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SCOTTISH STATUTORY INSTRUMENTS

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**2008 No. 322**

**FOOD**

**The Infant Formula and Follow-on Formula  
(Scotland) Amendment Regulations 2008**

*Made* - - - - 24th September 2008  
*Laid before the Scottish  
Parliament* - - - - 25th September 2008  
*Coming into force* - - 4th November 2008

The Scottish Ministers make the following Regulations 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) and all other powers enabling them to do so.

In accordance with section 48(4A)(2) of the Food Safety Act 1990, the Scottish Ministers have had regard to relevant advice given by the Food Standards Agency.

There has been 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(3).

**Citation and commencement**

1. These Regulations may be cited as the Infant Formula and Follow on Formula (Scotland) Amendment Regulations 2008 and come into force on 4th November 2008.

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- (1) 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); sections 16(1), 17(1) and 48(1) were amended by paragraph 8 of Schedule 5 to the Food Standards Act 1999 (c. 28) (“the 1999 Act”); section 26(3) was amended by the 1999 Act, Schedule 6: 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) (“the 2005 Order”).
- (2) Section 48(4A) was inserted by paragraph 21 of Schedule 5 to the 1999 Act.
- (3) O.J. No. L 31, 1.2.02, 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, 8.4.06, p.3) and by Commission Regulation (EC) No. 202/2008 (O.J. No. L 60, 5.3.08, p.17).

## **Amendment of the Infant Formula and Follow on Formula (Scotland) Regulations 2007**

2.—(1) The Infant Formula and Follow on Formula (Scotland) Regulations 2007(4) are amended in accordance with paragraphs (2) to (7).

(2) In regulation 3 (prohibition on the marketing of infant formula or follow on formula unless certain conditions are met)—

- (a) for “or 19” in paragraph (1) substitute “, 19 or 20(1)”;
- (b) for “or 19” in paragraph (2) substitute “, 19 or 20(2)”.

(3) For paragraphs (1) and (2) of regulation 20 (presentation (infant formula and follow on formula)) substitute—

“(1) The presentation of an infant formula shall comply with the provisions of regulations 17(1)(e), (2), (3) and (4) and 19.

(2) The presentation of a follow on formula shall comply with the provisions of regulations 18(2) and 19.”.

(4) In sub paragraph (a) of paragraph (1) of regulation 26 (export of infant formula to third countries) for “or 19” substitute “19 or 20(1)”.

(5) In paragraph (a) of regulation 27 (export of follow on formula to third countries) for “or 19” substitute “, 19 or 20(2)”.

(6) For paragraph (3) of regulation 31 (revocation and transitional arrangements) substitute—

“(3) In respect of any contravention or failure to comply before 1st January 2010, no person commits an offence under regulation 28(1) consisting of a contravention of or a failure to comply with—

- (a) regulation 3(1), where—
  - (i) the action that would otherwise constitute the offence consists of marketing infant formula which contravenes or fails to comply with regulation 5, 6, 8, 10, 11, 12 or 14(1), (2) or (3), and
  - (ii) that action does not constitute an offence under regulation 22(1) of the 1995 Regulations consisting of a contravention of or a failure to comply with regulation 2(a)(i) or (ii) of those Regulations;
- (b) regulation 3(1), where—
  - (i) the action that would otherwise constitute the offence consists of marketing infant formula which contravenes or fails to comply with regulation 17 or 19, and
  - (ii) that action, had it taken place on 10th January 2008, would not have constituted an offence under regulation 22(1) of the 1995 Regulations as they then stood consisting of a contravention of or a failure to comply with regulation 2(a)(iii) of those Regulations;
- (c) regulation 3(1), where—
  - (i) the action that would otherwise constitute the offence consists of marketing infant formula which contravenes or fails to comply with regulation 20(1) in so far as regulation 20(1) applies in relation to the shape, appearance and packaging of that infant formula concerned, and
  - (ii) that action, had it taken place on 10th January 2008, would not have constituted an offence under regulation 22(1) of the 1995 Regulations as they then stood consisting of a contravention of or a failure to comply

- with regulation 2(a)(iv) of those Regulations in so far as regulation 2(a)(iv) applied in relation to the shape, appearance and packaging of the product concerned;
- (d) regulation 3(2), where—
- (i) the action that would otherwise constitute the offence consists of marketing follow on formula which contravenes or fails to comply with regulation 5, 7, 9, 10, 11, 12 or 14(1), (2) or (3), and
  - (ii) that action does not constitute an offence under regulation 22(1) of the 1995 Regulations consisting of a contravention of or a failure to comply with regulation 3(a) or (b) of those Regulations;
- (e) regulation 3(2), where—
- (i) the action that would otherwise constitute the offence consists of marketing follow on formula which contravenes or fails to comply with regulation 18 or 19, and
  - (ii) that action, had it taken place on 10th January 2008, would not have constituted an offence under regulation 22(1) of the 1995 Regulations as they then stood consisting of a contravention of or a failure to comply with regulation (3)(c) of those Regulations;
- (f) regulation 3(2), where—
- (i) the action that would otherwise constitute the offence consists of marketing follow-on formula which contravenes or fails to comply with regulation 20(2) in so far as regulation 20(2) applies in relation to the shape, appearance and packaging of that follow on formula; and
  - (ii) that action, had it taken place on 10th January 2008, would not have constituted an offence under regulation 22(1) of the 1995 Regulations as they then stood consisting of a contravention of or a failure to comply with regulation 3(d) of those Regulations in so far as regulation 3(d) applied in relation to the shape, appearance and packaging of the product concerned;
- (g) regulation 4, where the action that would otherwise constitute the offence does not constitute an offence under regulation 22(1) of the 1995 Regulations consisting of a contravention of or a failure to comply with regulation 2(b)(i) or (ii) of those Regulations;
- (h) regulation 4, where the action that would otherwise constitute the offence, had it taken place on 10th January 2008, would not have constituted an offence under regulation 22(1) of the 1995 Regulations as they then stood consisting of a contravention of or a failure to comply with regulation 2(b)(iii) of those Regulations; or
- (i) regulation 4, where the action that would otherwise constitute the offence, had it taken place on 10th January 2008, would not have constituted an offence under regulation 22(1) of the 1995 Regulations as they then stood consisting of a contravention of or a failure to comply with regulation 2(b)(iv) of those Regulations in so far as regulation 2(b)(iv) applied in relation to the shape, appearance and packaging of the product concerned.”
- (7) In the Schedule (revocations) in columns 1 and 2 for “1977” substitute “1997”.

### **Amendment of the Foods for Special Medical Purposes (Scotland) Regulations 2000**

3. After regulation 7 of the Foods for Special Medical Purposes (Scotland) Regulations 2000(5) insert—

#### **“Transitional arrangements**

8. In respect of any contravention before 1st January 2010, no person commits an offence under regulation 5(a) consisting of a contravention of regulation 3(1)(a) where the action that would otherwise constitute the offence consists of selling a medical food the composition of which fails to comply with Article 3 of the Directive as read with the row relating to manganese set out in the second part of Table 1 (minerals) in the Annex to the Directive if the composition of that medical food would have complied with Article 3 of the Directive as read with the row relating to manganese set out in the second part of Table 1 (minerals) in the Annex to the Directive as it stood before it was amended by Commission Directive [2006/141/EC](#) on infant formulae and follow on formulae and amending Directive [1999/21/EC](#).”.

St Andrew’s House,Edinburgh  
24th September 2008

*S ROBISON*  
Authorised to sign by the Scottish Ministers

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## EXPLANATORY NOTE

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

These Regulations amend the Infant Formula and Follow on Formula (Scotland) Regulations 2007 (“the 2007 Regulations”).

The amendments are necessary to give effect to the decision of the Court of Session in the Petition of the Infant and Dietetic Food Association Limited and others for Judicial Review of a decision by the Scottish Ministers to make and lay before the Scottish Parliament the Infant Formula and Follow on Formula (Scotland) Regulations 2007. The Court’s judgement was issued on 10th June 2008, and held that the 2007 Regulations, in relation to the enforcement of the labelling requirements, were invalid. These Regulations seek to correct that position.

These Regulations amend the 2007 Regulations to–

- (a) revise the list of regulations with which the marketing of infant formula and follow on Formula must comply (regulation 2(2));
- (b) provide that the presentation of infant formula and follow on formula shall comply with the provisions of specific regulations (regulation 2(3));
- (c) revise the list of regulations with which infant formula exported to third countries must comply (regulation 2(4));
- (d) revise the list of regulations with which export of follow on formula to third countries must comply (regulation 2(5)); and
- (e) create transitional arrangements that apply in relation to the enforcement of–
  - (i) the labelling requirements for infant formula and follow-on formula, and
  - (ii) the requirements that apply in relation to the shape, appearance and packaging of infant formula and follow-on formula (regulation 2(6)).

These Regulations also provide transitional arrangements with regard to the Foods for Special Medical Purposes (Scotland) Regulations 2000 (regulation 3) and correct a typographical error in the Schedule to the 2007 Regulations (regulation 2(7)).

No regulatory impact assessment has been produced for this instrument.