

**2008 No. 2445**

**FOOD, ENGLAND**

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

<i>Made</i>	- - - -	<i>16th September 2008</i>
<i>Laid before Parliament</i>		<i>22nd September 2008</i>
<i>Coming into force</i>	- -	<i>29th October 2008</i>

The Secretary of State makes 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(a) and now vested in him(b).

In accordance with section 48(4A) of the Food Safety Act 1990, the Secretary of State has 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 Food Safety Authority and laying down procedures in matters of food safety(c) there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

**Title and commencement**

**1. These Regulations—**

- (a) may be cited as the Infant Formula and Follow-on Formula (England) (Amendment) Regulations 2008; and
- (b) come into force on 29th October 2008.

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(a) 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. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the 1999 Act and S.I. 2004/2990.

(b) 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 and, in relation to Scotland, the Secretary of State) 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 (2006 c.32). Those functions, so far as exercisable in relation to Scotland, were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c.46) as read with section 40(2) of the 1999 Act.

(c) OJ No. L31, 1.2.2002, p.1, as last amended by Commission Regulation (EC) No. 202/2008 amending Regulation (EC) No. 178/2002 of the European Parliament and of the Council as regards the number and names of the Scientific Panels of the European Food Safety Authority (OJ No. L60, 5.3.2008, p.17).

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

2.—(1) The Infant Formula and Follow-on Formula (England) Regulations 2007<sup>(a)</sup> are amended in accordance with the following paragraphs.

(2) For the provisions of regulation 3 (prohibition on the marketing of infant formula or follow-on formula unless certain conditions are met) there are substituted the following provisions—

“(1) No person shall market infant formula which contravenes or fails to comply with regulation 5, 6, 8, 10, 11, 12, 14(1), (2) or (3), 15, 17, 19 or 20(1).

(2) No person shall 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, 19 or 20(2).”.

(3) For paragraphs (1) and (2) of regulation 20 (presentation (infant formula and follow-on formula)) there are substituted the following paragraphs—

“(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) For sub-paragraph (a) of paragraph (1) of regulation 26 (export of infant formula to third countries) there is substituted the following sub-paragraph—

“(a) regulation 5, 6, 8, 10, 11, 12, 14(1), (2) or (3), 17, 19 or 20(1);”.

(5) For paragraph (a) of regulation 27 (export of follow-on formula to third countries) there is substituted the following paragraph—

“(a) regulation 5, 7, 9, 10, 11, 12, 14(1), (2) or (3), 18, 19 or 20(2);”.

(6) For paragraph (3) of regulation 31 (revocation and transitional arrangements) there is substituted the following paragraph—

“(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, and

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(a) S.I. 2007/3521.

- (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 that infant formula;
- (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 that follow-on formula;
- (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.”.

### **Amendment of the Medical Food (England) Regulations 2000**

3.—(1) The Medical Food (England) Regulations(a) are amended in accordance with paragraph (2).

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(a) S.I. 2000/845, amended by S.I. 2007/3521; there are other amending instruments but none is relevant.

(2) The following regulation is inserted immediately after regulation 7 (application of various provisions of the Food Safety Act 1990)—

**“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 whose composition 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 I (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 I (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.”.

Signed by authority of the Secretary of State for Health

16th September 2008

*Ben Bradshaw*  
Minister of State,  
Department of Health

## EXPLANATORY NOTE

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

1. These Regulations, which apply in relation to England only, make the legislative provisions described in paragraph 2 which are considered necessary to give effect to the judgment in the High Court of Justice in the case called *R v. the Secretary of State for Health and the Welsh Ministers on the application of the Infant and Dietetics Food Association Limited* (action number CO/230/2008). Judgment was delivered on 29th February 2008. Following that judgment, the High Court granted a declaration that the Infant Formula and Follow-on Formula (England) Regulations 2007 (S.I. 2007/3521) fail to comply with Commission Directive 2006/141/EC on infant formulae and follow-on formulae and amending Directive 1999/21/EC (OJ No. L401, 30.12.2006, p.1) to the extent that they prohibit as from 11 January 2008 (instead of as from 31 December 2009) trade in infant formula and follow-on formula whose labelling satisfies the labelling requirements of the Infant Formula and Follow-on Formula Regulations 1995 (S.I. 1995/77) but does not satisfy the labelling requirements of the Infant Formula and Follow-on Formula (England) Regulations 2007.

2. These Regulations amend the Infant Formula and Follow-on Formula (England) Regulations 2007 to—

- (a) revise the list of regulations that have to be complied with if a person is to market infant formula or follow-on formula (*regulation 2(2)*);
- (b) provide that the presentation of infant formula and follow-on formula must comply with the provisions of specified regulations (*regulation 2(3)*);
- (c) revise the list of regulations that have to be complied with if a person is to export infant formula to third countries (*regulation 2(4)*);
- (d) revise the list of regulations that have to be complied with if a person is to export follow-on formula to third countries (*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)*).

3. These Regulations also provide transitional arrangements with regard to the Medical Food (England) Regulations 2000 (S.I. 2000/845) (*regulation 3*).

4. A full impact assessment has not been produced for this instrument as no impact on the private or voluntary sectors is foreseen.

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STATUTORY INSTRUMENTS

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