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SCOTTISH STATUTORY INSTRUMENTS

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2007 No.

**FOOD**

The Infant Formula and Follow-on Formula (Scotland)  
Regulations 2007

<i>Made</i> - - - -	2007
<i>Laid before the Scottish Parliament</i>	2007
<i>Coming into force</i> - -	1st January 2008

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The Scottish Ministers make the following Regulations apart from regulations 2(5) 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(a).

The Scottish Ministers make regulations 2(5) 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(b).

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Scottish Ministers that it is expedient for certain references to Annexes to Commission Directive 2006/141/EC(c) to be construed as references to those Annexes as amended from time to time.

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

There has been a 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(d).

### **Citation, commencement and extent**

#### **1. These Regulations–**

- (a) may be cited as the Infant Formula and Follow-on Formula (Scotland) Regulations 2007;
- (b) come into force on–
  - (i) in the case of regulation 31(2), on 1st January 2010; and
  - (ii) otherwise on 1st January 2008;
- (c) extend to Scotland only.

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(a) 1990 c.16. Section 1(1) and (2) (definition of “food”) was substituted by the Food Safety Act 1990 (Amendment) Regulations 2004 (S.I. 2004/2990); section 48(1) was amended by paragraph 8 of Schedule 5 to the Food Standards Act 1999 (c.28) (“the 1999 Act”); amendments made by Schedule 5 to the 1999 Act which extend to Scotland shall be taken as pre-commencement enactments for the purposes of the Scotland Act 1998 (c.46) (“the 1998 Act”) by virtue of section 40(2) of the 1999 Act. The functions of the Secretary of State, in so far as exercisable within devolved competence, were transferred to the Scottish Ministers by virtue of section 53 of the 1998 Act. In so far as not so transferred, those functions were transferred to the Scottish Ministers by the Scotland Act 1998 (Transfer of Functions to the Scottish Ministers etc.) Order 2005 (S.I. 2005/849).

(b) 1972 c.68 (“the 1972 Act”). Section 2(2) was amended by the Scotland Act 1998 (c.46) (“the 1998 Act”), Schedule 8, paragraph 15(3). The function conferred on the Minister of the Crown under section 2(2) of the 1972 Act, so far as within devolved competence, was transferred to the Scottish Ministers by virtue of section 53 of the 1998 Act. Insofar as not so transferred and insofar as relating to food (including drink) including the primary production of food, that function was transferred to the Scottish Ministers by the Scotland Act 1998 (Transfer of Functions to the Scottish Ministers etc.) Order 2005 (S.I. 2005/849).

(c) O.J. No. L 401, 30.12.06, p.1.

(d) O.J. No. L 31, 1.2.2002, p.1, as amended by Regulation (EC) No. 1642/2003 (O.J. No. L 245, 29.9.03, p.4) and by Commission Regulation (EC) No. 575/2006 (O.J. No. L 100, 8.4.2006, p.3).

## **Interpretation**

2.—(1) In these Regulations—

“the Act” means the Food Safety Act 1990;

“the Agency” means the Food Standards Agency;

“the Directive” means Commission Directive 2006/141/EC on infant formulae and follow-on formulae and amending Directive 1999/21/EC(a);

“health care system” 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 it bears in the Act.

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

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

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

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

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

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

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

4. No person shall market a product or otherwise represent it 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 quality as to endanger the health of infants and young children**

5. Infant formula and follow-on formula shall 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 shall 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 shall 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.

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(a) O.J. No. L 401, 30.12.2006, p.1.

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

7. Follow-on formula shall 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 shall 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 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 shall 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 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 shall be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies; and
- (b) the infant formula shall be in accordance with the appropriate specifications set out in Annex VI.

**Compositional criteria for follow-on formula**

9. Follow-on formula shall comply with the compositional criteria set out in Annex II taking into 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 shall 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, shall 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—

- (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 the food business operator has notified 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 shall not contain residues of individual pesticides at levels exceeding 0.01 mg/kg.

(2) Infant formula and follow-on formula shall 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 shall 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 paragraphs (1) to (3) apply to the infant formula or follow-on formula–

- (a) manufactured 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 regulation shall 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–

- (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;