



STATUTORY INSTRUMENTS.

S.I. No. 209 of 2009

EUROPEAN COMMUNITIES (INFANT FORMULAE AND FOLLOW-
ON FORMULAE) (AMENDMENT) REGULATIONS 2009

(Prn. A9/0768)

EUROPEAN COMMUNITIES (INFANT FORMULAE AND FOLLOW-ON FORMULAE) (AMENDMENT) REGULATIONS 2009

I, MARY HARNEY, Minister for Health and Children, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972), and for the purpose of giving effect to Commission Regulation (EC) No. 1243/2008¹ of 12 December 2008 amending Annexes III and VI to Directive 2006/141/EC as regards compositional requirements for certain infant formulae and for the purpose of giving further effect to Commission Directive 2006/141/EC² of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC, hereby make the following Regulations—

1. (1) These Regulations may be cited as the European Communities (Infant Formulae and Follow-On Formulae) (Amendment) Regulations 2009.

(2) The Principal Regulations and these Regulations may be cited together as the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2007 and 2009.

2. In these Regulations, “Principal Regulations” means the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2007 (S.I. No. 852 of 2007).

3. The Principal Regulations are amended—

(a) in Regulation 1—

(i) by substituting “Regulation 30(1A), (1B), (1C) and (2)” for “Regulation 30(2)” in paragraph (2),

(ii) by substituting “31 December 2011” for “31 December 2009” in paragraph (3), and

(iii) by inserting after paragraph (3) the following paragraph:

“(4) Regulation 30(1A), (1B) and (1C) come into operation on the 31 December 2009.”

(b) in Regulation 2—

(i) by substituting “(k)” for second “(j)” in the definition of “official laboratory”, and

¹ OJ L 335, 13.12.2008, p. 25.

² OJ L 401, 30.12.2006, p. 1.

Notice of the making of this Statutory Instrument was published in “Iris Oifigiúil” of 5th June, 2009.

(ii) by inserting the following paragraph after paragraph (3):

“(4) References in existing laws, regulations and administrative provisions to Directive 91/321/EEC^{7A} of 14 May 1991 on infant formulae and follow-on formulae shall be construed as references to Directive 2006/141/EC¹ and shall be read in accordance with the correlation table in Annex XI of Directive 2006/141/EC¹.”

and by the addition of the following footnote thereto:

“^{7A}OJ L 175, 4.7.1991, p. 35.”

(c) in Regulation 30—

(i) by inserting the following paragraphs after paragraph (1):

“(1A) The following are revoked:

(a) Regulations 3, 4 (except paragraph (3) thereof), 5 (except paragraph (3) thereof), 6, 7, 10, 11, 12 and Regulations 14 to 28 of the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2004 (S.I. No. 242 of 2004), and

(b) Regulation 3(b) of the European Communities (Infant Formulae and Follow-On Formulae) (Amendment) Regulations 2007 (S.I. No. 242 of 2007).

(1B) The European Communities (Infant Formulae and Follow-On Formulae) Regulations 2004 (S.I. No. 242 of 2004) are amended—

(a) by substituting for Regulation 4(3) the following:

“Subject to Regulation 5(4) of the European Communities (Dietary Foods for Special Medical Purposes) Regulations 2009 (S.I. No. 187 of 2009), infant formulae that meet the requirements of dietary foods for special medical purposes intended specifically for infants, as referred to in point 4 of Schedule 1 to those Regulations, must comply with the compositional criteria specified in Schedule 1 of these Regulations.”, and

(b) by substituting for Regulation 5(3) the following:

“Subject to Regulation 5(4) of the European Communities (Dietary Foods for Special Medical

Purposes) Regulations 2009 (S.I. No. 187 of 2009), follow-on formulae that meet the requirements of dietary foods for special medical purposes intended specifically for infants, as referred to in point 4 of Schedule 1 to those Regulations, must comply with the compositional criteria specified in Schedule 2 of these Regulations.”

(1C) No person commits an offence under Regulation 25(1) consisting of a contravention of or a failure of dietary foods for special medical purposes intended specifically for infants to comply with:

(a) Regulation 4(4), (5) or (6) where there is no contravention of or failure to comply with Regulation 4(3) of the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2004 (S.I. No. 242 of 2004).

(b) Regulation 5(3) where there is no contravention of or failure to comply with Regulation 5(3) of the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2004 (S.I. No. 242 of 2004),”

and

(ii) by inserting the following paragraphs after paragraph (4):

“(5) Paragraph (1C) of this Regulation shall cease to have effect on 31 December 2011.

(6) Paragraph (3) of this Regulation shall cease to have effect on 31 December 2009.”

(d) in Schedule 3, by inserting the following at the top of the list entitled “3. Amino acids and other nitrogen compounds”:

“L-arginine and its hydrochloride ⁽¹⁾”

and by the addition of the following footnote thereto:

“(1) L-arginine and its hydrochloride shall only be used in the manufacture of infant formulae referred to in Regulation 4(6).”

(e) in Schedule 6, by inserting the following after the paragraph entitled “3. Protein processing”:

“4. Protein quality

The indispensable and conditionally indispensable amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal, are the following:

	Per 100 kJ ⁽¹⁾	Per 100 kcal
Arginine	16	69
Cystine	6	24
Histidine	11	45
Isoleucine	17	72
Leucine	37	156
Lysine	29	122
Methionine	7	29
Phenylalanine	15	62
Threonine	19	80
Tryptophan	7	30
Tyrosine	14	59
Valine	19	80

⁽¹⁾ 1 kJ = 0.239 kcal.”



GIVEN under my Official Seal,
3 June 2009

MARY HARNEY,
Minister for Health and Children.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation).

These Regulations give effect to Commission Regulation (EC) No. 1243/2008 of 12 December 2008 amending Annexes III and VI to Commission Directive 2006/141/EC as regards compositional requirements for certain infant formulae, and give further effect to Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC.

These Regulations amend the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2004 (S.I. No. 242 of 2004) in the manner specified in these Regulations.

These Regulations amend the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2007 (S.I. No. 852 of 2007) in the manner specified in these Regulations.

These Regulations may be cited as the European Communities (Infant Formulae and Follow-On Formulae) (Amendment) Regulations 2009.

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