STATUTORY INSTRUMENTS.

S.I. No. 490 of 2023

EUROPEAN UNION (FOOD INTENDED FOR INFANTS AND YOUNG CHILDREN, FOOD FOR SPECIAL MEDICAL PURPOSES, AND TOTAL DIET REPLACEMENT FOR WEIGHT CONTROL) (AMENDMENT) REGULATIONS 2023

1. (1) These Regulations may be cited as the European Union (Food Intended for Infants and Young Children, Food for Special Medical Purposes, and Total Diet Replacement for Weight Control) (Amendment) Regulations 2023.

(2) The Principal Regulations, the Regulations of 2022 and these Regulations may be cited together as the European Union (Food Intended for Infants and Young Children, Food for Special Medical Purposes, and Total Diet Replacement for Weight Control) Regulations 2019 to 2023.

2. In these Regulations –

“Principal Regulations” means the European Union (Food Intended for Infants and Young Children, Food for Special Medical Purposes, and Total Diet Replacement for Weight Control) Regulations 2019 (S.I. No. 425 of 2019);

“Regulations of 2022” means the European Union (Food Intended for Infants and Young Children, Food for Special Medical Purposes, and Total Diet

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1 OJ No. L 181, 29.6.2013, p. 35.
2 OJ No. L 64, 1.3.2023, p. 1.
6 OJ No. L 120, 8.4.2021, p. 4.
8 OJ No. L 104, 1.4.2022, p. 58.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 10th October, 2023.
Replacement for Weight Control) (Amendment) Regulations 2022 (S.I. No. 111 of 2022).

3. Regulation 2(1) of the Principal Regulations (as last amended by Regulation 3 of the Regulations of 2022) is hereby amended –

(a) by inserting the following definitions:

2022\(^8\) and Commission Delegated Regulation (EU) 2023/589 of 10 January 2023\(^9\);

‘follow-on formula’ means food intended for use by infants when appropriate complementary feeding is introduced and which constitutes the principal liquid element in a progressively diversified diet of such infants;

‘infant formula’ means food intended for use by infants during the first months of life and satisfying by itself the nutritional requirements of such infants until the introduction of appropriate complementary feeding;

‘infant’ means a child under the age of 12 months;

‘young child’ means a child aged between one and three years.”.

(b) by substituting for the definition of “EU Regulation 609/2013” the following:


(c) by substituting for the definition of “Union list” the following:

“‘Union list’ means the Union list annexed to EU Regulation 609/2013 as amended by Commission Delegated Regulation (EU) 2017/1091 of 10 April 2017\(^10\), Commission Delegated Regulation (EU) 2021/571 of 20 January 2021\(^11\) and Commission Delegated Regulation (EU) 2023/439 of 16 December 2022\(^2\) and which lists the various substances that may be added to one or more of the categories of food referred to in Regulation 3.”.

4. Regulation 14 of the Principal Regulations is hereby amended by substituting for paragraph (1) the following:

“(1) A food business operator who places on the market a food referred to in Regulation 3(3) but who fails to ensure that the following mandatory particulars, preceded by the words ‘important notice’ or their equivalent, are included on the package or on a label attached thereto—

(a) a statement that the product must be used under medical supervision,

(b) a statement as to whether the product is suitable for use as the sole source of nourishment,
(c) a statement that the product is intended for a specific age group, as appropriate, or
(d) where appropriate, a statement that the product poses a health hazard when consumed by persons who do not have the disease, disorder or medical condition for which the product is intended,

is guilty of an offence.”.

5. The Principal Regulations are hereby amended by substituting for Regulation 18 the following:

“A food business operator who places on the market in the State a food referred to in Regulation 3(3) but who fails to notify the Authority of the information appearing on the label, or labels, by sending to it a model of the label, or labels, used for the product, in a manner to be specified by the Authority, and any other information which the Authority may reasonably request to establish compliance with these Regulations or EU Regulation 2016/128, is guilty of an offence.”.

6. The Principal Regulations are amended by inserting after Part 3 the following:

“PART 3A

SPECIFIC COMPOSITIONAL AND INFORMATION REQUIREMENTS FOR INFANT FORMULA AND FOLLOW-ON FORMULA AND AS REGARDS REQUIREMENTS ON INFORMATION RELATING TO INFANT AND YOUNG CHILD FEEDING

18A. This Part only applies to food referred to in Regulation 3(1) and supplements Part 2 insofar as it applies to such food.

Placing on the market

18B. A food business operator who markets or otherwise represents a product other than infant formula as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life until the introduction of appropriate complementary feeding is guilty of an offence.

Compositional requirements

18C. (1) A food business operator who places on the market—
(a) infant formula and who fails to ensure that the food complies with the compositional requirements set out in Annex I to EU Regulation 2016/127 taking into account the values for the indispensable and conditionally indispensable amino acids set out in Annex III to EU Regulation 2016/127, or

(b) follow-on formula and who fails to ensure that the food complies with the compositional requirements set out in Annex II to EU Regulation 2016/127 taking into account the values for the indispensable and conditionally indispensable amino acids set out in Annex III to EU Regulation 2016/127.

is guilty of an offence.

(2) The values set out in Annex I to EU Regulation 2016/127 and Annex II to EU Regulation 2016/127 shall apply to the infant formula and follow-on formula ready for use, marketed as such, or after preparation in accordance with the manufacturer’s instructions. For such preparation nothing more than the addition of water shall be required.

Suitability of ingredients

18D. (1) A food business operator who places on the market—

(a) infant formula manufactured from protein sources (other than those set out in point 2 of Annex I to EU Regulation 2016/127) or other food ingredients, whose suitability for infants from birth has not been established by generally accepted scientific data, or

(b) follow-on formula manufactured from protein sources (other than those set out in point 2 of Annex II to EU Regulation 2016/127) or other food ingredients, whose suitability for infants aged over six months has not been established by generally accepted scientific data,

is guilty of an offence.

(2) The suitability referred to in subparagraphs (1)(a) and (1)(b) shall be demonstrated by the food business operator through a systematic review of the available data relating to the expected benefits and to safety considerations as well as, where necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

Requirements on pesticides

18E. (1) Subject to paragraph (3), a food business operator who places on the market a food referred to in Regulation 3(1) and who fails to ensure that such food—

(a) subject to subparagraph (b), does not contain residues at levels exceeding 0.01 mg/kg per active substance,

(b) does not, in the case of the active substances listed in Annex IV to EU Regulation 2016/127, contain residue levels exceeding those specified in that Annex, or
(c) subject to paragraph (2), has not been produced from agricultural products, for the production of which plant protection products containing the active substances listed in Annex V to EU Regulation 2016/127 have been used, is guilty of an offence.

(2) For the purpose of checks, plant protection products containing the active substances listed in Annex V to EU Regulation 2016/127 shall be considered not to have been used in agricultural products, if their residues do not exceed a level of 0.003mg/kg.

(3) The levels referred to in paragraphs (1) and (2) shall apply to food referred to in Regulation 3(1) ready for use, marketed as such or after preparation in accordance with the manufacturer’s instructions.

Name of the food

18F. A food business operator who places on the market food referred to in Regulation 3(1)—

(a) other than infant formula and follow-on formula manufactured entirely from cows’ milk or goats’ milk proteins, which is not named ‘Infant formula’ and ‘Follow-on formula’ respectively, or

(b) manufactured entirely from cows’ milk or goats’ milk proteins, which is not named ‘Infant milk’ and ‘Follow-on milk’ respectively,

is guilty of an offence.

Specific requirements on food information

18G. (1) A food business operator who places on the market infant formula but who fails to ensure that the following mandatory particulars are included on the package or on a label attached thereto—

(a) a statement that the product is suitable for infants from birth when they are not breast fed, or

(b) instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage,

is guilty of an offence.

(2) A food business operator who places on the market infant formula but who fails to ensure that the following mandatory particulars, preceded by the words ‘important notice’ or their equivalent, are included on the package or on a label attached thereto—

(a) a statement concerning the superiority of breast feeding, or

(b) a statement recommending that the product be used only on the advice of independent persons having qualifications in
(3) A person who fails to ensure that a statement concerning the superiority of breast feeding or a statement recommending that the product be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care, preceded by the words ‘important notice’ or their equivalent, is given in the presentation and advertising of infant formula, is guilty of an offence.

(4) A food business operator who places on the market follow-on formula but who fails to ensure that the following mandatory particulars are included on the package or on a label attached thereto—

(a) a statement that the product is suitable only for infants over the age of six months, that it should form only part of a diversified diet, that it is not to be used as a substitute for breast milk during the first six months of life and that the decision to begin complementary feeding, including any exception to six months of age, should be made only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care, based on the individual infant’s specific growth and development needs, or

(b) instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage,

is guilty of an offence.

(5) A food business operator who fails to ensure that the mandatory particulars listed in paragraphs (1), (2), (3) and (4) are printed on the package or on the label attached thereto—

(a) in such a way as to ensure clear legibility, and

(b) in characters using a font size where the x-height, as defined in Annex IV to EU Regulation 1169/2011, is—

(i) equal to or greater than 1.2 mm, or

(ii) equal to or greater than 0.9 mm, in the case of packaging or containers the largest surface of which has an area of less than 80cm²,

is guilty of an offence.

(6) A person who fails to ensure—

(a) that the mandatory particulars for food referred to in Regulation 3(1) set out in this Regulation appear in a language easily understood by the consumers,

(b) that the labelling, presentation or advertising of food referred to in Regulation 3(1) provides the necessary information about the
appropriate use of the products, so as not to discourage breastfeeding, or

(c) that the labelling, presentation or advertising of food referred to in Regulation 3(1) is designed in such a way that it avoids any risk of confusion between such foods and enables consumers to make a clear distinction between them, in particular as to the text, images and colours used,

is guilty of an offence.

(7) A person who uses the terms ‘humanised’, ‘maternalised’, ‘adapted’, or terms similar to them in the labelling, presentation or advertising of a food referred to in Regulation 3(1) is guilty of an offence.

Specific requirements on the nutrition declaration

18H. (1) A food business operator who places on the market a food referred to in Regulation 3(1) but who—

(a) fails to include a nutrition declaration on the package or on the label attached to such food, irrespective of the size of the largest surface area of the packaging or container,

(b) fails to include in the mandatory nutrition declaration under paragraph 1(a), in addition to the information referred to in Article 30(1) of EU Regulation 1169/2011—

(i) the amount of each mineral substance and of each vitamin listed in Annex I to EU Regulation 2016/127 or Annex II to EU Regulation 2016/127 respectively and present in the product, with the exception of molybdenum,

(ii) in the case of infant formula, the amount of choline, inositol and carnitine,

(c) notwithstanding Article 30(1) of EU Regulation 1169/2011, includes the amount of salt in the mandatory nutrition declaration under paragraph (1)(a),

(d) notwithstanding Article 30(3) of EU Regulation 1169/2011, repeats information included in the mandatory nutrition declaration under paragraph (1)(a), on the label attached to such a food,

(e) fails to ensure that the nutrients in the nutrition declaration comply with the calculation, expression and presentation and requirements under Articles 31 to 35 of EU Regulation 1169/2011, or

(f) fails to present the particulars included in the nutrition declaration that are not listed in Annex XV to EU Regulation 1169/2011 after—

(i) the most relevant entry of that Annex to which they belong or of which they are components, or
(ii) the last entry of that Annex, where they do not belong to or are not components of any of the entries of that Annex, is guilty of an offence.

(2) In addition to the information referred to in Article 30(2)(a) to (e) of EU Regulation 1169/2011, the content of the mandatory nutrition declaration for a food referred to in Regulation 3(1) may be supplemented with one or more of the following:

(a) the amounts of components of protein, carbohydrate or fat;
(b) the whey protein/casein ratio;
(c) the amount of any of the substances listed in Annex I to EU Regulation 2016/127 or Annex II to EU Regulation 2016/127 or in the Annex to EU Regulation 609/2013, where the indication of any of those substances is not covered by sub-paragraph 1(b) or (c), or
(d) the amount of any of the substances added to the product pursuant to Regulation 18D.

(3) Notwithstanding Article 31(3), 32(2) and 33(1) of EU Regulation 1169/2011, the energy value and the amounts of nutrients of a food referred to in Regulation 3(1) shall be expressed per 100 ml of the food ready for use after preparation in accordance with the manufacturer’s instructions. Where appropriate, the information may in addition refer to 100g of the food as sold.

(4) Notwithstanding Article 32(3) and (4) of EU Regulation 1169/2011, the energy value and the amount of nutrients of food referred to in Regulation 3(1) shall not be expressed as a percentage of the reference intakes set out in Annex XIII to that Regulation.

(5) In addition to the form of expression referred to in paragraph (3), in the case of follow-on formula, the declaration on vitamins and minerals in respect of the vitamins and minerals listed in Annex VII to EU Regulation 2016/127 may be expressed as a percentage of the reference intakes set out in that Annex in relation to per 100 ml of the food ready for use after preparation in accordance with the manufacturer’s instructions.

Nutrition and health claims for infant formula

18I. A food business operator who makes a nutrition or health claim on infant formula is guilty of an offence.

Statements related to lactose and docosahexaenoic acid (DHA)

18J. (1) A food business operator who places on the market a food referred to in Regulation 3(1) but who fails to ensure that—

(a) the statement ‘lactose only’ is only used where lactose is the only carbohydrate present in the product,
(b) the statement ‘lactose free’ is only used where the lactose content in the product is not greater than 2.5 mg/100kJ (10 mg/100 kcal), or

(c) the statement ‘lactose free’ when used for products manufactured from protein sources other than soya protein isolates, is accompanied by the statement ‘not suitable for infants with galactosaemia’, which is indicated with the same font size and prominence as the statement ‘lactose free’ and in close proximity to it,

is guilty of an offence.

(2) A food business operator who uses the statement ‘contains Docosahexaenoic acid (as required by the legislation for all infant formula)’ or ‘contains DHA (as required by the legislation for all infant formula)’ for infant formula placed on the market after 22 February 2025 is guilty of an offence.

Requirements for promotional and commercial practices for infant formula

18K. (1) A person who advertises infant formula in publications other than those specialising in baby care and scientific publications is guilty of an offence.

(2) A person who fails to ensure that there is no point-of-sale advertising, giving of samples or any other promotional device to induce sale of infant formula directly to the consumer at retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales is guilty of an offence.

(3) A manufacturer or distributor of infant formula who provides to the general public or to pregnant women, mothers or members of their families free or low-priced products, samples, or any other promotional gifts either directly or indirectly via the health care system or health workers is guilty of an offence.

(4) A person who provides donations or low-price supplies of infant formula to institutions or organisations, whether for use in the institutions or for distribution outside them, for use by infants other than those who have to be fed infant formula and only for as long as required by such infants in accordance with Article 10(4) of EU Regulation 2016/127 is guilty of an offence.

Requirements on information relating to infant and young child feeding

18L. (1) A person who provides information on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition which is not objective and consistent shall be guilty of an offence.

(2) Paragraph (1) shall apply to the planning, provision, design and dissemination of information and their control.
(3) A person who provides informational and educational material, whether written or audiovisual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children and who fails to include clear information on the following points:

(a) the benefits and superiority of breast feeding;
(b) maternal nutrition and the preparation for and maintenance of breast feeding;
(c) the possible negative effect on breast feeding of introducing partial bottle feeding;
(d) the difficulty of reversing the decision not to breast feed; or
(e) where needed, the proper use of infant formula, is guilty of an offence.

(4) A person who provides informational and educational material, whether written or audiovisual, about the use of infant formula and who fails to ensure that such information or materials—

(a) includes the social and financial implications of the use of infant formula, the health hazards of inappropriate foods or feeding methods, and, in particular, the health hazards of improper use of infant formula, or
(b) does not use any pictures which may idealise the use of infant formula,

is guilty of an offence.

(5) A manufacturer or distributor who donates informational or educational equipment or materials on infant and young child feeding—

(a) without a request and without the written approval of the Authority or not within the guidelines given by the Authority for this purpose,
(b) which refers to a proprietary brand of infant formula, or
(c) which is distributed other than through the healthcare system,

is guilty of an offence.

Offences arising from failure to notify the Authority

18M. (1) A food business operator who places on the market in the State infant formula but who fails to notify the Authority of the information appearing on the label, or labels, by sending to it a model of the label, or labels, used for the product, in a manner to be specified by the Authority, and any other information which the Authority may reasonably request to establish compliance with these Regulations or EU Regulation 2016/127, is guilty of an offence.

(2) A food business operator who places on the market in the State follow-on formula manufactured from protein hydrolysates or follow-on formula containing other substances than those listed in Annex II to EU Regulation
2016/127 but who fails to notify the Authority of the information appearing on the label, or labels, by sending to it a model of the label, or labels, used for the product, in a manner to be specified by the Authority, and any other information the Authority may reasonably request to establish compliance with these Regulations, or EU Regulation 2016/127, is guilty of an offence.”.

7. Regulation 31 of the Principal Regulations is amended by inserting after subparagraph (8) the following:

“(9) Notwithstanding the provisions of Part 3A, a food business operator is not guilty of an offence under these Regulations for failure to comply with EU Regulation 2016/127 in respect of infant formula and follow-on formula manufactured from protein hydrolysates and which, before 22 February 2022, was placed on the market or labelled in accordance with the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2007 (S.I. No. 852 of 2007).

(10) Notwithstanding Regulation 34, the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2007 (S.I. No. 852 of 2007), shall continue to apply, in respect of infant formula and follow-on formula manufactured from protein hydrolysates which was placed on the market or labelled before 22 February 2022, until the stocks of such food are exhausted.

(11) Notwithstanding the provisions of Part 3A, a food business operator is not guilty of an offence under these Regulations for failure to comply with EU Regulation 2016/127 in respect of a food which is referred to in Regulation 3(1) and which, before 22 February 2020, was placed on the market or labelled in accordance with the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2007 (S.I. No. 852 of 2007).

(12) Notwithstanding Regulation 34, the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2007 (S.I. No. 852 of 2007), shall continue to apply, in respect of a food referred to in Regulation 3(1) which was placed on the market or labelled before 22 February 2020, until the stocks of such food are exhausted.”.

8. Regulation 34(1) of the Principal Regulations is amended by inserting after subparagraph (c) the following:

“(d) European Communities (Infant Formulae and Follow-On Formulae) Regulations 2007 (S.I. No. 852 of 2007),

(e) European Communities (Infant Formulae and Follow-On Formulae) (Amendment) Regulations 2009 (S.I. No. 209 of 2009),

(f) European Communities (Infant Formulae and Follow-on Formulae) (Amendment) Regulations 2013 (S.I. No. 384 of 2013),
European Communities (Infant Formulae and Follow-on Formulae) (Amendment) Regulations 2014 (S.I. No. 92 of 2014)."

GIVEN under my Official Seal,
5 October, 2023.

STEPHEN DONNELLY,
Minister for Health.
EXPLANATORY NOTE

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


These Regulations amend the European Union (Food Intended for Infants and Young Children, Food for Special Medical Purposes, and Total Diet Replacement for Weight Control) Regulations 2019 (S.I. No. 425 of 2019) in the manner specified in these Regulations.

These Regulations may be cited as the European Union (Food Intended for Infants and Young Children, Food for Special Medical Purposes, and Total Diet Replacement for Weight Control) (Amendment) Regulations 2023.
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