

S.I. No. 852/2007 — European Communities (Infant formulae and Follow-on formulae) Regulations 2007

S.I. No. 852 of 2007

EUROPEAN COMMUNITIES (INFANT FORMULAE AND FOLLOW-ON FORMULAE) REGULATIONS 2007

Notice of the making of this Statutory Instrument was published in

“Iris Oifigiúil” of 18th January, 2008.

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 partial effect to Commission Directive 2006/141/EC ¹ of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC ², and for the purpose of giving further effect to Council Directive 92/52/EEC ³ of 18 June 1992 on infant formulae and follow-on formulae intended for export to third countries, hereby make the following regulations:

PART 1 Preliminary

1. (1) These Regulations may be cited as the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2007.

(2) These Regulations (other than Regulation 30(2)) come into operation on 1 January 2008.

(3) Regulation 30(2) comes into operation on the 31 December 2009.

2. (1) In these Regulations—

“Act of 1998” means the Food Safety Authority of Ireland Act 1998 (No. 29 of 1998);

“approved examiner” means—

- (a) an Agricultural Inspector located at a Dairy Science Laboratory,
- (b) an Assistant Agricultural Inspector located at a Dairy Science Laboratory,
- (c) a Chief Medical Scientist located at an official laboratory,
- (d) a Consultant Microbiologist located at an official laboratory,
- (e) a Deputy Public Analyst located at a Public Analyst’s Laboratory,
- (f) an Executive Analytical Chemist located at a Public Analyst’s Laboratory,
- (g) a Public Analyst located at a Public Analyst’s Laboratory,
- (h) a person, or member of a class of persons, designated by the Minister pursuant to Regulation 24;

“authorised officer” means an authorised officer appointed under section 49 of the Act of 1998;

“Authority” means the Food Safety Authority of Ireland established under section 9 of the Act of 1998;

“claim”, “health claim”, “nutrition claim” and “reduction of disease risk claim” shall be defined in accordance with Article 2(2) of Regulation (EC) No 1924/2006 ⁴;

“Directive 2006/141/EC” means Commission Directive 2006/141/EC 1 of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC 2 ;

“Directive 92/52/EEC” means Council Directive 92/52/EEC 3 of 18 June 1992 on infant formulae and follow-on formulae intended for export to third countries;

“Directives” means Directive 2006/141/EC 1 and Directive 92/52/EEC 3 ;

“follow-on formulae” means foodstuffs intended for particular nutritional use by infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such infants, and cognate words shall be construed accordingly;

“General Food Law Regulation” means Regulation (EC) No 178/2002 ⁵ of the European Parliament and of the Council of 28 January 2002 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;

“health care system” includes institutions or organisations engaged, directly or indirectly, in health care for mothers, infants and pregnant women, including nurseries or child-care institutions, and includes health workers in private practice;

“Health Service Executive” (HSE) means the Health Service Executive established under section 6 of the Health Act 2004 (No. 42 of 2004);

“infant formulae” means foodstuffs intended for particular nutritional use by infants during the first months of life and satisfying by themselves the nutritional requirements of such infants, until the introduction of appropriate complementary feeding, and cognate words shall be construed accordingly;

“infants” means children under the age of 12 months;

“Minister” means the Minister for Health and Children;

“official agency” means an official agency carrying out functions under a service contract and acting on behalf of the Authority pursuant to section 48 of the Act of 1998;

“Official Controls Regulation” means Regulation (EC) No 882/2004 ⁶ of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;

“official laboratory” means—

- (a) Dairy Science Laboratory, Backweston,
- (b) Public Analyst’s Laboratory, Cork,
- (c) Public Analyst’s Laboratory, Dublin,
- (d) Public Analyst’s Laboratory, Galway,
- (e) Public Health Laboratory, HSE, Dublin Mid-Leinster,
- (f) Public Health Laboratory, Sligo,
- (g) Public Health Laboratory, Waterford,
- (h) Public Health Microbiology Laboratory, Cork,
- (i) Public Health Microbiology Laboratory, Galway,
- (j) Public Health Microbiology Laboratory, Limerick,
- (j) a laboratory designated by the Minister pursuant to Regulation 24;

“pesticide residue” means the residue in infant formulae and follow-on formulae of a plant protection product, as defined in point 1 of Article 2 of Directive 91/414/EEC ⁷ , including its metabolites and products resulting from its degradation or reaction, and cognate words shall be construed accordingly;

“service contract” means a contract entered into between the Authority and an official agency pursuant to section 48 of the Act of 1998;

“young children” means children aged between one and three years.

(2) A word or expression which is used in these Regulations and which is also used in the Directives or in the General Food Law Regulation has, unless the context otherwise requires, the same meaning in these Regulations as it has in the Directives or in the General Food Law Regulation.

(3) (a) A reference in these Regulations to a Regulation is to a Regulation of these Regulations, unless it is indicated that reference to some other Regulations is intended.

(b) A reference in these Regulations to a paragraph or subparagraph is to the paragraph or subparagraph of the provision in which the reference occurs, unless it is indicated that reference to some other provision is intended.

(c) A reference in these Regulations to a Schedule is to a Schedule to these Regulations, unless it is indicated that reference to some other Regulations is intended.

(d) A reference in these Regulations to an Article is to an Article of the Directives, unless it is indicated that reference to some other instrument is intended.

PART 2 Infant Formulae and Follow-On Formulae Intended to be Placed on the Market in a Member State

3. (1) These Regulations concern infant formulae and follow-on formulae, and this Part is concerned with infant formulae and follow-on formulae intended to be placed on the market in a Member State.

(2) A person shall not—

(a) manufacture infant formulae or place infant formulae on the market unless the requirements of this Part applicable to infant formulae are complied with,

(b) use the description ‘infant formula’ in the marketing of any product which is not infant formulae as defined in Regulation 2(1), or

(c) represent any product which is not infant formulae as defined in Regulation 2(1) as being 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.

(3) Infant formulae shall be placed on the market under the name ‘infant formula’, save where it is manufactured entirely from cows’ milk proteins, in which case it shall be sold under the name ‘infant milk’.

(4) A person shall not—

(a) manufacture follow-on formulae or place follow-on formulae on the market unless the requirements of this Part applicable to follow-on formulae are complied with, or

(b) use the description ‘follow-on formula’ in the marketing of any product which is not follow-on formulae as defined in Regulation 2(1).

(5) Follow-on formula shall be placed on the market under the name ‘follow-on formula’, save where it is manufactured entirely from cows’ milk proteins, in which case it shall be sold under the name ‘follow-on milk’.

(6) The other names listed in Articles 11 and 12 of the Directive, or any of them, may also be included in addition to the names indicated in paragraphs (3) and (5).

(7) A person shall not distribute, publish or issue any materials containing information on infant or young child feeding, unless the requirements of this Part are complied with.

4. (1) Infant formulae shall be manufactured from protein sources defined in point 2 of Schedule 1 and other food ingredients, as the case may be, whose suitability for particular nutritional use by infants from birth has been established by generally accepted scientific data, and demonstrated in accordance with paragraph (2).

(2) Suitability shall be demonstrated 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.

(3) The prohibitions and limitations on the use of food ingredients in infant formulae set down in Schedule 1 shall be observed.

(4) Subject to paragraphs (5) and (6), infant formulae shall comply with the compositional criteria specified in Schedule 1 taking into account the specifications in Schedule 5.

(5) In the case of infant formulae manufactured from cows' milk proteins specified in point 2.1 of Schedule 1 with a protein content between the minimum and 0.5g/100 kJ (2g/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.

(6) In the case of infant formulae manufactured from protein hydrolysates specified in point 2.2 of Schedule 1 with a protein content between the minimum and 0.56g/100 kJ (2.25g/100 kcal):

(a) 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) the infant formula shall be in accordance with the appropriate specifications set out in Schedule 6.

(7) In order to make infant formulae ready for use, nothing more shall be required than the addition of water.

(8) Only the substances listed in Schedule 3 may be used in the manufacture of infant formulae in order to satisfy the requirements on mineral substances, vitamins, amino acids and other nitrogen compounds, and other substances having a particular nutritional purpose.

(9) Purity criteria for substances, as provided for in Community legislation concerning the use of substances listed in Schedule 3, in the manufacture of foodstuffs for purposes other than those covered by Directive 2006/141/EC 1, shall apply to infant formulae.

(10) For those substances for which no purity criteria have been provided for in Community legislation, generally acceptable purity criteria recommended by international bodies shall apply to infant formulae until the adoption of such criteria at Community level.

(11) Infant formulae shall not contain any substance in such quantity as to endanger the health of infants and young children.

(12) Subject to paragraph (17), infant formulae shall not contain residues of individual pesticides at levels exceeding 0.01mg/kg of the product as proposed ready for consumption or as reconstituted according to the instructions of the manufacturer.

(13) Analytical methods for determining the levels of pesticide residues shall be generally acceptable standardised methods.

(14) Subject to paragraphs (15) and (16), those pesticides listed in Schedule 8 shall not be used in agricultural products intended for the production of infant formulae.

(15) For the purposes of controls, pesticides listed in Table 1 of Schedule 8 are considered not to have been used if their residues do not exceed a level of 0.003mg/kg.

(16) For the purposes of controls, pesticides listed in Table 2 of Schedule 8 are considered not to have been used if their residues do not exceed a level of 0.003mg/kg.

(17) For the pesticides listed in Schedule 9, the maximum residue levels specified therein shall apply.

(18) The levels referred to in paragraphs (15), (16) and (17) shall apply to the products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers.

5. (1) Follow-on formulae shall be manufactured from protein sources defined in point 2 of Schedule 2 and other food ingredients, as the case may be, whose suitability for particular nutritional use by infants aged over 6 months has been established by generally accepted scientific data, as demonstrated in accordance with Regulation 4(2).

(2) The prohibitions and limitations on the use of food ingredients in follow-on formulae set down in Schedule 2 shall be observed.

(3) Follow-on formulae shall comply with the compositional criteria specified in Schedule 2 taking into account the specifications set out in Schedule 5.

(4) In order to make follow-on formulae ready for use, nothing more shall be required than the addition of water.

(5) Only the substances listed in Schedule 3 may be used in the manufacture of follow-on formulae in order to satisfy the requirements on mineral substances, vitamins, amino acids and other nitrogen compounds, and other substances having a particular nutritional purpose.

(6) Purity criteria for substances, as provided for in Community legislation concerning the use of substances listed in Schedule 3, in the manufacture of

foodstuffs for purposes other than those covered by Directive 2006/141/EC¹, shall apply to follow-on formulae.

(7) For those substances for which no purity criteria have been provided for in Community legislation, generally acceptable purity criteria recommended by international bodies shall apply to follow-on formulae until the adoption of such criteria at Community level.

(8) Follow-on formulae shall not contain any substance in such quantity as to endanger the health of infants and young children.

(9) Subject to paragraph (14), follow-on formulae shall not contain residues of individual pesticides at levels exceeding 0.01mg/kg of the product as proposed ready for consumption or as reconstituted according to the instructions of the manufacturer.

(10) Analytical methods for determining the levels of pesticide residues shall be generally acceptable standardised methods.

(11) Subject to paragraphs (12) and (13), those pesticides listed in Schedule 8 shall not be used in agricultural products intended for the production of follow-on formulae.

(12) For the purposes of controls, pesticides listed in Table 1 of Schedule 8 are considered not to have been used if their residues do not exceed a level of 0.003mg/kg.

(13) For the purposes of controls, pesticides listed in Table 2 of Schedule 8 are considered not to have been used if their residues do not exceed a level of 0.003mg/kg.

(14) For the pesticides listed in Schedule 9, the maximum residue levels specified therein shall apply.

(15) The levels referred to in paragraphs (12), (13) and (14) shall apply to the products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers.

6. (1) The labelling of infant formulae shall bear, in addition to those provided for in Article 3(1) of Directive 2000/13/EC⁸ of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, the following mandatory particulars:

(a) a statement to the effect that the product is suitable for particular nutritional use by infants from birth when they are not breast-fed,

(b) the available energy value, expressed in kJ and kcal, per 100ml of the product ready for use,

(c) the content of proteins, carbohydrates and lipids, expressed in numerical form, per 100ml of the product ready for use,

(d) the average quantity of each mineral substance and of each vitamin mentioned in Schedule 1, expressed in numerical form, per 100ml of the product ready for use,

(e) where applicable, the average quantity of choline, inositol and carnitine, expressed in numerical form, per 100ml of the product ready for use,

(f) instructions for appropriate preparation, storage and disposal of the product, and

(g) a warning against the health hazards of inappropriate preparation and storage.

(2) The labelling of infant formulae may bear the average quantity of nutrients mentioned in Schedule 3 when such declaration is not covered by the provisions of subparagraphs (d) and (e) of paragraph (1), expressed in numerical form, per 100ml of the product ready for use.

(3) The labelling of infant formulae shall be designed to provide the necessary information about the appropriate use of the products so as not to discourage breast-feeding.

(4) In the labelling of infant formulae, the use of the terms 'humanised', 'maternalised', 'adapted' or similar terms shall be prohibited.

(5) The labelling of infant formulae shall, in addition, bear the following mandatory particulars, preceded by the words 'Important Notice' or their equivalent:

(a) a statement concerning the superiority of breast-feeding, and

(b) 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.

(6) The labelling of infant formulae shall not include pictures of infants, nor shall it include other pictures or text which may idealise the use of the product. It may, however, include graphic representations for easy identification of the product and for illustrating methods of preparation.

(7) The labelling of infant formulae may bear nutrition and health claims only in the cases listed in Schedule 4 and in accordance with the conditions set out therein.

(8) Infant formulae shall be labelled in such a way as to enable consumers to make a clear distinction between infant formulae and follow-on formulae so as to avoid any risk of confusion between such products.

(9) The requirements, prohibitions and restrictions referred to in paragraphs (3) to (8) shall also apply to:

(a) the presentation of the products concerned, in particular their shape, appearance or packaging, the packaging materials used, the way in which they are arranged and the setting in which they are displayed, and

(b) advertising.

(10) A food business operator placing an infant formula product on the market in the State, shall notify the Authority of that placing on the market by forwarding to it a model of the label used for the product.

7. (1) The labelling of follow-on formulae shall bear, in addition to those provided for in Article 3(1) of Directive 2000/13/EC 8 of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, the following mandatory particulars:

(a) a statement to the effect that the product is suitable only for particular nutritional use by infants over the age of 6 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 6 months of life and that the decision to begin complementary feeding, including any exception to 6 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,

(b) the available energy value, expressed in kJ and kcal, per 100ml of the product ready for use,

(c) the content of proteins, carbohydrates and lipids, expressed in numerical form, per 100ml of the product ready for use,

(d) the average quantity of each mineral substance and of each vitamin mentioned in Schedule 2, expressed in numerical form, per 100ml of the product ready for use,

(e) where applicable, the average quantity of choline, inositol, and carnitine, expressed in numerical form, per 100ml of the product ready for use,

(f) instructions for appropriate preparation, storage and disposal of the product, and

(g) a warning against the health hazards of inappropriate preparation and storage.

(2) The labelling of follow-on formulae may bear:

(a) the average quantity of nutrients mentioned in Schedule 3 when such declaration is not covered by the provisions of subparagraphs (d) and (e) of paragraph (1), expressed in numerical form, per 100ml of the product ready for use, and

(b) in addition to numerical information, information on vitamins and minerals included in Schedule 7, expressed as a percentage of the reference values given therein, per 100ml of the product ready for use.

(3) The labelling of follow-on formulae shall be designed to provide the necessary information about the appropriate use of the products so as not to discourage breast-feeding.

(4) In the labelling of follow-on formulae, the use of the terms 'humanised', 'maternalised', 'adapted' or similar terms shall be prohibited.

(5) Follow-on formulae shall be labelled in such a way as to enable consumers to make a clear distinction between infant formulae and follow-on formulae so as to avoid any risk of confusion between such products.

(6) The requirements, prohibitions and restrictions referred to in paragraphs (3) to (5) shall also apply to—

(a) the presentation of the products concerned, in particular their shape, appearance or packaging, the packaging materials used, the way in which they are arranged and the setting in which they are displayed, and

(b) advertising.

8. (1) Advertising of infant formulae shall be restricted to publications specialising in baby care and scientific publications.

(2) The requirements, prohibitions and restrictions referred to in paragraphs (3) to (8) of Regulation 6 shall also apply to advertising, and advertisements for

infant formulae shall be subject to the conditions laid down therein.

(3) Advertisements for infant formulae shall contain only information of a scientific and factual nature.

(4) Advertisements for infant formulae shall not imply or create a belief that bottle-feeding is equivalent or superior to breast-feeding.

(5) There shall be no point-of-sale advertising, giving of samples or any other promotional device to induce sales of infant formula directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales.

(6) Manufacturers and distributors of infant formulae shall not provide, 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.

9. (1) Where information is provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition, such information shall be objective and consistent.

(2) Paragraph (1) shall apply to the planning, provision, design and dissemination of information and their control.

(3) Informational and educational materials, whether written or audiovisual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, shall include clear information on all the following points:

(a) the benefits and superiority of breast-feeding,

(b) the importance of 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, and

(e) where needed, the proper use of infant formulae.

(4) Where the materials referred to at paragraph (3) contain information about the use of infant formulae, they shall include information on the social and financial implications of its use, the health hazards of inappropriate foods or feeding methods, and, in particular, the health hazards of improper use of infant formulae.

(5) The materials referred to at paragraph (3) shall not use any pictures which may idealise the use of infant formulae.

(6) Donations of informational or educational equipment or materials by manufacturers or distributors shall be made only on request and with the written approval of the Authority or within guidelines issued by the Authority for that purpose.

(7) The equipment and materials referred to at paragraph (6) may bear the donating company's name or logo, but shall not refer to a proprietary brand of infant formulae and shall be distributed only through the health care system.

(8) Donations and low-price sales of supplies of infant formulae to institutions or organisations, whether for use in the institutions or for distribution outside them, shall only be used by or distributed for infants who have to be fed on infant formulae and only for as long as required by such infants.

10. Products complying with this Part may be placed on the market from 1 January 2008.

PART 3 Infant Formulae and Follow-On Formulae Intended for Export to Third Countries

11. This Part is concerned with infant formulae and follow-on formulae intended for export to third countries.

12. (1) A person shall not—

(a) export infant formulae unless the requirements of this Part applicable to infant formulae are complied with,

(b) use the description 'infant formula' in the marketing of any product intended for export, which is not infant formulae as defined in Regulation 2(1), or

(c) represent any product intended for export, which is not infant formulae as defined in Regulation 2(1), as being suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life.

(2) Unless otherwise requested or stipulated by provisions established by the importing country, and subject to Article 12 of the General Food Law Regulation,

a person shall not export infant formulae unless:

- (a) either the requirements set down in Regulation 4 of these Regulations or the relevant applicable world standards established by Codex Alimentarius are complied with,
- (b) the requirements set down in paragraphs (1) to (7) of Regulation 6 of these Regulations are complied with, and
- (c) the provisions of Council Directive 89/396/EEC ⁹ of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs, are complied with.

(3) The stipulations, prohibitions and restrictions laid down in paragraphs (1) to (7) of Regulation 6 of these Regulations shall also apply to the presentation of infant formulae intended for export, and in particular their form, aspect or packaging and the packaging materials used.

13. (1) A person shall not—

- (a) export follow-on formulae unless the requirements of this Part applicable to follow-on formulae are complied with, or
- (b) use the description ‘follow-on formula’ in the marketing of any product intended for export which is not follow-on formulae as defined in Regulation 2(1).

(2) Unless otherwise requested or stipulated by provisions established by the importing country, and subject to Article 12 of the General Food Law Regulation, a person shall not export follow-on formulae, unless—

- (a) either the requirements set down in Regulation 5 of these Regulations or the relevant applicable world standards established by Codex Alimentarius are complied with,
- (b) the requirements set down in paragraphs (1) to (4) of Regulation 7 of these Regulations are complied with, and
- (c) the provisions of Council Directive 89/396/EEC ⁹ of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs, are complied with.

(3) The stipulations, prohibitions and restrictions laid down in paragraphs (1) to (4) of Regulation 7 shall also apply to the presentation of follow-on formulae intended for export, and in particular their form, aspect or packaging and the packaging materials used.

14. (1) Infant formulae and follow-on formulae intended for export shall be labelled in an appropriate language.

(2) Infant formulae and follow-on formulae intended for export shall be labelled in such a way as to avoid any risk of confusion between them.

PART 4 Enforcement

15. (1) The enforcement of these Regulations and of the Directives shall be carried out in accordance with the provisions of these Regulations.

(2) These Regulations shall be deemed to be food legislation for the purposes of the Act of 1998.

(3) These Regulations shall be enforced by the Authority or by an official agency acting pursuant to a service contract with the Authority, or by both, and, without prejudice to paragraph (1), the enforcement provisions contained in the Act of 1998 shall apply for the purposes of ensuring compliance with the requirements of these Regulations.

16. (1) An authorised officer may, for the purposes of these Regulations, purchase or take without payment a sample of infant formulae or follow-on formulae or other relevant substance.

(2) An authorised officer may, for the purpose of taking a sample of infant formulae or follow-on formulae or other relevant substance, open any receptacle.

(3) Where an authorised officer purchases or takes without payment a sample of infant formulae or follow-on formulae or other relevant substance with the intention of having it analysed, he or she shall after purchasing or taking the sample forthwith notify the food business operator, or the person in apparent charge or control of the infant formulae or follow-on formulae or other substance of his or her intention of having the sample analysed.

(4) Where an authorised officer purchases or takes without payment, with the intention of having it analysed, a sample of infant formulae or follow-on formulae or other relevant substance which is suspected by him or her to fail to comply with the provisions of these Regulations, he or she may, by notice in writing to the food business operator, or the person in apparent charge or control of such foods or other substances, prohibit their removal except to any place which may be specified in the notice, during such period as may be specified in the notice, but not exceeding 15 days from the date of the taking of the sample.

17. (1) Where a sample of infant formulae or follow-on formulae or other relevant substance is taken pursuant to these Regulations, for the purposes of official

analysis and where the division of the sample is reasonably practicable, the authorised officer concerned may divide the sample into three approximately equal parts, (enforcement, trade (defence) and referee), each of which he or she shall mark in such a way as to identify it as a part of the sample taken by the officer. The authorised officer shall, in the presence of the food business operator, or the person in apparent charge or control of such food:

- (a) mark, seal and fasten each part in such a manner as its nature will permit, and in such a way that the integrity of the sample is not compromised;
- (b) forward one part to the approved examiner in an official laboratory for analysis;
- (c) give or send one part to the food business operator, and
- (d) retain the third part.

(2) Where an authorised officer takes a sample consisting of infant formulae or follow-on formulae or other relevant substance contained in unopened containers and its division into parts:

- (a) is not reasonably practicable, or
- (b) might affect the composition or impede the proper analysis of the sample,

the provisions of paragraph (1) as regards the division of samples into parts shall be deemed to be complied with if the authorised officer divides the containers into three lots and deals with each lot as if it were a sample as specified under paragraph (1).

(3) In proceedings for an offence under these Regulations, the result of any test, examination or analysis of, or report on a sample of infant formulae or follow-on formulae or other relevant substance taken pursuant to these Regulations, shall not be adduced unless before the proceedings were instituted the sample was divided as specified in paragraphs (1) and (2) of this Regulation. The part, package or container retained by the authorised officer shall be produced at the hearing.

18. (1) The approved examiner or a person under his or her direction shall analyse as soon as possible any sample of infant formulae or follow-on formulae or other relevant substance submitted to him or her in pursuance of these Regulations and the approved examiner shall certify to the person who submitted the sample to him or her the result of such analysis. The form of certificate set out in Schedule 10 to these Regulations or a certificate in like form shall be used.

(2) An official certificate given in accordance with paragraph (1) shall be *prima facie* evidence of the matters contained therein until the contrary is proved.

19. Where a sample of infant formulae or follow-on formulae or other relevant substance is taken by an authorised officer in pursuance of these Regulations for analysis by an approved examiner, the Authority, or an official agency as the case may be, shall draw up a report in accordance with Article 9 of the Official Controls Regulation, where the certificate given in accordance with Regulation 18 indicates that there has been non-compliance with these Regulations, the Authority, or the official agency, as the case may be, shall provide the food business operator with a copy of the report.

20. An authorised officer may, for the purposes of these Regulations, inspect and take copies, or samples, of:

- (a) labels used on infant formulae, follow-on formulae, or other products being placed on the market as such, or
- (b) informational materials.

21. The provisions of Regulations 16, 17, 18, 19 and 20 shall also apply in respect of:

- (a) products which are not infant formulae or follow-on formulae, as defined in Regulation 2(1), but which are being placed on the market as such, and
- (b) any other products which the authorised officer suspects are being treated, manufactured or placed on the market in contravention of these Regulations.

22. (1) An authorised officer may, for the purposes of these Regulations, seize, remove, detain or direct the withdrawal from the market of any infant formulae or follow-on formulae, or other products, which are suspected by him or her to fail to comply with the provisions of these Regulations.

(2) An authorised officer may, with the consent in writing of the food business operator, or the person in apparent charge or control of such infant formulae or follow-on formulae or other products or in accordance with an order of a judge of the District Court under paragraph (4) of this Regulation, destroy or otherwise dispose of same so as to prevent them being used for human consumption.

(3) An authorised officer who has seized, removed, detained or directed the withdrawal from the market of infant formulae or follow-on formulae or other products in pursuance of the provisions of this Regulation may, on giving notice in writing to the food business operator of his or her intention to do so, apply to a judge of the District Court for an order directing that such products be destroyed or otherwise disposed of.

(4) A judge of the District Court, to whom an application is made for an order under paragraph (3), may, if satisfied that such foods or products fail to comply with these Regulations, order that they be destroyed or otherwise disposed of, after such period, not exceeding 14 days, as may be specified in such order, and an authorised officer shall destroy or dispose of them accordingly.

23. Where an authorised officer has reasonable grounds for believing that a person has contravened any provision of these Regulations and so informs that person, the authorised officer may require that person to state his or her name and address and, if the authorised officer thinks it necessary, to produce corroborative evidence of same.

24. The Minister may, for the purposes of these Regulations designate, by notice in writing published in *Iris Oifigiúil*:

- (a) a laboratory as a laboratory at which samples taken under these Regulations may be analysed, and testing and verification may be carried out, and
- (b) a person as being a person who, or a class of persons the members of which, may, at a designated laboratory, engage in analysis, testing and verification for the purposes of these Regulations.

25. (1) A person is guilty of an offence if he or she fails to comply with these Regulations.

(2) Paragraph (1) shall not apply to an authorised officer or an approved examiner acting in the course of his or her duties pursuant to these Regulations.

(3) A person is guilty of an offence if he or she:

- (a) obstructs or interferes with an authorised officer in the exercise of the officer’s powers under these Regulations,
- (b) fails or refuses to state his or her name or address in compliance with a request under these Regulations,
- (c) fails to comply with a request or notice from an authorised officer under these Regulations,
- (d) makes a statement to an authorised officer which the person knows is false or misleading, or
- (e) gives in purported compliance with a request under these Regulations a name, address or corroborative evidence which is false or misleading,

26. Where an offence under these Regulations is committed by a body corporate or by a person acting on behalf of a body corporate and is proved to have been so committed with the consent, connivance or approval of, or to be attributed to any neglect or default on the part of, any director, manager, secretary or any other officer of such body, or a person who was purporting to act in any such capacity, such person is also guilty of an offence and is liable to be proceeded against and punished as if he or she were guilty of the first-mentioned offence.

27. (1) A person is guilty of an offence if he or she forges, or utters knowing it to be forged, a certificate of analysis or other document purporting to be issued, granted or given under these Regulations or required for the purposes of these Regulations, (hereafter referred to as “a forged document”).

(2) A person is guilty of an offence if he or she alters with intent to defraud or deceive, or who utters knowing it to be so altered, a certificate of analysis or other document issued, granted or given under these Regulations, or required for the purposes of these Regulations (hereafter referred to as “an altered document”).

(3) A person is guilty of an offence if he or she without lawful authority, has in his or her possession a forged document or an altered document, knowing it to be a forged or altered document as the case may be.

(4) A person is guilty of an offence if he or she with the intent to defraud or deceive:

- (a) tampers with any substance or thing with the result that a sample taken pursuant to these Regulations does not correctly represent the substance sampled, or
- (b) tampers or interferes with any sample taken under these Regulations.

(5) A person is guilty of an offence if he or she falsely represents himself or herself to be an authorised officer.

28. (1) For the purposes of these Regulations, every contravention of a Regulation shall be deemed a separate contravention and every contravention of a paragraph or a subparagraph shall also be deemed to be a separate contravention and shall carry the same penalty as for a single contravention of any Regulation.

(2) A person who is guilty of an offence under these Regulations is liable:

- (a) on summary conviction to a fine not exceeding €5,000 or at the discretion of the Court to imprisonment for a term not exceeding 3 months, or both, or,
- (b) on conviction on indictment, to a fine not exceeding €500,000, or imprisonment for a term not exceeding 3 years, or both.

29. Notwithstanding section 57 of the Act of 1998, a summary offence under these Regulations may be prosecuted by—

(a) the Authority, or

(b) an official agency

or both.

PART 5 Revocations and Transitional Arrangements

30. (1) Regulations 8, 9 and 13 of the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2004 ([S.I. No. 242 of 2004](#)) Regulations are revoked.

(2) The following are revoked:

(a) the European Communities (Infant Formulae and Follow-on Formulae) Regulations 2004 ([S.I. No. 242 of 2004](#)), and

(b) the European Communities (Infant Formulae and Follow-on Formulae) (Amendment) Regulations 2007 ([S.I. No. 242 of 2007](#)).

(3) No person commits an offence under regulation 25(1) consisting of a contravention of or failure to comply with:

(a) Regulation 3 where there is no contravention of or failure to comply with Regulation 3 of the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2004,

(b) Regulation 4 where there is no contravention of or failure to comply with Regulation 4 of the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2004,

(c) Regulation 5 where there is no contravention of or failure to comply with Regulation 5 of the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2004,

(d) Regulation 6 where there is no contravention of or failure to comply with Regulation 6 of the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2004,

(e) Regulation 7 where there is no contravention of or failure to comply with Regulation 7 of the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2004,

(f) Regulation 12 where there is no contravention of or failure to comply with Regulation 11 of the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2004,

(g) Regulation 13 where there is no contravention of or failure to comply with Regulation 12 of the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2004.

(4) Regulation 24 of the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2004 ([S.I. No. 242 of 2004](#)) is amended by inserting after paragraph (2) the following paragraph:

“(3) No person commits an offence under paragraph (1) consisting of a contravention of or failure to comply with:

(a) Regulation 3, where there is no contravention of or failure to comply with Regulation 3 of the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2007,

(b) Regulation 4 where there is no contravention of or failure to comply with Regulation 4 of the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2007,

(c) Regulation 5 where there is no contravention of or failure to comply with Regulation 5 of the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2007,

(d) Regulation 6 where there is no contravention of or failure to comply with Regulation 6 of the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2007,

(e) Regulation 7 where there is no contravention of or failure to comply with Regulation 7 of the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2007,

(f) Regulation 11 where there is no contravention of or failure to comply with Regulation 12 of the European Communities (Infant Formulae and

Follow-On Formulae) Regulations 2007,

(g) Regulation 12 where there is no contravention of or failure to comply with Regulation 13 of the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2007.”.

SCHEDULE 1 ESSENTIAL COMPOSITION OF INFANT FORMULAE WHEN RECONSTITUTED AS INSTRUCTED BY THE MANUFACTURER

The values set out in this Schedule refer to the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.

1. Energy

Minimum 250 kJ/100ml (60 kcal/100ml)

Maximum 295 kJ/100ml (70 kcal/100ml)

2. Proteins

(Protein content = nitrogen content 6.25)

2.1 Infant Formulae manufactured from cows’ milk proteins

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

Maximum 0.7g/100 kJ (3g/100 kcal)

(¹) Infant formulae manufactured from cows’ milk protein with a protein content between the minimum and 0.5g/100 kJ (2g/100 kcal) shall be in accordance with Regulation 4(5).

For an equal energy value, the infant formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Schedule 5). Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2. The ratio of methionine:cystine may be greater than 2 but shall not be greater than 3 provided that the suitability of the product for the particular nutritional use by infants is demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

2.2 Infant formulae manufactured from protein hydrolysates

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

Maximum 0.7g/100 kJ (3g/100 kcal)

(¹) Infant formulae manufactured from protein hydrolysates with a protein content between the minimum and 0.56g/100 kJ(2.25g/100 kcal) shall be in accordance with Regulation 4(6).

For an equal energy value, the infant formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Schedule 5). Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2. The ratio of ofmethionine:cystine may be greater than 2 but shall not be greater than 3 provided that the suitability of the product for the particular nutritional use by infants is demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

The L-carnitine content shall be at least equal to 0.3mg/100 kJ (1.2mg/100 kcal).

2.3 Infant formulae manufactured from soya protein isolates, alone or in a mixture with cows’ milk proteins

Minimum 0.56g/100 kJ (2.25g/100 kcal)

Maximum 0.7g/100 kJ (3g/100 kcal)

Only protein isolates from soya shall be used in manufacturing these infant formulae.

For an equal energy value the infant formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Schedule 5). Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2. The ratio of methionine: cystine may be greater than 2 but shall not be greater than 3 provided that the suitability of the product for the particular nutritional use by infants is demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

The L-carnitine content shall be at least equal to 0.3mg/100 kJ (1.2mg/100 kcal).

2.4 In all cases, amino acids may be added to infant formulae solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.

3. Taurine

If added to infant formulae, the amount of taurine shall not be greater than 2.9mg/100 kJ (12mg/100 kcal).

4. Choline

Minimum 1.7mg/100 kJ (7mg/100 kcal)

Maximum 12mg/100 kJ (50mg/100 kcal)

5. Lipids

Minimum 1.05g/100 kJ (4.4g/100 kcal)

Maximum 1.4g/100 kJ (6.0g/100 kcal)

5.1 The use of the following substances shall be prohibited:

- sesame seed oil,
- cotton seed oil,

5.2 Lauric acid and myristic acid

Minimum No minimum specified

Maximum separately or as a whole:20% of the total fat content.

- 5.3 The *trans* fatty acid content shall not exceed 3% of the total fat content.
- 5.4 The erucic acid content shall not exceed 1% of the total fat content.

5.5 Linoleic acid (in the form of glycerides = linoleates)

Minimum 70mg/100 kJ (300mg/100 kcal)

Maximum 285mg/100 kJ (1200mg/100 kcal)

5.6 The alpha-linolenic acid content shall not be less than 12mg/100 kJ (50mg/100 kcal).

The linoleic:alpha-linolenic acid ratio shall not be less than 5 nor greater than 15.

5.7 Long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids (LCP) may be added. In that case their content shall not exceed:

—1% of the total fat content for n-3 LCP, and

—2% of the total fat content for n-6 LCP (1% of the total fat content for arachidonic acid (20:4 n-6))

The eicosapentaenoic acid (20:5 n-3) content shall not exceed that of docosaehaenoic (22:6 n-3) acid content.

The docosaehaenoic acid (22:6 n-3) content shall not exceed that of n-6 LCP.

6. Phospholipids

The amount of phospholipids in infant formulae shall not be greater than 2g/l.

7. Inositol

Minimum 1mg/100 kJ (4mg/100 kcal)

Maximum 10mg/100 kJ (40mg/100 kcal)

8. Carbohydrates

Minimum 2.2g/100 kJ (9g/100 kcal)

Maximum 3.4g/100 kJ (14g/100 kcal)

8.1 Only the following carbohydrates may be used:

—lactose,

—maltose,

—sucrose,

—glucose,

—malto-dextrins,

—glucose syrup or dried glucose syrup,

—pre-cooked starch — naturally free of gluten,

—gelatinised starch — naturally free of gluten.

8.2 Lactose

Minimum 1.1g/100 kJ (4.5g/100 kcal)

Maximum No maximum specified

This provision shall not apply to infant formulae in which soya protein isolates represent more than 50% of the total protein content.

8.3 *Sucrose*

Sucrose may only be added to infant formulae manufactured from protein hydrolysates. If added, the sucrose content shall not exceed 20% of the total carbohydrate content.

8.4 *Glucose*

Glucose may only be added to infant formulae manufactured from protein hydrolysates. If added, the glucose content shall not exceed 0.5g/100 kJ (2g/100 kcal).

8.5 *Pre-cooked starch and/or gelatinised starch*

Minimum No minimum specified

Maximum 2g/100ml, and 30% of the total carbohydrate content

9. **Fructo-Oligosaccharides and Galacto-Oligosaccharides**

Fructo-oligosaccharides and galacto-oligosaccharides may be added to infant formulae. In that case their content shall not exceed: 0.8g/100 ml in a combination of 90% oligogalactosyl-lactose and 10% high molecular weight oligofructosyl-saccharose.

Other combinations and maximum levels of fructo-oligosaccharides and galacto-oligosaccharides may be used in accordance with Regulations 4(1) and 4(2).

10. **Mineral Substances**

10.1 *Infant Formulae manufactured from cows’ milk proteins or protein hydrolysates*

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Sodium (mg)	5	14	20	60
Potassium(mg)	15	38	60	160
Chloride (mg)	12	38	50	160
Calcium (mg)	12	33	50	140
Phosphorus (mg)	6	22	25	90
Magnesium (mg)	1.2	3.6	5	15
Iron (mg)	0.07	0.3	0.3	1.3
Zinc (mg)	0.12	0.36	0.5	1.5
Copper (g)	8.4	25	35	100
Iodine (g)	2.5	12	10	50
Selenium (g)	0.25	2.2	1	9

Manganese (g)	0.25	25	1	100
Fluoride (g)	-	25	-	100

The calcium:phosphorus ratio shall not be less than 1 nor greater than 2.

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

All requirements of point 10.1 shall apply, except for those concerning iron and phosphorus, which shall be as follows:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Iron (mg)	0.12	0.5	0.45	2
Phosphorus (mg)	7.5	25	30	100

11. Vitamins

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A (g —RE) (¹)	14	43	60	180
Vitamin D (g) (²)	0.25	0.65	1	2.5
Thiamin (g)	14	72	60	300
Riboflavin (g)	19	95	80	400
Niacin (g) (³)	72	375	300	1500
Pantothenic acid (g)	95	475	400	2000
Vitamin B 6 (g)	9	42	35	175
Biotin (g)	0.4	1.8	1.5	7.5
Folic Acid (g)	2.5	12	10	50
Vitamin B 12 (g)	0.025	0.12	0.1	0.5
Vitamin C (mg)	2.5	7.5	10	30
Vitamin K (g)	1	6	4	25
Vitamin E (mg —TE) (⁴)	0.5/g poly-unsaturated fatty acids expressed as linoleic acid as corrected for the double bonds (⁵) but in no case less	1.2	0.5/g poly-unsaturated fatty acids expressed as linoleic acid as corrected for the double bonds (⁵) but in no case less	5

than 0.1mg per
100 available kJ

than 0,5mg per
100 available kcal

- (¹) RE = all *trans* retinol equivalent.
- (²) In the form of cholecalciferol, of which 10g = 400 i.u. of vitamin D.
- (³) Preformed niacin.
- (⁴) - TE = d- - tocopherol equivalent.
- (⁵) 0,5mg -TE/1g linoleic acid (18:2 n-6); 0,75mg -TE/1g -linolenic acid (18:3 n-3); 1.0mg -TE/1g arachidonic acid (20:4 n-6); 1,25mg -TE/1g eicosapentaenoic acid (20:5 n-3); 1.5mg -TE/1g docosahexaenoic acid (22:6 n-3).

12. Nucleotides

The following nucleotides may be added:

	Maximum(¹)	
	(mg/100 kJ)	(mg/100 kcal)
cytidine 5'-monophosphate	0.600	2.501
uridine 5'-monophosphate	0.420	1.751
adenosine 5'-monophosphate	0.360	1.500
guanosine 5'-monophosphate	0.120	0.501
inosine 5'-monophosphate	0.24	1.00

- (¹) The total concentration of nucleotides shall not exceed 1.2mg/100 kJ (5mg/100 kcal).

SCHEDULE 2 ESSENTIAL COMPOSITION OF FOLLOW-ON FORMULAE WHEN RECONSTITUTED AS INSTRUCTED BY THE MANUFACTURER

The values set out in this Schedule refer to the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.

1. Energy

Minimum 250 kJ /100ml (60 kcal/100ml)

Maximum 295 kJ /100ml (70 kcal/100ml)

2. Proteins

(Protein content = nitrogen content 6.25)

2.1 Follow-on formulae manufactured from cows' milk proteins

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

Maximum 0.8g/100 kJ (3.5g/100 kcal)

For an equal energy value, the follow-on formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Schedule 5).

Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine ratio is not greater than 3, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2.

2.2 Follow-on formulae manufactured from protein hydrolysates

Minimum 0.56g/100 kJ (2.25g/100 kcal)

Maximum 0.8g/100 kJ (3.5g/100 kcal)

For an equal energy value, the follow-on formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Schedule 5).

Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine ratio is not greater than 3, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2.

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

Minimum 0.56g/100 kJ (2.25g/100 kcal)

Maximum 0.8g/100 kJ (3.5g/100 kcal)

Only protein isolates from soya shall be used in manufacturing these formulae.

For an equal energy value the follow-on formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Schedule 5).

Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine ratio is not greater than 3, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2.

2.4 In all cases, amino acids may be added to follow-on formulae solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.

3. Taurine

If added to follow-on formulae, the amount of taurine shall not be greater than 2.9mg/100 kJ (12mg/100 kcal).

4. Lipids

Minimum 0.96g/100 kJ (4.0g/100 kcal)

Maximum 1.4g/100 kJ (6.0g/100 kcal)

4.1 The use of the following substances shall be prohibited:

- sesame seed oil,
- cotton seed oil.

4.2 Lauric acid and myristic acid

Minimum No minimum specified

Maximum separately or as a whole:20% of the total fat content.

4.3 The trans fatty acid content shall not exceed 3% of the total fat content.

4.4 The erucic acid content shall not exceed 1% of the total fat content.

4.5 Linoleic acid (in the form of glycerides = linoleates)

Minimum 70mg/100 kJ (300mg/100 kcal)

Maximum 285mg/100 kJ (1200mg/100 kcal)

4.6 The alpha-linolenic acid content shall not be less than 12mg/100 kJ (50mg/100 kcal).

The linoleic:alpha-linolenic acid ratio shall not be less than 5 nor greater than 15.

4.7 Long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids (LCP) may be added. In that case their content shall not exceed:

—1% of the total fat content for n-3 LCP, and

—2% of the total fat content for n-6 LCP (1% of the total fat content for arachidonic acid (20:4 n-6))

The eicosapentaenoic acid (20:5 n-3) content shall not exceed that of docosahexaenoic (22:6 n-3) acid content.

The docosahexaenoic (22:6 n-3) acid content shall not exceed that of n-6 LCP.

5. Phospholipids

The amount of phospholipids in follow-on formulae shall not be greater than 2g/l.

6. Carbohydrates

Minimum 2.2g/100 kJ (9g/100 kcal)

Maximum 3.4g/100 kJ (14g/100 kcal)

6.1 The use of ingredients containing gluten shall be prohibited.

6.2 Lactose

Minimum 1.1g/100 kJ (4.5g/100 kcal)

Maximum No maximum specified

This provision shall not apply to follow-on formulae in which soya protein isolates represent more than 50% of the total protein content.

6.3 Sucrose, fructose, honey

Minimum No minimum specified

Maximum separately or as a whole:20% of the total carbohydrate content.

Honey shall be treated to destroy spores of Clostridium botulinum

6.4 Glucose

Glucose may only be added to follow-on formulae manufactured from protein hydrolysates. If added, the glucose content shall not exceed 0.5g/100 kJ (2g/100 kcal).

7. Fructo-Oligosaccharides and Galacto-Oligosaccharides

Fructo-oligosaccharides and galacto-oligosaccharides may be added to follow-on formulae. In that case their content shall not exceed: 0.8g/100 ml in a combination of 90% oligogalactosyl-lactose and 10% high molecular weight oligofructosyl-saccharose. Other combinations and maximum levels of fructo-oligosaccharides and galacto-oligosaccharides may be used in accordance with Regulation 5(1).

8. Mineral substances

8.1 Follow-on formulae manufactured from cows’ milk proteins or protein hydrolysates

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Sodium (mg)	5	14	20	60
Potassium (mg)	15	38	60	160
Chloride (mg)	12	38	50	160
Calcium (mg)	12	33	50	140
Phosphorus (mg)	6	22	25	90
Magnesium (mg)	1.2	3.6	5	15
Iron (mg)	0.14	0.5	0.6	2
Zinc (mg)	0.12	0.36	0.5	1.5
Copper (g)	8.4	25	35	100
Iodine (g)	2.5	12	10	50
Selenium (g)	0.25	2.2	1	9
Manganese (g)	0.25	25	1	100
Fluoride (g)	-	25	-	100

The calcium:phosphorus ratio in follow-on formulae shall not be less than 1.0 nor greater than 2.0.

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

All requirements of point 8.1 shall apply, except for those concerning iron, and phosphorus, which shall be as follows:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Iron (mg)	0.22	0.65	0.9	2.5
Phosphorus (mg)	7.5	25	30	100

9. Vitamins

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A (g —RE) (¹)	14	43	60	180
Vitamin D (g) (²)	0.25	0.75	1	3
Thiamin (g)	14	72	60	300
Riboflavin (g)	19	95	80	400
Niacin (g) (³)	72	375	300	1500
Pantothenic acid (g)	95	475	400	2000
Vitamin B 6 (g)	9	42	35	175
Biotin (g)	0.4	1.8	1.5	7.5
Folic Acid (g)	2.5	12	10	50
Vitamin B 12 (g)	0.025	0.12	0.1	0.5
Vitamin C (mg)	2.5	7.5	10	30
Vitamin K (g)	1	6	4	25
Vitamin E (mg —TE) (⁴)	0.5/g poly-unsaturated fatty acids expressed as linoleic acid as corrected for the double bonds (⁵) but in no case less than 0.1mg per 100 available kJ	1.2	0.5/g poly-unsaturated fatty acids expressed as linoleic acid as corrected for the double bonds (⁵) but in no case less than 0.5mg per 100 available kcal	5

(¹) RE = all *trans* retinol equivalent.

(²) In the form of cholecalciferol, of which 10g = 400 i.u. of vitamin D.

(³) Preformed niacin.

(⁴) - TE = d- - tocopherol equivalent.

(⁵) 0.5mg -TE/1g linoleic acid (18:2 n-6); 0.75mg -TE/1g -linolenic acid (18:3 n-3); 1.0mg -TE/1g arachidonic acid (20:4 n-6); 1.25mg -TE/1g eicosapentaenoic acid (20:5 n-3); 1.5mg -TE/1g docosahexaenoic acid (22:6 n-3).

10. Nucleotides

The following nucleotides may be added:

Maximum(¹)	
(mg/100 kJ)	(mg/100 kcal)

cytidine 5'-monophosphate uridine 5'-monophosphate adenosine 5'-monophosphateguanosine 5'-monophosphate inosine 5'-monophosphate	0.600.420.360.120.24	2.501.751.500.501.00
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(¹) The total concentration of nucleotides shall not exceed 1.2mg/100 kJ (5mg/100 kcal).

SCHEDULE 3 NUTRITIONAL SUBSTANCES

1. Vitamins

Vitamin	Vitamin Formulation
Vitamin A	Retinyl acetate Retinyl palmitate Retinol
Vitamin D	Vitamin D 2 (ergocalciferol)Vitamin D 3 (cholecalciferol)
Vitamin B 1	Thiamin hydrochloride Thiamin mononitrate
Vitamin B 2	RiboflavinRiboflavin-5'-phosphate, sodium
Niacin	NicotinamideNicotinic acid
Vitamin B 6	Pyridoxine hydrochloride Pyridoxine-5'-phosphate
Folate	Folic acid
Pantothenic acid	D-pantothenate, calcium D-pantothenate, sodium Dexpanthenol
Vitamin B 12	Cyanocobalamin Hydroxocobalamin
Biotin	D-biotin
Vitamin C	L-ascorbic acid Sodium L-ascorbate Calcium L-ascorbate 6-palmityl-L-ascorbic acid (ascorbyl palmitate) Potassium ascorbate
Vitamin E	D-alpha tocopherol DL-alpha tocopherol D-alpha tocopherol acetate DL-alpha tocopherol acetate
Vitamin K	Phylloquinone (Phytomenadione)

2. Mineral substances

Mineral substances	Permitted salts
Calcium (Ca)	Calcium carbonate Calcium chloride Calcium salts of citric acid Calcium gluconate Calcium glycerophosphate Calcium lactate Calcium salts of orthophosphoric acidCalcium hydroxide
Magnesium (Mg)	Magnesium carbonate Magnesium chloride Magnesium oxide Magnesium salts of orthophosphoric acidMagnesium sulphate Magnesium gluconate Magnesium hydroxide Magnesium salts of citric acid
Iron (Fe)	Ferrous citrate Ferrous gluconate Ferrous lactate Ferrous sulphate Ferric

	ammonium citrate Ferrous fumarate Ferric diphosphate (Ferric pyrophosphate)Ferrous bisglycinate
Copper (Cu)	Cupric citrate Cupric gluconate Cupric sulphate Copper-lysine complex Cupric carbonate
Iodine (I)	Potassium iodide Sodium iodide Potassium iodate
Zinc (Zn)	Zinc acetate Zinc chloride Zinc lactate Zinc sulphate Zinc citrate Zinc gluconate Zinc oxide
Manganese (Mn)	Manganese carbonate Manganese chloride Manganese citrate Manganese sulphate Manganese gluconate
Sodium (Na)	Sodium bicarbonate Sodium chloride Sodium citrate Sodium gluconate Sodium carbonate Sodium lactate Sodium salts of orthophosphoric acid Sodium hydroxide
Potassium (K)	Potassium bicarbonate Potassium carbonate Potassium chloride Potassium salts of citric acid Potassium gluconate Potassium lactate Potassium salts of orthophosphoric acid Potassium hydroxide
Selenium (Se)	Sodium selenateSodium selenite

3. Amino acids and other nitrogen compounds

L-cystine and its hydrochloride

L-histidine and its hydrochloride

L-isoleucine and its hydrochloride

L-leucine and its hydrochloride

L-lysine and its hydrochloride

L-cysteine and its hydrochloride

L-methionine

L-phenylalanine

L-threonine

L-tryptophan

L-tyrosine

L-valine

L-carnitine and its hydrochloride

L-carnitine-L-tartrate

Taurine

Cytidine 5’-monophosphate and its sodium salt

Uridine 5’-monophosphate and its sodium salt

Adenosine 5’-monophosphate and its sodium salt

Guanosine 5’-monophosphate and its sodium salt

Inosine 5’-monophosphate and its sodium salt

4. Other nutritional substances

Choline

Choline chloride

Choline citrate

Choline bitartrate

Inositol

SCHEDULE 4 NUTRITION AND HEALTH CLAIMS FOR INFANT FORMULAE AND CONDITIONS WARRANTING A CORRESPONDING CLAIM

1. Nutrition Claims

Nutrition claim related to	Conditions warranting the nutrition claim
1.1 Lactose only	Lactose is the only carbohydrate present.
1.2 Lactose free	Lactose content is not greater than 2.5mg/100 kJ (10mg/100 kcal).
1.3 Added LCP or an equivalent nutrition claim related to the addition of docosahexaenoic acid	The docosahexaenoic acid content is not less than 0.2% of the total fatty acid content.
1.4 Nutrition claims on the addition of the following optional ingredients:	
1.4.1 taurine)
)
1.4.2 fructo-oligosaccharides and galacto-oligosaccharides) Voluntarily added at a level that would be) appropriate for the intended particular use) by infants and in accordance with the) conditions set out in Schedule 1.
1.4.3 nucleotides)

2. Health Claims (Including Reduction of Disease Risk Claims)

Nutrition claim related to

Conditions warranting the health claim

2.1 Reduction of risk to allergy to milk proteins. This health claim may include terms referring to reduced allergen or reduced antigen properties.

- (a) Objective and scientifically verified data as proof to the claimed properties must be available;
- (b) The infant formulae shall satisfy the provisions set out in point 2.2 of Schedule 1 and the amount of immunoreactive protein measured with methods generally acceptable as appropriate shall be less than 1% of nitrogen containing substances in the formulae;
- (c) The label shall indicate that the product must not be consumed by infants allergic to the intact proteins from which it is manufactured unless generally accepted clinical tests provide proof of the infant formulae's tolerance in more than 90% of infants (confidence interval 95%) hypersensitive to proteins from which the hydrolysate is manufactured;
- (d) The infant formulae administered orally must not induce sensitisation, in animals, to the intact proteins from which the infant formulae are manufactured.

SCHEDULE 5 INDISPENSABLE AND CONDITIONALLY INDISPENSABLE AMINO ACIDS IN BREAST MILK

For the purpose of these Regulations, 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
CystineHistidineIsoleucineLeucineLysineMethioninePhenylalanineThreonineTryptophanTyrosineValine	9102240275201881821	384090166113238377327688
(¹) 1 kJ = 0.239 kcal.		

SCHEDULE 6 SPECIFICATION FOR THE PROTEIN CONTENT AND SOURCE AND THE PROCESSING OF PROTEIN USED IN THE MANUFACTURE OF INFANT FORMULAE WITH A PROTEIN CONTENT LESS THAN 0.56g/100 kJ (2.25g/100 kcal) MANUFACTURED FROM HYDROLYSATES OF WHEY PROTEINS DERIVED FROM COWS' MILK PROTEIN

1. Protein content

Protein content = nitrogen content 6.25

Minimum 0.44g/100 kJ (1.86g/100 kcal)

Maximum 0.7g/100 kJ (3g/100 kcal)

2. Protein source

Demineralised sweet whey protein derived from cows' milk after enzymatic precipitation of caseins using chymosin, consisting of:

- (a) 63% caseino-glycomacropeptide free whey protein isolate with a minimum protein content of 95% of dry matter and protein denaturation of less than 70% and a maximum ash content of 3%; and
- (b) 37% sweet whey protein concentrate with a minimum protein content of 87% of dry matter and protein denaturation of less than 70% and a maximum ash content of 3.5%.

3. Protein processing

Two-stage hydrolysis process using a trypsin preparation with a heat-treatment step (from 3 to 10 minutes at 80 to 100 °C) between the two hydrolysis steps.

SCHEDULE 7 REFERENCE VALUES FOR NUTRITION LABELLING FOR FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN

Nutrient	Labelling reference value
Vitamin A	(g)
Vitamin D	400(g)
Vitamin E	7(mg TE)
Vitamin K	5(g)
Vitamin C	12(mg)
Thiamin	45(mg)
Riboflavin	0.5(mg)
Niacin	0.7(mg)
Vitamin B 6	7(mg)
Folate	0.7(g)
Vitamin B 12	125(g)
Pantothenic acid	0.8(mg)
Biotin	3(g)
Calcium	10(mg)
Phosphorus	550(mg)
Potassium	550(mg)
Sodium	1000(mg)
Chloride	400(mg)
Iron	500(mg)
Zinc	8(mg)
Iodine	5(g)
Selenium	80(g)
Copper	20(mg)
Magnesium	0.5(mg)
Manganese	80(mg)
	1.2

SCHEDULE 8 PESTICIDES WHICH SHALL NOT BE USED IN AGRICULTURAL PRODUCTION INTENDED FOR THE PRODUCTION OF INFANT FORMULAE AND FOLLOW-ON FORMULAE

Table 1

Chemical name of the substance (residue definition)
Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone expressed as disulfoton)
Fensulfothion (sum of fensulfothion, its oxygen analogue and their sulfones, expressed as fensulfothion)
Fentin, expressed as triphenyltin cation
Haloxypop (sum of haloxypop, its salts and esters including conjugates, expressed as haloxypop)
Heptachlor and <i>trans</i> -heptachlor epoxide, expressed as heptachlor
Hexachlorobenzene
Nitrofen
Omethoate
Terbufos (sum of terbufos, its sulfoxide and sulfone, expressed as terbufos)

Table 2

Chemical name of the substance

Aldrin and dieldrin, expressed as dieldrin

Endrin

SCHEDULE 9 SPECIFIC MAXIMUM RESIDUE LEVELS OF PESTICIDES OR METABOLITES OF PESTICIDES IN INFANT FORMULAE AND FOLLOW-ON FORMULAE

Chemical name of the substance	Maximum residue level (mg/kg)
Cadusafos	0.006
Demeton-S-methyl/demeton-S-methyl sulfone/oxydemeton-methyl (individually or combined, expressed as demeton-S-methyl)	0.006
Ethoprophos	0.008
Fipronil (sum of fipronil and fipronil-desulfinyl, expressed as fipronil)	0.004
Propineb/propylenethiourea (sum of propineb and propylenethiourea)	0.006

SCHEDULE 10

Form of official certificate to be given by an approved examiner to an authorised officer.

European Communities

(Infant Formulae and Follow-On Formulae) Regulations 2007

Certificate of Analysis

To ⁽¹⁾

I, the undersigned ⁽²⁾

being an approved examiner for the purpose of the above Regulations certify that on

the.....day of..... 20.....

a sample marked ⁽³⁾

Date.....

Number.....

Weight or Measure.....

was submitted to me by you and I certify that the sample was prepared and analysed/examined by me or under my direction ⁽⁴⁾

and as a result I am of the opinion that ⁽⁵⁾

Observations: ⁽⁶⁾

I further certify that the sample has undergone no change which would affect my opinion/observations expressed above.

Certified by me this..... day of..... 20.....

at ⁽⁷⁾

Name in BLOCK LETTERS.....

Status.....

Signature.....

.....

Official Stamp

NOTES

- (1) Insert the name and address of the person submitting the sample for analysis.
- (2) Insert description (e.g. Executive Analytical Chemist located at a Public Analyst’s Laboratory).
- (3) Insert particulars of marking (e.g. name, date etc.) and the weight or measure (this may be left unanswered if the sample cannot be conveniently weighed or measured or if the weight or measurement is not material to the result of analysis).
- (4) Indicate whether the approved examiner carried out the analysis himself or herself or whether it was carried out by another under the direction of the approved examiner.
- (5) Here the approved examiner should specify the result of the analysis having regard to the provisions of the relevant legislation.
- (6) Here the approved examiner may insert, at his or her discretion, his or her opinion whether the analysis indicates any addition, abstraction, deficiency or the presence of foreign matter or other defect and whether the composition or quality is thereby affected; any physical, chemical or other properties bearing on the composition or quality of the article; whether the article is injurious to health or unfit for human consumption; whether and in what respect a label and description relating to the sample is incorrect or misleading; and he or she may add any other observations as he or she may consider relevant.
- (7) Insert the name and address of the laboratory carrying out the analysis/examination.

GIVEN under my Official Seal,

21 December 2007

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 Directive 2006/141/EC of 22 December 2006 on compositional, labelling, marketing and informational requirements for infant formulae and follow-on formulae intended for infants and young children, and give further effect to Council Directive 92/52/EEC on infant formulae and follow-on formulae intended for export to third countries. These Regulations do not give effect to those aspects of Commission Directive 2006/141/EC that amend Directive 1999/21/EC.

In order to provide for the transitional arrangements under Commission Directive 2006/141/EC, certain provisions of the European Communities (Infant

Formulae and Follow-on Formulae) Regulations 2004 (S.I. No. 242 of 2004) are revoked, while the remainder will remain in effect until 31 December 2009.

These Regulations revoke the European Communities (Infant Formulae and Follow-on Formulae) (Amendment) Regulations 2007 (S.I. No. 242 of 2007).

These Regulations may be cited as the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2007.

1 OJ L 401, 30.12.2006, p. 1.

2 OJ L 91, 7.4.1999, p. 29.

3 OJ L 179, 1.7.1992, p. 129.

4 OJ L 404, 30.12.2006, p. 9, as affected by Corrigendum to Regulation (EC) No. 1924/2006, OJ L 12, 18.1.2007, p. 3.

5 OJ L 31, 1.2.2002, p. 1.

6 OJ L 165, 30.4.2004, p. 1, as affected by the Corrigendum to Regulation (EC) No 882/2004, OJ L 191, 28.5.2004, p. 1.

7 OJ L 230, 19.8.1991, p. 1.

8 OJ L 109, 6.5.2000, p. 29.

9 OJ L 186, 30.6.1989, p. 21, as amended.