



STATUTORY INSTRUMENTS.

S.I. No. 92 of 2014



EUROPEAN COMMUNITIES (INFANT FORMULAE AND FOLLOW-ON
FORMULAE) (AMENDMENT) REGULATIONS 2014

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I, JAMES REILLY, Minister for Health, 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 Directive 2013/46/EU of 28 August 2013¹, hereby make the following regulations:

1. (1) These Regulations may be cited as the European Communities (Infant Formulae and Follow-on Formulae) (Amendment) Regulations 2014.

(2) The Principal Regulations, the Regulations of 2009, the Regulations of 2013 and these Regulations may be cited together as the European Communities (Infant Formulae and Follow-on Formulae) Regulations 2007 to 2014.

2. In these Regulations—

“Principal Regulations” means the European Communities (Infant Formulae and Follow-on Formulae) Regulations 2007 (S.I. No. 852 of 2007);

“Regulations of 2009” means European Communities (Infant Formulae and Follow-on Formulae) (Amendment) Regulations 2009 (S.I. No. 209 of 2009);

“Regulations of 2013” means European Communities (Infant Formulae and Follow-on Formulae) (Amendment) Regulations 2013 (S.I. No. 384 of 2013).

3. Regulation 2(1) (as amended by Regulation 3 of the Regulations of 2013) of the Principal Regulations is amended by substituting for the definition of “Directive 2006/141/EC” the following:

“‘Directive 2006/141/EC’ means Commission Directive 2006/141/EC of 22 December 2006², as amended by Commission Regulation (EC) No. 1243/2008 of 12 December 2008³, Commission Directive 2013/26/EU of 8 February 2013⁴ and Commission Directive 2013/46/EU of 28 August 2013¹”.

4. Regulation 3 of the Principal Regulations is amended—

(a) in paragraph (3), by substituting “cows’ milk or goats’ milk proteins” for “cows’ milk proteins”, and

(b) in paragraph (5), by substituting “cows’ milk or goats’ milk proteins” for “cows’ milk proteins”.

¹OJ No. L. 230, 29.8.2013, p.16.

²OJ No. L. 401, 30.12.2006, p. 1.

³OJ No. L. 335, 13.12.2008, p. 25.

⁴OJ No. L. 158, 10.6.2013, p. 376.

*Notice of the making of this Statutory Instrument was published in
“Iris Oifigiúil” of 21st February, 2014.*

5. Regulation 4(5) of the Principal Regulations is amended by substituting “cows’ milk or goats’ milk proteins” for “cows’ milk proteins”.
6. Regulation 5 of the Principal Regulations is amended—
- (a) in paragraph (3), by substituting “Subject to paragraph 3A, follow-on formulae” for “Follow-on formulae”, and
 - (b) by inserting after paragraph (3) the following paragraph:

“(3A) In the case of follow-on formulae manufactured from protein hydrolysates defined in point 2.2 of Schedule 2 with a protein content between the minimum and 0.56g/100 kJ (2.25g/100 kcal):

 - (a) the suitability of the follow-on 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) shall be in accordance with the appropriate specifications set out in Schedule 6”.
7. Schedule 1 to the Principal Regulations is amended—
- (a) in point 2.1—
 - (i) in the title, by substituting “cows’ milk or goats’ milk proteins” for “cows’ milk proteins”, and
 - (ii) in footnote 1, by substituting “cows’ milk or goats’ milk proteins” for “cows’ milk proteins”,
 - (b) in the title to point 2.3, by substituting “cows’ milk or goats’ milk proteins” for “cows’ milk proteins”,
 - (c) in the title to point 10.1, by substituting “cows’ milk or goats’ milk proteins” for “cows’ milk proteins”, and
 - (d) in the title to point 10.2, by substituting “cows’ milk or goats’ milk proteins” for “cows’ milk proteins”.
8. Schedule 2 to the Principal Regulations is amended—
- (a) in the title to point 2.1, by substituting “cows’ milk or goats’ milk proteins” for “cows’ milk proteins”,
 - (b) in point 2.2—
 - (i) by substituting for the maximum and minimum values the following:

“Minimum(1) 0.45 g/100 kJ (1.8 g/100 kcal)

Maximum 0.8 g/100 kJ (3.5 g/100 kcal)”, and

- (ii) by inserting after the maximum and minimum values the following footnote:

“(1) Follow-on formulae manufactured from protein hydrolysates with a protein content between the minimum and 0.56 g/100 kJ (2.25 g/100 kcal) shall be in accordance with Regulation 5(3A).”

- (c) in the title to point 2.3, by substituting “cows’ milk or goats’ milk proteins” for “cows’ milk proteins”,
- (d) in the title to point 8.1, by substituting “cows’ milk or goats’ milk proteins” for “cows’ milk proteins”, and
- (e) in the title to point 8.2, by substituting “cows’ milk or goats’ milk proteins” for “cow’s milk proteins”.

9. Point 3 of Schedule 3 (as amended by Regulation 3 (d) of the Regulations of 2009) to the Principal Regulations is amended by substituting for footnote 1 the following:

“(1) L-arginine and its hydrochloride shall only be used in the manufacture of infant formulae referred to in Regulation 4(6) and follow-on formulae referred to in Regulation 5(3A).”

10. The title to Schedule 6 to the Principal Regulations is amended by inserting “INFANT FORMUAE AND FOLLOW-ON FORMULAE” for “INFANT FORMULAE”.



GIVEN under my Official Seal,
11 February 2014.

JAMES REILLY,
Minister for Health.

EXPLANATORY NOTE

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

These Regulations transpose into Irish law Commission Directive 2013/46/EU of 28 August 2013 amending Directive 2006/141/EC with regard to the protein requirements for infant formulae and follow-on formulae.

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 2014.

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