STATUTORY INSTRUMENTS.

S.I. No. 242 of 2004.

EUROPEAN COMMUNITIES (INFANT FORMULAE AND FOLLOW-ON FORMULAE) REGULATIONS 2004.

I, MICHEÁL MARTIN, 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), having regard to Council Directive 89/398/EEC[1] of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses, as amended by Directive 96/84/EC[2] of the European Parliament and of the Council of 19 December 1996, and Directive 1999/41/EC[3] of the European Parliament and of the Council of 7 June 1999, and Commission Directive 2001/15/EC[4] of 15 February 2001, and for the purpose of giving effect to Commission Directive 91/321/EEC[5] of 14 May 1991 on infant formulae and follow-on formulae, as amended by Council Directive 92/52/EEC[6] of 18 June 1992, and Commission Directive 96/4/EC[7] of 16 February 1996, and Commission Directive 1999/50/EC[8] of 25 May 1999, and Commission Directive 2003/14/EC[9] of 10 February 2003, hereby make the following regulations:

[9]OJ L 41, 14.2.2003, p. 37.

[8]OJ L 139, 2.6.1999, p. 29.

[7]OJ L 49, 28.2.1996, p. 12.

[6]OJ L 179, 1.7.1992, p. 129.

[5]OJ L 175, 4.7.1991, p. 35.

[4]OJ L 52, 22.2.2001, p. 19, as amended

[3]OJ L 172, 8.7.1999, p. 38.

[2]OJ L 48, 19.2.1997, p. 20.

[1]OJ L 186, 30.6.1989, p. 27.

1. (1) These Regulations may be cited as the EuropeanCommunities (Infant Formulae and Follow-On Formulae) Regulations 2004 and, subject to paragraph (2), they shall come into effect on the date they are signed by the Minister.

(2) The requirements of —

(*a*) paragraphs (9), (10), (11), (12) and (13) of Regulation 4,
(*b*) paragraphs (9), (10), (11), (12) and (13) of Regulation 5, and
(*c*) Regulations 11 and 12, insofar as they relate to the provisions referred to at subparagraphs (*a*) and (*b*),
shall not come into effect until 6 March 2005.

(3) From the date of coming into effect of these Regulations, a person may trade in products complying with the provisions referred to in paragraph (2).

2. (1) In these Regulations—

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

"approved examiner" in these Regulations means—

(*a*) a Public Analyst located at a Public Analyst's Laboratory,
(*b*) a Deputy Public Analyst located at a Public Analyst's Laboratory,
(*c*) an Executive Analytical Chemist located at a Public Analyst's Laboratory,
(*d*) a Consultant Microbiologist located at an Official Laboratory,
(*e*) a Chief Laboratory Technologist located at an Official Laboratory, or
(*f*) a person designated by the Minister pursuant to Regulation 23;

"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;

"Directive" means Commission Directive 91/321/EEC[5] of 14 May 1991 on infant formulae and follow-on formulae, as amended by Council Directive 92/52/EEC[6] of 18 June 1992, and Commission Directive 96/4/EC[7] of 16 February 1996, and Commission Directive 1999/50/EC[8] of 25 May 1999, and Commission Directive 2003/14/EC[9] of 10 February 2003;

[9]OJ L 41, 14.2.2003, p. 37.

[8]OJ L 139, 2.6.1999, p. 29.

[7]OJ L 49, 28.2.1996, p. 12.

[6]OJ L 179, 1.7.1992, p. 129.

[5]OJ L 175, 4.7.1991, p. 35.

"export" means exportation to a third country;

"follow-on formulae" means foodstuffs intended for particular nutritional use by infants aged over 4 months and constituting the principal liquid element in a progressively diversified diet of this category of persons, and cognate words shall be construed accordingly;

"food" or "foodstuff" means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be, ingested by humans;

"food" includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC[10] and without prejudice to the requirements of Directives 80/778/EEC[11] and 98/83/EC[10];

[10]OJ L 330, 5.12.1998, p. 32.

[11]OJ L 229, 30.8.1980, p. 11.

[10]OJ L 330, 5.12.1998, p. 32.

"food" shall not include —

(*a*) feed,
(*b*) live animals unless they are prepared for placing on the market for human consumption,
(*c*) plants prior to harvesting,

(*d*) medicinal products within the meaning of Council Directives 65/65/EEC[12] and 92/73/EEC[13],

[13]OJ L 297, 13.10.1992, p. 8.

[12]OJ L 22, 9.2.1965, p. 369.
(*e*) cosmetics within the meaning of Council Directive 76/768/EEC[14],

[14]OJ L 262, 27.9.1976, p. 169.
(*f*) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC[15],

[15]OJ L 359, 8.12.1989, p. 1.
(*g*) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971, or
(*h*) residues and contaminants;
"health care system" includes institutions or organisations engaged, directly or indirectly, in health care for mothers, infants and pregnant women, including nurseries or childcare institutions, and includes the private practices of health workers;

"import" means importation from a third country, save in Part 3 where import means importation into a third country;

"infant formulae" means foodstuffs intended for particular nutritional use by infants during the first 4 to 6 months of life and satisfying by themselves the nutritional requirements of this category of persons, and cognate words shall be construed accordingly;

"infants" means children under the age of 12 months;

"manufacture" includes the production and processing of food, other than primary production for private domestic use and domestic preparation, handling and storage of food for private domestic consumption, and cognate words shall be construed accordingly;

"Member State" means a Member State of the European Community and shall be construed as including reference to those States that are Contracting Parties to the EEA Agreement;

"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 laboratory" in these Regulations means—

(*a*) the Food Microbiology Laboratory, Cork,
(*b*) the Food Microbiology Laboratory, Galway,
(*c*) the Microbiology Laboratory, Dublin,
(*d*) the Microbiology Laboratory, Limerick,
(*e*) the Public Analyst's Laboratory, Cork,
(*f*) the Public Analyst's Laboratory, Dublin,
(*g*) the Public Analyst's Laboratory, Galway,
(*h*) the Public Health Laboratory, Sligo,
(*i*) the Public Health Laboratory, Waterford, or
(*j*) a laboratory designated by the Minister pursuant to Regulation 23;
"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 Council Directive 91/414/EEC[16], as amended, including its metabolites and products resulting from its degradation or reaction, and cognate words shall be construed accordingly;

[16]OJ L 230, 19.8.1991, p. 1.
"place on the market" means—

(*a*) import,
(*b*) sell,
(*c*) offer or expose for sale,
(*d*) invite the making by a person of an offer to purchase,
(*e*) distribute free of charge,
(*f*) supply for any of those purposes (whether or not for profit)
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;

"third country" means a country which is not a Member State;

"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 Directive has, unless the context otherwise requires, the same meaning in these Regulations as it has in the Directive.

(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.
3. (1) These Regulations concern infant formulae and follow-onformulae, 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 descriptions 'infant formula' or 'infant formulae' in the marketing of any product which is not infant formula as defined in Regulation 2(1), or
(*c*) represent any product which is not infant formula as defined in Regulation 2(1) as being suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first 4 to 6 months of life.
(3) Infant formula shall be placed on the market under the name 'infant formula' or 'infant formulae', 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 descriptions 'follow-on formula' or 'follow-on formulae' in the marketing of any product which is not follow-on formula as defined in Regulation 2(1).
(5) Follow-on formula shall be placed on the market under the name 'follow-on formula' or 'follow-on formulae', save where it is manufactured entirely from cows' milk proteins, in which case it shall be sold under the name 'follow-on milk'.

(6) 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 the Schedules 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.

(2) The prohibitions and limitations on the use of food ingredients laid down in Schedule 1 shall be observed.

(3) Infant formulae must comply with the compositional criteria specified in Schedule 1.

(4) In order to make infant 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 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.

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

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

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

(9) Subject to paragraphs (10) and (11), those pesticides listed in Schedule 9 shall not be used in agricultural products intended for the production of infant formulae and where such pesticides have been used, the products shall not be used in the production of infant formulae.

(10) For the purposes of control, pesticides listed in Table 1 of Schedule 9 are considered not to have been used if their residues do not exceed a level of 0.003 mg/kg.

(11) For the purposes of control, pesticides listed in Table 2 of Schedule 9 are considered not to have been used if their residues do not exceed a level of 0.003 mg/kg.

(12) For the pesticides listed in Schedule 10, the maximum residue levels specified therein shall apply.

(13) The levels referred to in paragraphs (10), (11) and (12) 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 the Schedules and other food ingredients, as the case may be, whose suitability for particular nutritional use by infants aged over 4 months has been established by generally accepted scientific data.

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

(3) Follow-on formulae must comply with the compositional criteria specified in Schedule 2.

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

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

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

(9) Subject to paragraphs (10) and (11), those pesticides listed in Schedule 9 shall not be used in agricultural products intended for the production of follow-on formulae and where such pesticides have been used, the products shall not be used in the production of follow on formulae.

(10) For the purposes of control, pesticides listed in Table 1 of Schedule 9 are considered not to have been used if their residues do not exceed a level of 0.003 mg/kg.

(11) For the purposes of control, pesticides listed in Table 2 of Schedule 9 are considered not to have been used if their residues do not exceed a level of 0.003 mg/kg.

(12) For the pesticides listed in Schedule 10, the maximum residue levels specified therein shall apply.

(13) The levels referred to in paragraphs (10), (11) and (12) 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 of Directive 2000/13/EC[17] of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, the following mandatory particulars —

[17]OJ L 109, 6.5.2000, p. 29.

(*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*) in the case of infant formulae that do not contain added iron, a statement to the effect that, when the product is given to infants over the age of 4 months, their total iron requirements must be met from other additional sources,

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

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

(*e*) 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,

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

(*g*) instructions for appropriate preparation of the product, and

(*h*) a warning against the health hazards of inappropriate preparation.

(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 (*e*) and (*f*) of paragraph (1), expressed in numerical form, per 100 ml of the product ready for use.

(3) The labelling of infant formulae shall be designed toprovide 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 theterms 'humanised', 'maternalised', or similar terms shall be prohibited.

(5) The labelling of infant formulae—

(*a*) may use the term 'adapted' only in the case listed in Schedule 4, and
(*b*) may bear claims concerning the special composition of infant formulae only in the cases listed in Schedule 4,
and only in accordance with the conditions laid down in Schedule 4.

(6) 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.

(7) 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.

(8) The requirements, prohibitions and restrictions referred to in paragraphs (3) to (7) shall also apply to 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.

7. (1) The labelling of follow-on formulae shall bear, inaddition to those provided for in Article 3 of Directive 2000/13/EC[17] of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, the following mandatory particulars—

[17]OJ L 109, 6.5.2000, p. 29.

(*a*) a statement to the effect that the product is suitable only for particular nutritional use by infants over the age of 4 months, that it should form only part of a diversified diet and that it is not to be used as a substitute for breast milk during the first 4 months of life,
(*b*) the available energy value expressed in kJ and kcal, per 100 ml of the product ready for use,
(*c*) the content of proteins, carbohydrates and lipids, expressed in numerical form, per 100 ml 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 100 ml of the product ready for use,
(*e*) where applicable, the average quantity of choline, inositol, carnitine and taurine, expressed in numerical form, per 100 ml of the product ready for use,
(*f*) instructions for appropriate preparation of the product, and
(*g*) a warning against the health hazards of inappropriate preparation.

(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 100 ml of the product ready for use, and
(*b*) in addition to numerical information, information on vitamins and minerals included in Schedule 8, expressed as a percentage of the reference values given therein, per 100 ml of the product ready for use, provided that the quantities present are at least equal to 15 per cent of the reference values.

(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', or similar terms shall be prohibited.

(5) The requirements, prohibitions and restrictions referred to in paragraphs (3) and (4) 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 specializing in baby care and scientific publications.

(2) The requirements, prohibitions and restrictions referred to in paragraphs (3) to (7) 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 formulae 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.

(7) In accordance with Article 8 of the Directive, the Minister may by Order impose further restrictions on the advertising or promotion of infant formulae.

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, whether manufactured industrially or home-prepared.

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

11. (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 descriptions 'infant formula' or 'infant formulae' in the marketing of any product intended for export, which is not infant formula as defined in Regulation 2(1), or
(*c*) represent any product intended for export, which is not infant formula as defined in Regulation 2(1), as being suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first 4 to 6 months of life.
(2) 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[18] of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs, are complied with.

[18]OJ L 186, 30.6.1989, p. 21, as amended.
(3) A person is not required to comply with paragraph (2)where the authorities of the importing country have requested otherwise, or where such compliance would be incompatible with the laws, regulations, standards, codes of practice or other legal or administrative procedures in force in the importing country.

(4) 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.

12. (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 descriptions 'follow-on formula' or 'follow-on formulae' in the marketing of any product intended for export which is not follow-on formula as defined in Regulation 2(1).
(2) 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[18] of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs, are complied with.

[18]OJ L 186, 30.6.1989, p. 21, as amended.

(3) A person is not required to comply with paragraph (2)where the authorities of the importing country have requested otherwise, or where such compliance would be incompatible with the laws, regulations, standards, codes of practice or other legal or administrative procedures in force in the importing country.

(4) 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.

13. (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.

14. Control of the foodstuffs affected by these Regulations and the enforcement of these Regulations shall be carried out in accordance with the provisions of these Regulations.

15. These Regulations shall be deemed to be food legislation for the purposes of the Act of 1998.

16. These Regulations shall be enforced by the Authority or by an official agency pursuant to a service contract with the Authority and without prejudice to Regulation 14, the enforcement provisions contained in the Act of 1998 shall apply for the purposes of ensuring compliance with these Regulations.

17. (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.

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

(3) 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 which are 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 seller, owner or person in apparent charge or control of such infant formulae or follow-on formulae, prohibit the removal of the infant formulae or follow-on formulae 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 detention of the sample.

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

18. (1) Where a sample of infant formulae or follow-on formulae is taken pursuant to these Regulations, and where the division of the sample is reasonably practicable, the authorised officer concerned may divide the sample into not more than three approximately equal parts

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 mark, seal and fasten each part in such a manner as its nature will permit, forward one part to the approved examiner in an official laboratory for analysis, give or send one part to the seller, owner or person in apparent charge or control of the infant formulae or follow-on formulae and retain the third part.

(2) Where an authorised officer takes a sample consisting of infant formulae or follow-on formulae 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) of this Regulation 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) of this Regulation.

(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 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.

19. (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 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 11 to these Regulations or a certificate in like form shall be used.

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

20. Where a sample of infant formulae or follow-on formulae is taken by an authorised officer in pursuance of these Regulations for analysis by an approved examiner, and where the seller, owner or person in apparent charge or control of the infant formulae or follow-on formulae requests in writing the results of such analysis the request shall be made to—

(*a*) the Authority, where the officer was appointed by the Authority, or
(*b*) the official agency, where the officer was appointed by an official agency
and the Authority, or the official agency (as the case may be) shall comply with such request.

21. (1) The provisions of Regulations 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,
(*b*) any other products which the authorised officer suspects are being treated, manufactured or placed on the market in contravention of these Regulations.
(2) 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.
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, follow-on formulae or any 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 owner or person in apparent charge or control of such infant formulae, 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, follow-on formulae or other products in pursuance of the provisions of this Regulation may, on giving notice in writing to the owner or person in apparent charge or control of such products 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 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. 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.

24. (1) A person who fails to comply with these Regulations shall be guilty of an offence.

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

25. 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 shall also be guilty of an offence and shall be liable to be proceeded against and punished as if he or she were guilty of the first-mentioned offence.

26. (1) Any person who 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 in this Regulation referred to as "a forged document"), is guilty of an offence.

(2) Any person who alters with intent to defraud ordeceive, 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 in this Regulation referred to as "an altered document"), is guilty of an offence.

(3) Any person who, without lawful authority, has in his or her possession a forged document or an altered document is guilty of an offence.

(4) Any person who, with intent to defraud or deceive—

(*a*) tampers with any thing so as to procure that any 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

is guilty of an offence.

27. (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 of these Regulations.

(2) A person who is guilty of an offence under these Regulations shall be liable on summary conviction to a fine not exceeding €3,000 or at the discretion of the Court to imprisonment for a term not exceeding 12 months or both.

28. An offence under these Regulations may be prosecuted by —

(*a*) the Authority, or
(*b*) an official agency.

29. (1) The following are revoked—

(*a*) the European Communities (Infant Formulae and Follow-on Formulae) Regulations 1998 (S.I. No. 243 of 1998), and
(*b*) the European Communities (Infant Formulae and Follow-on Formulae) (Amendment) Regulations 2000 (S.I. No. 446 of 2000).

(2) References in any other instrument to the Regulations revoked under paragraph (1) shall be construed as references to these Regulations, as appropriate.

NB: The values refer to the product ready for use

1. Energy

Minimum

250kJ (60kcal)/100ml

Maximum

315kJ (75kcal)/100ml

2. Protein

(Protein content = nitrogen content × 6.38) for cows' milk proteins.
(Protein content = nitrogen content × 6.25) for soya protein isolates and protein partial hydrolysates.
The "chemical index" shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein.

2.1 Formulae manufactured from cows' milk proteins

Minimum

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

Maximum

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

For an equal energy value, the formula must contain an available quantity of each essential and semi-essential 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.

2.2 Formulae manufactured from protein partial hydrolysates

Minimum

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

Maximum

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

For an equal energy value, the formula must contain an available quantity of each essential and semi-essential 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.

The protein efficiency ratio (PER) and the net protein utilization (NPU) must be at least equal to those of casein.

The taurine content shall be equal to at least 10 µmoles/100 kJ (42 µmoles/100 kcal) and the L-carnitine content shall be equal to at least 1.8 µmoles/100 kJ (7.5µmoles/100kcal).

2.3 Formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins

Minimum

0.56g/100 kJ (2.56g/100 kcal)

Maximum

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

Only soya protein isolates must be used in manufacturing these formulae.

The chemical index shall be equal to at least 80% of that of the reference protein (breast milk, as defined in Schedule 6).

For an equal energy value the formula must contain an available quantity of methionine at least equal to that contained in the reference protein (breast milk, as defined in Schedule 5).

The L-carnitine content shall be at least equal to 1.8 µmoles/100 kJ (7.5 µmoles/100 kcal).

2.4 In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.

3. Lipids

Minimum

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

Maximum
1.5g/100 kJ (6.5g/100 kcal)

3.1 The use of the following substances is prohibited:
—sesame seed oil

—cotton seed oil

3.2 Lauric acid
Minimum
No minimum specified

Maximum
15% of the total fat content

3.3 Myristic acid
Minimum
No minimum specified

Maximum
15% of the total fat content

3.4 Linoleic acid (in the form of glycerides = linoleates)
Minimum
70mg/100 kJ (300mg/100 kcal)

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

3.5 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.
3.6 The trans fatty acid content shall not exceed 4% of the total fat content.
3.7 The erucic acid content shall not exceed 1% of the total fat content.
3.8 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)

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

4. Carbohydrates

Minimum

1.7g/100 kJ (7 g/100 kcal)

Maximum

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

4.1 Only the following carbohydrates may be used:

—lactose

—maltose

—sucrose

—malto — dextrins

—glucose syrup or dried glucose syrup

—pre-cooked starch — naturally free of gluten

—gelatinised starch — naturally free of gluten

4.2 Lactose

Minimum

0.85g/100 kJ (3.5g/100 kcal)

Maximum

No maximum specified

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

4.3 Sucrose

Minimum

No minimum specified

Maximum

20% of the total carbohydrate content

4.4 Pre-cooked starch and/or gelatinised starch

Minimum

No minimum specified

Maximum

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

5. Mineral substances

5.1 Formulae manufactured from cows' milk proteins

Per 100 kJ

Per 100 kcal

Minimum

Maximum

Minimum

	Maximum
Sodium (mg)	
	5
	14
	20
	60
Potassium(mg)	
	15
	35
	60
	145
Chloride (mg)	
	12
	29
	50
	125
Calcium (mg)	
	12
	—
	50
	—
Phosphorus (mg)	
	6
	22
	25
	90
Magnesium (mg)	
	1.2
	3.6
	5
	15
Iron (mg) ([1])	
	0.12
	0.36

	0.5
	1.5
Zinc (mg)	
	0.12
	0.36
	0.5
	1.5
Copper (µg)	
	4.8
	19
	20
	80
Iodine (µg)	
	1.2
	—
	5
	—
Selenium ([2]) (µg)	
	—
	0.7
	—
	3

([1])Limit applicable to formulae with added iron

([2])Limit applicable to formulae with added selenium

The calcium/phosphorus ratio shall not be less than 1.2 nor greater than 2.0.

5.2 Formulae manufactured from soya proteins, alone or in a mixture with cows' milk proteins

All requirements of paragraph 5.1 are applicable except those concerning iron and zinc, which are listed below:

	Per 100 kJ	Per 100 kcal
	Minimum	

	Maximum
	Minimum
	Maximum
Iron (mg)	
	0.25
	0.5
	1
	2
Zinc (mg)	
	0.18
	0.6
	0.75
	2.4

6. Vitamins

	Per 100 kJ
	Per 100 kcal
	Minimum
	Maximum
	Minimum
	Maximum
Vitamin A (µg-RE) ([1])	
	14
	43
	60
	180
Vitamin D (µg)([2])	
	0.25
	0.65
	1
	2.5

Thiamin (µg)		
	10	—
	40	—
Riboflavin (µg)		
	14	—
	60	—
Niacin (mg-NE)		
	0.2	—
	0.8	—
Pantothenic acid (µg)		
	70	—
	300	—
Vitamin B_6(µg)		
	9	—
	35	—
Biotin (µg)		
	0.4	—
	1.5	—
Folic acid (µg)		
	1	—
	4	

—

Vitamin B_{12} (µg)

0.025

—

0.1

—

Vitamin C (µg)

1.9

—

8

—

Vitamin K (µg)

1

—

4

—

Vitamin E (mg α-TE) ([3])

0.5g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0.1 mg per 100 available kJ

—

0.5g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0.5 mg per 100 available kcal

—

([1])RE = all trans retinol equivalent.

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

([3]) α-TE = d- α-tocopherol equivalent.

7. The following nucleotides may be added:

Maximum([1])

(mg/100 kJ)

(mg/100 kcal)

cytidine 5'-monophosphate

	0.60
	2.50
uridine 5'-monophosphate	
	0.42
	1.75
adenosine 5'-monophosphate	
	0.36
	1.50
guanosine 5'-monophosphate	
	0.12
	0.50
inosine 5'-monophosphate	
	0.24
	1.00

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

NB: The values refer to the product ready for use

1. Energy

Minimum

250kJ (60kcal)/100ml

Maximum

335kJ (80kcal)/100ml

2. Proteins

(Protein content = nitrogen content × 6.38) for cows' milk proteins.
(Protein content = nitrogen content × 6.25) for soya protein isolates.

Minimum

0.5g/100 kJ (2.25g/100 kcal)

Maximum

1g/100 kJ (4.5g/100 kcal)

The chemical index of the proteins present shall be at least equal to 80% of that of the reference protein (casein or breast milk as defined in Schedule 6).
The 'chemical index' shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein.
For follow-on formulae manufactured from soya proteins, alone or in a mixture with cows' milk proteins, only protein isolates from soya may be used.
Amino acids may be added to follow-on formulae for the purpose of improving the nutritional value of the proteins, in the proportions necessary for that purpose.
For an equal energy value, these formulae must contain an available quantity of methionine at least equal to that contained in breast milk as defined in Schedule 4.

3. Lipids

Minimum

0.8g/100 kJ (3.3g/100 kcal)

Maximum

1.5g/100 kJ (6.5g/100 kcal)

3.1 The use of the following substances is prohibited:

—sesame seed oil

—cotton seed oil

3.2 Lauric acid

Minimum

No minimum specified

Maximum

15% of the total fat content

3.3 Myristic acid

Minimum

No minimum specified

Maximum

15% of the total fat content

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

Minimum

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

Maximum

No maximum specified

this limit applies only to follow-on formulae containing vegetable oils

3.5 The trans fatty acid content shall not exceed 4% of the total fat content.

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

4. Carbohydrates

Minimum

1.7g/100 kJ (7g/100 kcal)

Maximum

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

4.1 The use of ingredients containing gluten is prohibited.

4.2 Lactose

Minimum

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

Maximum

No maximum specified

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

4.3 Sucrose, fructose, honey

Minimum

No minimum specified

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

5. Mineral substances

5.1

	Per 100 kJ / Per 100 kcal	
	Minimum	Maximum
Iron (mg)	0.25	
	0.5	
	1	
	2	
Iodine (µg)	1.2	
	—	
	5	
	—	

5.2. Zinc

5.2.1. Follow-on formulae manufactured entirely from cows' milk

Minimum
0.12mg/100 kJ (0.5mg/100 kcal)

Maximum

No maximum specified

5.2.2. Follow-on formulae containing soya protein isolates, or mixed with cows' milk
Minimum

0.18mg/100 kJ (0.75mg/100 kcal)

Maximum

No maximum specified

5.3 *Other mineral substances*:

The concentrations are at least equal to those normally found in cows' milk, reduced, where appropriate, in the same ratio as the protein concentration of the follow-on formulae to that of cows' milk. The typical composition of cows' milk is given, for guidance, in Schedule 8.

5.4 The calcium/phosphorus ratio shall not exceed 2.0.

6. Vitamins

	Per 100 kJ	Per 100 kcal
	Minimum	
	Maximum	
	Minimum	
	Maximum	
Vitamin A (µg -RE) ([1])		
	14	
	43	
	60	
	180	
Vitamin D (µg) ([2])		
	0.25	
	0.75	
	1	
	3	

Vitamin C (µg)

1.9

—

8

—

Vitamin E (mg α -TE) ([3])

0.5g poly- unsaturated fatty acids expressed as linoleic acid but in no case less than 0.1 mg per 100 available kJ

0.5g poly- unsaturated fatty acids expressed as linoleic acid but in no case less than 0,5 mg per 100 available kcal

([1])RE = all trans retinol equivalent.

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

([3])α -TE = d- α -tocopherol equivalent.

7. The following nucleotides may be added:

Maximum([1])

(mg/100 kJ)
(mg/100 kcal)

cytidine 5'-monophosphate

0.60
2.50

uridine 5'-monophosphate

0.42
1.75

adenosine 5'-monophosphate

0.36
1.50

guanosine 5'-monophosphate

0.12
0.50

inosine 5'-monophosphate

0.24

1.00

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

1. Vitamins

Vitamin Vitamin Formulation
Vitamin A Retinyl acetate
Retinyl palmitate
Beta-carotene
Retinol
Vitamin B_1 Thalmin hydrochloride
Thalmin mononitrate
Vitamin B_2 Riboflavin
Riboflavin-5-phosphate, sodium
Vitamin B_6 Pyridoxine hydrochloride
Pyridoxine-5-phosphate
Vitamin B_{12}

Cyanocobalamin

Hydroxocobalamin

Biotin
D-biotin

Folate
Folic acid

Niacin
Nictotinamide

Nicotinic acid

Pantothenic acid
D-pantothenate, calcium

D-pantothenate, sodium

Dexpanthenol

Vitamin C
L-ascorbic acid

Sodium L-ascorbate

Calcium L-ascorbate

6-palmityl-L-ascorbic acid (ascorbyl palmitate)

Potassium ascorbate

Vitamin D

Vitamin D_2 (ergocalciferol)

Vitamin D_3 (cholecalciferol)

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 acid

Calcium hydroxide

Copper (Cu)

Cupric citrate

Cupric gluconate

Cupric sulphate

Copper-lysine complex

Cupric carbonate

Iodine (I)

Potassium iodide

Sodium iodide

Potassium iodate

Iron (Fe)

Ferrous citrate

Ferrous gluconate

Ferrous lactate

Ferrous sulphate

Ferric ammonium citrate

Ferrous fumarate

Ferric diphosphate (Ferric pyrophosphate)

Magnesium (Mg)

Magnesium carbonate

Magnesium chloride

Magnesium oxide

Magnesium salts of orthophosphoric acid

Magnesium sulphate

Magnesium gluconate

Magnesium hydroxide

Magnesium salts of citric acid

Manganese (Mn)

Manganese carbonate

Manganese chloride

Manganese citrate

Manganese sulphate

Manganese gluconate

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 selenate

Sodium selenite

Sodium (Na)

Sodium bicarbonate

Sodium chloride

Sodium citrate

Sodium gluconate

Sodium carbonate

Sodium lactate

Sodium salts of orthophosphoric acid

Sodium hydroxide

Zinc (Zn)

Zinc acetate

Zinc chloride

Zinc lactate

Zinc sulphate

Zinc citrate

Zinc gluconate

Zinc oxide

3. Amino acids and other nitrogen compounds

L-arginine and its hydrochloride
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
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. Others

Choline
Choline chloride
Choline citrate
Choline bitartrate
Inositol

Claim related to

Conditions warranting the claim

1. Adapted protein

The protein content is lower than 0.6 g/100 kJ (2.5 g/100 kcal) and the whey protein/casein ratio is not less than 1.0.

2. Low sodium

The sodium content is lower than 9 mg/100 kJ (39 mg/100 kcal).

3. Sucrose free

No sucrose is present.

4. Lactose only

Lactose is the only carbohydrate present.

5. Lactose free

No lactose is present.

6. Iron enriched

Iron is added.

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

(*a*) The formulae shall satisfy the provisions laid down in Section 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;

(*b*) The label shall indicate that the product must not be consumed by infants allergic to the intact proteins from which it is made unless generally accepted clinical tests provide proof of the formulae's tolerance in more than 90% of infants (confidence interval 95%) hypersensitive to proteins from which the hydrolysate is made;

(*c*) The formulae administered orally should not induce sensitisation from which the formulae are derived;

(*d*) Objective and scientifically verified data as proof to the claimed properties must be available.

For the purpose of this Regulation, the essential and semi-essential amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal, are the following:

	Per 100 kJ Per 100 kcal
Arginine	16 69
Cystine	6 24
Histidine	11 45

Isoleucine		
	17	
	72	
Leucine		
	37	
	156	
Lysine		
	29	
	122	
Methionine		
	7	
	29	
Phenylalanine		
	15	
	62	
Threonine		
	19	
	80	
Tryptophan		
	7	
	30	
Tyrosine		
	14	
	59	
Valine		
	19	
	80	

	Casein
	Breast milk

Arginine	
	3.7
	3.8
Cystine	
	0.3
	1.3
Histidine	
	2.9
	2.5
Isoleucine	
	5.4
	4.0
Leucine	
	9.5
	8.5
Lysine	
	8.1
	6.7
Methionine	
	2.8
	1.6
Phenylalanine	
	5.2
	3.4
Threonine	
	4.7
	4.4
Tryptophan	
	1.6
	1.7
Tyrosine	

	5.8
	3.2
Valine	
	6.7
	4.5

As a reference, the contents of mineral elements in cows' milk expressed per 100 g of solids-non-fat (SNF) and per g of proteins are the following:

	Per 100g of SNF
	Per g of proteins
Sodium (mg)	
	550
	15
Potassium (mg)	
	1680
	43
Chloride (mg)	
	1050
	28
Calcium (mg)	
	1350
	35
Phosphorus (mg)	
	1070
	28
Magnesium (mg)	
	135
	3.5
Copper (µg)	
	225

Iodine	Not specified
	Not specified

Nutrient	Labelling reference value
Vitamin A	(µg) 400
Vitamin D	(µg) 10
Vitamin C	(mg) 25
Thiamin	(mg) 0.5
Riboflavin	(mg) 0.8
Niacin equivalents	(mg) 9
Vitamin B_6	(mg) 0.7
Folate	(µg) 100
Vitamin B_{12}	(µg) 0.7
Calcium	(mg) 400

Iron

(mg) 6

Zinc

(mg) 4

Iodine

(µg) 70

Selenium

(µg) 10

Copper

(mg) 0.4

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

Haloxfop (sum of haloxyfop, its salts and esters including conjugates, expressed as haloxyfop)

Heptachlor and trans-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

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 demetron-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

European Communities
(Infant Formulae and Follow-On Formulae) Regulations 2004
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 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 himsel for 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.

Ⓛ.S.

Given under the Official Seal of the Minister for Health and Children, 27th day of May 2004.

MICHEÁL MARTIN, T.D.,
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 91/321/EEC of 14 May 1991, Council Directive 92/52/EEC of 18 June 1992, Commission Directive 96/4/EC of 16 February 1996, Commission Directive 1999/50/EC of 25 May 1999 and Commission Directive 2003/14/EC of 10 February 2003 on compositional, labelling, marketing and informational requirements for infant formulae and follow-on formulae intended for infants in good health.

These Regulations revoke the European Communities (Infant Formulae and Follow-on Formulae) Regulations 1998 (S.I. No. 243 of 1998) and the European Communities (Infant Formulae and Follow-on Formulae) (Amendment) Regulations 2000 (S.I. No. 446 of 2000).

These Regulations may be cited as the European Communities (Infant Formulae and Follow-On Formulae) Regulations 2004.