

L.N. 75 of 2014

**FOOD SAFETY ACT
(CAP. 449)**

**Infant Formulae and Follow-on Formulae
(Amendment) Regulations, 2014**

IN exercise of the powers conferred by article 10 of the Food Safety Act, the Minister for Social Policy has made the following regulations:-

Citation and
commencement.

S.L.449.52

1. (1) The title of these regulations is the Infant Formulae and Follow-on Formulae (Amendment) Regulations, 2014, and these regulations shall be read and construed as one with the Infant Formulae and Follow-on Formulae Regulations, hereinafter referred to as "the principal regulations".

(2) These regulations shall be deemed to have come into force on the 28 February, 2014.

Scope.

2. These regulations implement the provisions of Commission Directive 2013/46/EU of 28 August 2013 amending Directive 2006/141 with regard to protein requirements for infant formulae and follow-on formulae.

Amends
regulation 7 of
the principal
regulations.

3. Regulation 7 of the principal regulations shall be amended as follows:

(a) in sub-regulation (1) thereof, for the paragraph starting with the words "In the case of infant formulae manufactured from cows' milk proteins" and ending with the words "expert guidance on the design and conduct of such studies.", there shall be substituted the following:

"In the case of infant formulae manufactured from cows' milk or goats' milk proteins defined in point 2.1 of the First Schedule with a protein content between the minimum and 0,5 g/100 kJ (2 g/100 kcal), the suitability of the infant 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) in sub-regulation (2) thereof, immediately after the words "set out in the Fifth Schedule.", there shall be added the following new paragraph:

"In the case of follow-on formulae manufactured from protein hydrolysates defined in point 2.2 of the Second Schedule with a protein content between the minimum and 0,56 g/100 kJ (2,25 g/100 kcal), 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 shall be in accordance with the appropriate specifications set out in the Sixth Schedule."

4. Regulation 9 of the principal regulations shall be amended as follows:

Amends regulation 9 of the principal regulations.

(a) paragraph (b) of sub-regulation (1) thereof shall be substituted by the following:

"(b) The name under which the products covered by regulation 4(2)(c) and (d) are sold shall be respectively:

"infant formula" and "follow-on formula".

However, the name of the products manufactured entirely from cows' milk or goats' milk proteins, shall be respectively:

"infant milk" and "follow-on milk"."; and

(b) in sub-regulation (2) thereof, for the words

"The name under which infant formulae and follow-on formulae manufactured entirely from cows' milk proteins are sold, shall be respectively:",

there shall be substituted the words:

"The name under which infant formulae and follow-on formulae manufactured entirely from cows' milk or goats' milk proteins are sold shall be respectively:".

5. The First Schedule to the principal regulations shall be amended as follows:

Amends the First Schedule to the principal regulations.

(a) for the heading of point 2.1 thereof, there shall be substituted the following:

"2.1 Infant formulae manufactured from cows'

milk or goats' milk proteins";

(b) for footnote 1 of point 2.1 thereof, there shall be substituted the following:

"(1) Infant formulae manufactured from cows' milk or goats' milk protein with a protein content between the minimum and 0,5 g/100 kJ (2 g/100 kcal) shall be in accordance with the second subparagraph of regulation 7(1).";

(c) for the heading of point 2.3 thereof, there shall be substituted the following:

"2.3 Infant formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins.";

(d) for the heading of point 10.1 thereof, there shall be substituted the following:

"10.1 Infant formulae manufactured from cows' milk or goats' milk proteins or protein hydrolysates."; and

(e) for the heading of point 10.2 thereof, there shall be substituted the following:

"10.2 Infant formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins.".

Amends the
Second
Schedule to the
principal
regulations.

6. The Second Schedule to the principal regulations shall be amended as follows:

(a) for the heading of point 2.1 thereof, there shall be substituted the following:

"2.1 Follow-on formulae manufactured from cows' milk or goats' milk proteins.";

(b) for the table under point 2.2 thereof, there shall be substituted the following:

"	Minimum ⁽¹⁾	Maximum
	0,45 g/100 kJ	0,8 g/100 kJ
	(1,8 g/100 kcal)	(3,5 g/100 kcal)
(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 the second subparagraph of regulation 7(2).";		

(c) for the heading of point 2.3 thereof, there shall be substituted the following:

"2.3 Follow-on formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins.";

(d) for the heading of point 8.1 thereof, there shall be substituted the following:

"8.1 Follow-on formulae manufactured from cows' milk or goats' milk proteins or protein hydrolysates." and

(e) for the heading of point 8.2 thereof, there shall be substituted the following:

"8.2 Follow-on formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins.".

7. The Third Schedule to the principal regulations shall be amended as follows:

Amends the Third Schedule to the principal regulations.

(a) in the table relating to point 3 "Amino acids and other nitrogen compounds" thereof, immediately before the item "L-cystine and its hydrochloride" there shall be added the following new item:

"L-arginine and its hydrochloride⁽¹⁾"; and

(b) immediately at the end of the said table, there shall be added the following corresponding footnote:

"⁽¹⁾ L-arginine and its hydrochloride shall only be used in the manufacture of infant formulae referred to in the third subparagraph of regulation 7(1) and follow-on formulae referred to in the second subparagraph of regulation 7(2).".

8. For the heading of the Sixth Schedule, there shall be substituted the following:

Amends the Sixth Schedule to the principal regulations.

"Specification for the protein content and source and the processing of protein used in the manufacture of infant formulae and follow-on formulae with a protein content less than 0,56 g/100 kJ (2,25 g/100 kcal) manufactured from hydrolysates of whey proteins derived from cows' milk protein'.".

