in the case of section 10(1)) specified in sub-paragraph (2), for the purposes of—

- (a) enabling an improvement notice to be served on a person requiring the person to secure compliance with any of the requirements specified in paragraph 2; and
- (b) making the failure to comply with a notice referred to in paragraph (a) an offence.

(2) For section 10(1) of the Act (improvement notices) substitute—

“(1) If an authorised officer of an enforcement authority has reasonable ground for suspecting that a person is failing to comply with paragraph 2 of Schedule 4 to the Infant Formula and Follow-on Formula (Wales) Regulations 2020, 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 suspecting that the person is failing to comply or as the case may be, that the food does not comply with the relevant provision;

- (b) specify the matters which constitute the failure to so 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.”
- (3) Section 32(1) to (8) of the Act (powers of entry) applies, with the modification (in the case of section 32(1)) specified in sub-paragraph (4), 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 the requirements of paragraph 2 is, or has been sold; and
 - (b) to exercise a power of entry to ascertain whether there is any evidence of any contravention of paragraph 2.
- (4) For paragraphs (a) to (c) of section 32(1) (powers of entry) of the Act substitute—
- “(a) to enter any premises within the authority’s area for the purposes of ascertaining whether there has been any contravention of paragraph 2 of Schedule 4 to the Infant Formula and Follow-on Formula (Wales) Regulations 2020; and
 - (b) to enter any business premises, whether within or outside the authority’s area, for the purpose of ascertaining whether there is on the premises any evidence of any contravention of that paragraph.”
- (5) Section 35 of the Act (punishment of offences) applies, with the modification specified in sub-paragraph (6), for the purpose of specifying the punishment of an offence committed under paragraph 26(1)(b).
- (6) In section 35 (punishment of offences) of the Act, after subsection (1) insert—
- “(1A) A person guilty of an offence under section 10(2), as applied and modified by paragraph 26(1) and (2) of Schedule 4 to the Infant Formula and Follow-on Formula (Wales) Regulations 2020, is liable, on summary conviction, to a fine.”
- (7) Section 37(1), (3), (5) and (6) of the Act (appeals) applies for the purpose of enabling a decision to serve a notice referred to in paragraph 26(1)(a) to be repealed, with the following modifications—
- (a) for the heading substitute “Appeals”;
 - (b) for section 37(1) substitute—
 - “(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 paragraph 26(1) and (2) of Schedule 4 to the Infant Formula and Follow-on Formula (Wales) Regulations 2020, may apply to the magistrates’ court.”;
 - (c) for section 37(5) substitute—
 - “(5) The period within which such an appeal as is mentioned in sub-section (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.”;
 - (d) in section 37(6)—
 - (i) for “subsection (3) or (4)” substitute “subsection (1)”; and

(ii) in paragraph (a), omit “or to the sheriff”.

(8) Section 39 of the Act (appeals against improvement notices) applies, with the modification specified in sub-paragraph (9), for the purpose of dealing with appeals against a decision to serve a notice referred to in paragraph 26(1)(a).

(9) In section 39(3) (appeals against improvement notices), omit “for want of prosecution”.

Application of various sections of the Act

27. The following provisions of the Act apply for the purposes of this Schedule with the modification that any reference in those provisions to the Act or Part thereof are to be construed as a reference to this Schedule—

- (a) section 3 (presumptions that food intended for human consumption);
- (b) section 20 (offences due to fault of another person);
- (c) section 21 (defence of due diligence), as it applies for the purpose of section 14 or 15;
- (d) section 30(8) (which relates to documentary evidence);
- (e) section 33(1) (obstruction etc. of officers);
- (f) section 33(2), with the modification that the reference to “any such requirement as is mentioned in subsection (1)(b) above” is to be construed as a reference to any such requirement as is mentioned in section 33(1)(b) as applied by sub-paragraph (e);
- (g) section 35(1) (punishment of offences), in so far as it relates to offences under section 33(1) as applied by sub-paragraph (e);
- (h) section 35(2), in so far as it relates to offences under section 33(2) as applied by sub-paragraph (f);
- (i) section 36 (offences by bodies corporate);
- (j) section 36A (offences by Scottish partnerships); and
- (k) section 44 (protection of officers acting in good faith).]

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.

Changes to legislation:

There are currently no known outstanding effects for the The Infant Formula and Follow-on Formula (Wales) Regulations 2020.