WELSH STATUTORY INSTRUMENTS

2007 No. 3573 (W.316)

FOOD, WALES

The Infant Formula and Follow-on 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.

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.

Title, commencement and application

1.—(1) The title of these Regulations is the Infant Formula and Follow-on Formula (Wales) Regulations 2007.

(2) These Regulations come into force—

(a) in the case of regulation 31(2), on 1 January 2010; and

(b) otherwise, on 11 January 2008.

(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 Agency" ("*yr Asiantaeth*") means the Food Standards Agency;

"the Directive" ("*y Gyfarwyddeb*") means Commission Directive 2006/141/EC on infant formulae and follow-on formulae and amending Directive 1999/21/EC;

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

"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.

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

(3) Notwithstanding paragraph (2), any expression used both in these Regulations and in the Directive has the meaning that it bears in the Directive.

(4) Where any functions under the Act are assigned—

(a) by an order under section 2 or 7 of the Public Health (Control of Disease) Act 1984(**6**), to a port health authority; or

(b) by an order under section 6 of the Public Health Act 1936(**7**), to a joint board for a united district,

any reference in these Regulations to a food authority is to be construed, so far as relating to those functions, as a reference to the authority to whom they are so assigned.

(5) In these Regulations any reference to a numbered Annex is a reference to the Annex bearing that number in the Directive.

(6) In these Regulations any reference to an Annex to the Directive is a reference to that Annex as amended from time to time.

(**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).

(**6**) 1984 c. 22; section 7(3)(d) was substituted by paragraph 27 of Schedule 3 to the Food Safety Act 1990 (1990 c. 16).

(**7**) 1936 c. 49; section 6 is to be read with paragraph 1 of Schedule 3 to the Food Safety Act 1990.

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

3.—(1) No person may market infant formula which contravenes or fails to comply with regulation 5, 6, 8, 10, 11, 12, 14(1), (2) or (3), 15, 17 or 19.

(2) No person may market follow-on formula which contravenes or fails to comply with regulation 5, 7, 9, 10, 11, 12, 14(1), (2) or (3), 16, 18 or 19.

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

4. 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

5. 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 sources and other food ingredients suitable for infants from birth (infant formula)

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

(a) the protein sources specified in point 2 of Annex I; 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 paragraph (2).

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

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

7. Follow-on formula must be manufactured from—

(a) the protein sources specified in point 2 of Annex II; and

(b) other food ingredients the suitability of which for particular nutritional use by infants aged over six months has been established by generally accepted scientific data and demonstrated in accordance with regulation 6(2).

Compositional criteria for infant formula

8.—(1) Subject to paragraphs (2) and (3), 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 those cows' milk proteins specified in point 2.1 of Annex I with a protein content between the minimum and 0.5g/100kJ (2g/100 kcal) the suitability of the infant formula for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life until the introduction of appropriate complementary feeding must be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

(3) In the case of infant formula manufactured from those 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 satisfying by itself the nutritional requirements of normal healthy infants during the first months of life until the introduction of appropriate 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 infant formula must be in accordance with the appropriate specifications set out in Annex VI.

Compositional criteria for follow-on formula

9. Follow-on formula must comply with the compositional criteria set out in Annex II taking account the specifications set out in Annex V.

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

10. 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)

11. 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)

12.—(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 paragraph (1) must meet the relevant purity criteria.

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

(a) the purity criteria for substances, as provided for in Community legislation 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.

Notification of infant formula

13. No food business operator may place an infant formula on the market that has not yet been placed on the market in the United Kingdom unless he or she has given prior notice to the Agency by forwarding to it a model of the label used for the product.

Pesticide residues (infant formula and follow-on formula)

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

(2) Infant formula and follow-on formula may not contain any 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 may not contain any 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 paragraphs (1) to (3) apply in relation to infant formula or follow-on formula—

(a) manufactured as ready for consumption; or

(b) if it is not so manufactured, as reconstituted according to the manufacturer's instructions.

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

Naming of infant formula

15. Infant formula may not be sold unless it is sold under the name—

(a) in the case of a product which is not manufactured entirely from cows' milk proteins, the name "infant formula"; or

(b) in the case of a product which is manufactured entirely from cows' milk proteins, the name "infant milk".

Naming of follow-on formula

16. Follow-on formula may not be sold unless it is sold under the name—

(a) in the case of a product which is not manufactured entirely from cows' milk proteins, the name "follow-on formula"; or

(b) in the case of a product which is manufactured entirely from cows' milk proteins, the name "follow-on milk".

Labelling of infant formula

17.—(1) Infant formula may not be sold unless the labelling bears the following particulars—

(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