WELSH STATUTORY INSTRUMENTS

2007 No. 3573 (W.316)

FOOD, WALES

^{F1}The Infant Formula and Followon Formula (Wales) Regulations 2007

Made	18 December 2007
Laid before the National	
Assembly for Wales	20 December 2007

Coming into force in accordance with regulation 1

The Welsh Ministers make the following Regulations apart from regulations 2(6) and 24 in exercise of the powers conferred by sections 16(1)(e), 17(1), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990(1).

The Welsh Ministers make regulations 2(6) and 24 in exercise of the powers conferred by section 2(2) of and paragraph 1A of Schedule 2 to the European Communities Act 1972(2).

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(3).

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 any reference to an Annex to Commission Directive 2006/141/EC on infant formulae and follow-on formulae and amending Directive 1999/21/EC(4) to be construed as a reference to that Annex as amended from time to time.

In accordance with section 48(4A) of the Food Safety Act 1990, the Welsh Ministers have had regard to relevant advice given by the Food Standards Agency.^{F1}

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

^{(1) 1990} c. 16. Section 1(1) and (2) (definition of "food") was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c. 28), "the 1999 Act". Section 48 was also amended by S.I. 2004/2990. Section 26(3) was amended by Schedule 6 to the 1999 Act.

 ^{(2) 1972} c. 68. In relation to Wales, the functions formerly exercised by "the Ministers" (being, in relation to England and Wales and actin 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 and, in relation to Scotland, the Secretary of State) 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 sections 58 and 59 of and paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (c. 32).
(3) S.I. 2005/1971.

⁽⁴⁾ OJ No. L401, 30.12.2006, p.1.

Food Safety Authority and laying down procedures in matters of food safety(5) there has been open and transparent public consultation during the preparation and evaluation of these Regulations.^{F1}

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Title, commencement and application **E+W**

- F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Interpretation E+W

- F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

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

- F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Prohibition on the marketing of products other than infant formula for normal health infants E+W

Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula F1 and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already

⁽⁵⁾ OJ No. L31, 1.2.2002, p.1, as last amended by Commission Regulation (EC) No. 575/2006 amending Regulation (EC) No. 178/2002 of the European Parliament and of the Council as regards the number and names of the permanent Scientific Panels of the European Food Safety Authority (OJ No. L100, 8.4.2006, p.3).

in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

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

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Protein sources and other food ingredients suitable for infants from birth (infant formula) **E+W**

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Protein sources and other food ingredients suitable for infants aged over six months (followon formula) E+W

^{F1}7.....

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Compositional criteria for infant formula E+W

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Compositional criteria for follow-on formula E+W

- **F1** Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already

in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Addition of water (infant formula and follow-on formula) E+W

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Prohibitions and limitations on the use of food ingredients (infant formula and follow-on formula) **E+W**

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

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

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Notification of infant formula **E+W**

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg.

1(2), Sch. 3 (with reg. 5(2)(3))

Pesticide residues (infant formula and follow-on formula) E+W

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Naming of infant formula E+W

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Naming of follow-on formula E+W

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Labelling of infant formula E+W

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Labelling of follow-on formula E+W

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Avoidance of the risk of confusion between infant formula and follow-on formula **E+W**

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Presentation (infant formula and follow-on formula) **E+W**

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Restrictions on advertising infant formula E+W

- F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Restrictions on advertising follow-on formula E+W

^{F1}22.

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Restrictions on the promotion of infant formula E+W

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Provision of informational and educational material dealing with the feeding of infants **E** +W

^{F1}24.

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Free or reduced rate infant formula **E+W**

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already

in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Export of infant formula to third countries **E+W**

F2 Regs. 26, 27 revoked (2.8.2016) by The Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016 (S.I. 2016/639), regs. 1(3), **5(b**)

Export of follow-on formula to third countries **E+W**

F2 Regs. 26, 27 revoked (2.8.2016) by The Food for Specific Groups (Information and Compositional Requirements) (Wales) Regulations 2016 (S.I. 2016/639), regs. 1(3), **5(b)**

Offences and enforcement E+W

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Application of the improvement notice provisions of the Act E+W

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Application of various sections of the Food Safety Act 1990 E+W

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

Amendment of the Medical Food (Wales) Regulations 2000 E+W

F3 Reg. 30 revoked (22.2.2020) by The Food for Specific Groups (Information and Compositional Requirements) (Wales) (Amendment) Regulations 2020 (S.I. 2020/92), reg. 1(2), **Sch.** (with reg. 9(2))

Revocation and transitional arrangements E+W

^{F1}31.

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

G. Thomas Under authority of the Minister for Health and Social Services, one of the Welsh Ministers



Regulation 28A

Modification of the improvement notice provisions of the Act



Modification of section 10(1)

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))



Modification of section 32(1)

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

PART 3 E+W

Modification of section 35

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

PART 4 E+W

Modification of section 37(1), (5) and (6)

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

- F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))
- **F1** Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))



Modification of section 39(3)

^{F1}7.

F1 Regulations revoked (except reg. 30) (22.2.2020 for all purposes except in respect of infant formula and follow-on formula manufactured from protein hydrolysates and 22.2.2021 in so far as not already in force) by The Infant Formula and Follow-on Formula (Wales) Regulations 2020 (S.I. 2020/89), reg. 1(2), Sch. 3 (with reg. 5(2)(3))

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations, which apply in relation to Wales, give effect to Commission Directive 2006/141/EC on infant formula and follow-on formula and amending Directive 1999/21/EC (OJ No. L401, 20.12.2006, p.1) and Council Directive 92/52/EEC on infant formulae and follow-on formulae intended for export to third countries (OJ No. L179, 1.7.1992, p.129).

2. These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 (1972 c. 68) and references to Annex to Directive 2006/141/EC are to be construed as references to that Annex as amended from time to time (regulation 2(6)).

- 3. These Regulations—
 - (a) prohibit marketing of infant formula and follow-on formula which contravenes or fails to comply with specified regulations (regulation 3);
 - (b) prohibit marketing or otherwise representing 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 (regulation 4);

- (c) provide that infant formula and follow-on formula must not contain any substance in such quantity as to endanger the health of infants and young children (regulation 5);
- (d) provide that infant formula must be manufactured from specified protein sources and other suitable food ingredients (regulation 6);
- (e) provide that follow-on formula must be manufactured from specified protein sources and other suitable food ingredients (regulation 7);
- (f) provide that infant formula must comply with specified compositional criteria (regulation 8);
- (g) provide that follow-on formula must comply with specified compositional criteria (regulation 9);
- (h) provide that in order to make infant formula or follow-on formula ready for use nothing more must be required than the addition of water (regulation 10);
- (i) provide that the use of food ingredients in infant formula and follow-on formula must observe specified prohibitions and limitations (regulation 11);
- (j) provide that only specified substances may be used in the manufacture of infant formula and follow-on formula in order to satisfy specified requirements of Directive 2006/141/ EC and that those substances must meet specified purity criteria (regulation 12);
- (k) prohibit a food business operator placing an infant formula on the market that has not yet been placed on the market in the United Kingdom unless that food business operator has given prior notice to the Food Standards Agency (regulation 13);
- (l) provide that infant formula and follow-on formula may not contain pesticide residues above specified levels (regulation 14);
- (m) provide that infant formula may only be sold under certain names (regulation 15);
- (n) provide that follow-on formula may only be sold under certain names (regulation 16);
- (o) provide for the labelling of infant formula (regulation 17);
- (p) provide for the labelling of follow-on formula (regulation 18);
- (q) provide that infant formula and follow-on formula must be labelled to make a clear distinction between such products so as to avoid any risk of confusion between them (regulation 19);
- (r) apply the provisions of specified regulations to the presentation of infant formula and follow-on formula (regulation 20);
- (s) prohibit advertising of infant formula except in specified publications unless the advertisement complies with the provisions of specified regulations (regulation 21(1));
- (t) impose restrictions on the content of advertisements for infant formula (regulation 21(2) and (3));
- (u) prohibit advertising of follow-on formula where the advertisement contravenes or fails to comply with the provisions of specified regulations (regulation 22);
- (v) impose restrictions on the promotion of infant formula (regulation 23);
- (w) impose restrictions on the production or publication of informational or educational material dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children (regulation 24(1), (2) and (3));
- (x) prohibit donation of informational or educational equipment or materials by manufacturers or distributors of infant formula unless certain conditions are met (regulation 24(4));

- (y) impose restrictions on what an institution or organisation may do with infant formula that it has received free of charge or at a reduced rate (regulation 25);
- (z) prohibit export to a third country of infant formula which contravenes or fails to comply with specified regulations, a specified international standard or the Food (Lot Marking) Regulations (S.I.1996/1502) (regulation 26(1));
- (aa) prohibit export to a third country of a product represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first four to six months of life unless that product is infant formula (regulation 26(2));
- (bb) prohibit export to a third country of follow-on formula which contravenes or fails to comply with specified regulations, a specified international standard or the Food (Lot Marketing) Regulations 1996 (regulation 27);
- (cc) provide that a person who contravenes or fails to comply with specified regulations is guilty of an offence and provide a penalty for contravening or failing to comply with those regulations (regulation 28(1));
- (dd) provide that each food authority must enforce and execute these Regulations within its area (regulation 28(2));
- (ee) apply specified provisions of the Food Safety Act 1990 (1990 c. 16) with modifications (regulation 29);
- (ff) amend the Medical Food (Wales) Regulations (S.I. 2000/1866 (W.25)) (regulation 30); and
- (gg) revoke the Infant Formula and Follow-on Formula Regulations (S.I. 1995/77) in so far as they apply in relation to Wales (S.I. 1995/77 applies in relation to the whole of Great Britain) and provide transitional arrangements with regard to S.I. 1995/77 (regulation 31).

4. A full regulatory impact assessment of the effect that this instrument will have has been prepared. Copies may be obtained from the Food Standards Agency, 11th Floor, Southgate House, Wood Street, Cardiff, CF10 1EW.

Changes to legislation: There are currently no known outstanding effects for the The Infant Formula and Follow-on Formula (Wales) Regulations 2007.