

**2008 No. 405**

**FOOD**

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

*Made* - - - - *2nd October 2008*

*Coming into operation* - *4th November 2008*

The Department of Health, Social Services and Public Safety(a) makes the following Regulations in exercise of the powers conferred by Articles 15(1)(e), 16(1), 25(1)(a) and (3) and 47(2) of the Food Safety (Northern Ireland) Order 1991(b).

In accordance with Article 47(3A) of the Food Safety (Northern Ireland) Order 1991, the Department of Health, Social Services and Public Safety 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.

**Citation and commencement**

1. These Regulations—

- (a) may be cited as the Infant Formula and Follow-on Formula (Amendment) Regulations (Northern Ireland) 2008; and
- (b) come into operation on 4th November 2008.

**Amendment of the Infant Formula and Follow-on Formula Regulations (Northern Ireland) 2007**

2.—(1) The Infant Formula and Follow-on Formula Regulations (Northern Ireland) 2007(d) are amended in accordance with paragraphs (2) to (6).

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

---

(a) Formerly the Department of Health and Social Services; see S.I. 1999/283 (N.I.1) Article 3(6)  
(b) S.I. 1991/762 (N.I.7) as amended by S.I. 1996/1663 (N.I.12), paragraphs 26 to 42 of Schedule 5 and Schedule 6 to the Food Standards Act 1999 c.28 and S.R.2004 Nos. 482 and 505  
(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)  
(d) S.R. 2007 No. 506

“(1) A person shall not market infant formula which contravenes regulation 5, 6, 8, 10, 11, 12, 14(1), (2) or (3), 15, 17, 19 or 20(1).

(2) A person shall not market follow-on formula which contravenes regulation 5, 7, 9, 10, 11, 12, 14(1), (2) or (3), 16, 18, 19 or 20(2).”.

(3) In regulation 20 (presentation (infant formula and follow-on formula))—

(a) for paragraph (1) substitute —

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

(b) for paragraph (2) substitute —

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

(4) For regulation 26(1)(a) (export of infant formula to third countries) substitute—

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

(5) For regulation 27(a) (export of follow-on formula to third countries) substitute—

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

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

“(3) In respect of any contravention before 1st January 2010, a person does not commit an offence under regulation 28(1) consisting of a contravention of —

(a) regulation 3(1), where—

(i) the action that would otherwise constitute the offence consists of marketing infant formula which contravenes regulation 5, 6, 8, 10, 11, 12 or 14(1), (2) or (3), and

(ii) that action does not constitute an offence under regulation 10(1) of the 1995 Regulations consisting of a contravention of regulation 2(1)(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 regulation 17 or 19, and

(ii) that action, had it taken place on 10th January 2008, would not have constituted an offence under regulation 10(1) of the 1995 Regulations as they then stood consisting of a contravention of regulation 2(1)(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 regulation 20(1) in so far as regulation 20(1) applies in relation to the shape, appearance and packaging of that infant formula, and

(ii) that action, had it taken place on 10th January 2008, would not have constituted an offence under regulation 10(1) of the 1995 Regulations as they then stood consisting of a contravention of regulation 2(1)(a)(iv) of those Regulations in so far as regulation 2(1)(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 regulation 5, 7, 9, 10, 11, 12 or 14(1), (2) or (3), and

(ii) that action does not constitute an offence under regulation 10(1) of the 1995 Regulations consisting of a contravention of regulation 2(2)(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 regulation 18 or 19, and
  - (ii) that action, had it taken place on 10th January 2008, would not have constituted an offence under regulation 10(1) of the 1995 Regulations as they then stood consisting of a contravention of regulation 2(2)(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 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 10(1) of the 1995 Regulations as they then stood consisting of a contravention of regulation 2(2)(d) of those Regulations in so far as regulation 2(2)(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 10(1) of the 1995 Regulations consisting of a contravention of regulation 2(1)(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 10(1) of the 1995 Regulations as they then stood consisting of a contravention of regulation 2(1)(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 10(1) of the 1995 Regulations as they then stood consisting of a contravention of regulation 2(1)(b)(iv) of those Regulations in so far as regulation 2(1)(b)(iv) applied in relation to the shape, appearance and packaging of the product concerned.”.

### **Amendment of the Medical Food Regulations (Northern Ireland) 2000**

3.—(1) The Medical Food Regulations (Northern Ireland) 2000(a) are amended in accordance with paragraph (2).

(2) The following regulation is inserted immediately after regulation 7 (application of various provisions of the Order)—

#### **“Transitional arrangements**

8. In respect of any contravention before 1st January 2010, a person does not commit 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.”.

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 2nd October 2008.

---

(a) S.R. 2000 No. 187; the relevant amending instrument is S.R. 2007 No. 506



*Christine Jendoubi*  
A senior officer of the Department of Health, Social Services and Public Safety

## EXPLANATORY NOTE

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

These Regulations amend the Infant Formula and Follow-on Formula Regulations (Northern Ireland) 2007 (S.R. 2007 No. 506) (“the 2007 Regulations”).

The amendments are required to give effect to the order of the High Court of Justice in Northern Ireland of 25<sup>th</sup> June 2008 in the matter of an application by the Infant and Dietetic Foods Association Ltd (“the IDFA”) for Judicial Review and in the matter of the Infant Formula and Follow-on Formula Regulations (NI) 2007 (case ref. CO1932838).

The order recited that the 2007 Regulations 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 (Northern Ireland) 1995 (S.R. 1995 No. 85, as amended) but does not satisfy the labelling requirements of the 2007 Regulations.

These Regulations amend the Infant Formula and Follow-on Formula Regulations (Northern Ireland) 2007 to—

- (a) revise the list of regulations that must 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 must be complied with if a person is to export infant formula to third countries (*regulation 2(4)*);
- (d) revise the list of regulations that must 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, (*regulation 2(6)* and
  - (ii) the requirements that apply in relation to the shape, appearance and packaging of infant formula and follow-on formula (*regulation 2(6)*). This amendment is considered necessary as a result of the judgments of the Court of Session in Scotland in the related case of the Petition of the IDFA and others for Judicial Review of a decision by the Scottish Ministers to make and lay before the Scottish Parliament the Infant Formula and the Follow-on Formula (Scotland) Regulations 2007 ([2008] CSOH87, case ref. P126/08) and the High Court in England in the related case of R v the Secretary of State for Health and the Welsh Ministers on the application of the IDFA ([2008] EWHC 575 (Admin), action number CO/230/2008.).

These Regulations also provide transitional arrangements with regard to the Medical Food Regulations (Northern Ireland) 2000 (S.R. 2000 No. 187) (*regulation 3*).

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

**2008 No. 405**

**FOOD**

The Infant Formula and Follow-on Formula (Amendment)  
Regulations (Northern Ireland) 2008