

Statutory Instrument

S.I. No. 433 of 2004

European Communities (Processed Cereal-Based Foods and Baby Foods for Infants and Young Children) 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/EEC¹ 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/EC² of the European Parliament and of the Council of 19 December 1996, and Directive 1999/41/EC³ of the European Parliament and of the Council of 7 June 1999, and having regard to Commission Directive 2001/15/EC⁴ of 15 February 2001 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses, and for the purpose of giving effect to Commission Directive 96/5/EC,⁵ Euratom of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children, as amended by Commission Directive 98/36/EC⁶ of 2 June 1998, and Commission Directive 1999/39/EC⁷ of 6 May 1999, and Commission Directive 2003/13/EC⁸ of 10 February 2003, hereby make the following regulations:

⁸OJ L 41, 14.2.2003, p. 33.

⁷OJ L 124, 18.5.1999, p. 8.

⁶OJ L 167, 12.6.1998, p. 23.

⁵OJ L 49, 28.2.1996, p. 17.

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

³OJ L 172, 8.7.1999, p. 38.

²OJ L 48, 19.2.1997, p. 20.

¹OJ L 186, 30.6.1989, p. 27.

1. (1) These Regulations may be cited as the European Communities (Processed Cereal-Based Foods and Baby Foods for Infants and Young Children) 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 paragraphs (10) and (11) of Regulation 4 shall come into effect on 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 16;

"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;

"baby foods" means foodstuffs, other than processed cereal-based foods, for particular nutritional use fulfilling the particular requirements of infants and young children in good health and intended for use by infants while they are being weaned, and by young children as a supplement to their diet or for their progressive adaptation to ordinary food or both;

"Directive" means Commission Directive 96/5/EC⁵, Euratom of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children, as amended by Commission Directive 98/36/EC⁶ of 2 June 1998, and Commission Directive 1999/39/EC⁷ of 6 May 1999, and Commission Directive 2003/13/EC⁸ of 10 February 2003;

⁸OJ L 41, 14.2.2003, p. 33.

⁷OJ L 124, 18.5.1999, p. 8.

⁶OJ L 167, 12.6.1998, p. 23.

⁵OJ L 49, 28.2.1996, p. 17.

"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/EC⁹, without prejudice to the requirements of Directives 80/778/EEC¹⁰ and 98/83/EC⁹;

⁹ OJ L 330, 5.12.1998, p. 32.

¹⁰OJ L 229, 30.8.1980, p. 11.

⁹ 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/EEC¹¹ and 92/73/EEC¹²,

¹² OJ L 297, 13.10.1992, p. 8.

¹¹ OJ 22, 9.2.1965, p. 369.

(e) cosmetics within the meaning of Council Directive 76/768/EEC¹³,

¹³ OJ L 262, 27.9.1976, p. 169.

(f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC¹⁴,

¹⁴ 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;

"import" means importation from a country other than a Member State, save in the context of Regulation 3(5) where 'imported' means importation from a Member State into a country other than a Member State;

"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 16;

"pesticide residue" means the residue in processed cereal-based foods and baby foods of a plant protection product, as defined in point 1 of Article 2 of Council Directive 91/414/EEC¹⁵, as amended, including its metabolites and products resulting from its degradation or reaction, and cognate words shall be construed accordingly;

¹⁵ 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;

"processed cereal-based foods" means foodstuffs for particular nutritional use fulfilling the particular requirements of infants and young children in good health and intended for use by infants while they are being weaned, and by young children as a supplement to their diet or for their progressive adaptation to ordinary food or both, and divided into the following four categories -

(a) simple cereals which are, or have to be, reconstituted with milk or other appropriate nutritious liquids,

(b) cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid,

(c) pastas which are to be used after cooking in boiling water or other appropriate liquids, and

(d) rusks and biscuits which are to be used either directly, or, after pulverisation, with the addition of water, milk or other suitable liquids;

"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 1 and 3 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 apply to foodstuffs for particular nutritional use fulfilling the particular requirements of infants and young children in good health and intended for use by infants while they are being weaned, and by young children, as a supplement to their diet, or for their progressive adaptation to ordinary food, or both.

(2) The foodstuffs referred to at paragraph (1) comprise processed cereal-based foods and baby foods.

(3) These Regulations shall not apply to milks intended for young children.

(4) A person shall not -

(a) manufacture processed cereal-based foods or baby foods, or products presented as such, or

(b) place processed cereal-based foods or baby foods, or products presented as such, on the market,

unless the requirements of these Regulations are complied with.

(5) A person is only required to comply with paragraph (4)(a) insofar as the country into which the foods are intended to be imported does not otherwise stipulate or request by its provisions.

(6) Agricultural products intended for the production of processed cereal-based foods or baby foods shall be treated in accordance with the requirements of these Regulations.

4. (1) Processed cereal-based foods and baby foods shall be manufactured from ingredients whose suitability for particular nutritional use by infants and young children has been established by generally accepted scientific data.

(2) Processed cereal-based foods shall comply with the compositional criteria specified in Schedule 1.

(3) Baby foods which are described in Schedule 2 shall comply with the compositional criteria specified therein.

(4) Only the nutritional substances listed in Schedule 4 may be added in the manufacture of processed cereal-based foods and baby foods.

(5) Notwithstanding paragraph (4), a substance listed in Schedule 6 shall not be added in the manufacture of processed cereal-based foods and baby foods in a quantity that is greater than the maximum permitted level for that substance as specified in that Schedule.

(6) Processed cereal-based foods and baby foods shall not contain any substance in such quantity as to endanger the health of infants and young children.

(7) Processed cereal-based foods and baby foods shall not contain residues of individual pesticides at levels exceeding 0.01 mg per kg, except for those substances for which specific levels have been set in Schedule 7, in which case those specific levels shall apply.

(8) The levels referred to at paragraph (7) apply to processed cereal-based foods and baby foods as proposed ready for consumption or as reconstituted according to the instructions of the manufacturer.

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

(10) Those pesticides listed in Schedule 8 shall not be used in agricultural products intended for the production of processed cereal-based foods and baby foods. However, for the purpose of control, pesticides listed in Tables 1 and 2 of Schedule 8 are considered not to have been used if their residues do not exceed a level of 0.003mg per kg.

(11) The levels referred to in paragraph (10) shall apply to the products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers.

5. (1) The labelling of processed cereal-based foods and baby foods shall bear in addition to the particulars provided for in Article 3 of Directive 2000/13/EC¹⁶ 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-

¹⁶ OJ L 109, 6.5.2000, p.29.

(a) a statement as to the appropriate age from which the product may be used, with regard to its composition, texture or other particular properties. The stated age shall not be less than 4 months for any product. Products recommended for use from the age of 4 months may indicate that they are suitable from that age unless independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care, advise otherwise.

(b) information as to the presence or absence of gluten if the indicated age from which the product may be used is below 6 months,

(c) the available energy value expressed in kJ and kcal, and the protein, carbohydrate and lipid content, expressed in numerical form, per 100 g or 100 ml of the product as sold and, where appropriate, per specified quantity of the product as proposed for consumption,

(d) the average quantity of each mineral substance and of each vitamin governed by a specific level in Schedules 1 and 2 respectively, expressed in numerical form,

per 100g or 100ml of the product as sold and, where appropriate, per specified quantity of the product as proposed for consumption, and

(e) instructions for appropriate preparation, when necessary, and a statement as to the importance of following those instructions.

(2) The labelling of processed cereal-based foods and baby foods may bear -

(a) the average quantity of the nutrients set out in Schedule 4 when such declaration is not covered by the provisions of paragraph (1)(d), expressed in numerical form, per 100g or 100ml of the product as sold and, where appropriate, per specified quantity of the product as proposed for consumption, and

(b) in addition to numerical information, information on vitamins and minerals shown in Schedule 5, expressed as a percentage of the reference values given therein, per 100g or 100ml of the product as sold, and where appropriate, per specified quantity of the product as proposed for consumption, provided that the quantities present are at least equal to 15% of the reference values.

6. 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.

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

8. 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 6, the enforcement provisions contained in the Act of 1998 shall apply for the purposes of ensuring compliance with these Regulations.

9. (1) An authorised officer may, for the purposes of these Regulations, purchase or take without payment a sample of processed cereal-based foods or baby foods.

(2) An authorised officer may, for the purpose of taking a sample of processed cereal-based foods or baby foods, open any receptacle.

(3) Where an authorised officer purchases or takes without payment, with the intention of having it analysed, a sample of processed cereal-based foods or baby foods 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 processed cereal-based foods or baby foods, prohibit the removal of the processed cereal-based foods or baby foods 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 processed cereal-based foods or baby foods 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 processed cereal-based foods or baby foods of his or her intention of having the sample analysed.

10. (1) Where a sample of processed cereal-based foods or baby foods 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 processed cereal-based foods or baby foods and retain the third part.

(2) Where an authorised officer takes a sample consisting of processed cereal based foods or baby foods 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 processed cereal-based foods or baby foods 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.

11. (1) The approved examiner or a person under his or her direction shall analyse as soon as possible any sample of processed cereal-based foods or baby foods 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 9 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.

12. Where a sample of processed cereal-based foods or baby foods 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 processed cereal-based foods or baby foods 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.

13. An authorised officer may, for the purposes of these Regulations, inspect and take copies, or samples, of labels used on processed cereal-based foods or baby foods.

14. The provisions of Regulations 9, 10, 11, 12 and 13 shall also apply in respect of -

(a) products which are not baby foods or processed cereal-based foods, 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.

15. (1) An authorised officer may, for the purposes of these Regulations, seize, remove, detain or direct the withdrawal from the market of any processed cereal-based foods, baby foods, 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 processed cereal-based foods, baby foods 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, processed cereal-based foods, baby foods 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.

16. 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.

17. (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.

18. 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.

19. (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 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 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.

20. (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.

21. An offence under these Regulations may be prosecuted by -

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

22. (1) The European Communities (Processed Cereal-Based Foods and Baby Foods for Infants and Young Children) Regulations 2000 (S.I. No. 142 of 2000) are revoked.

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

The requirements concerning nutrients refer to the products ready for use marketed as such or reconstituted as instructed by the manufacturer.

1. Cereal Content

Processed cereal-based foods are prepared primarily from one or more milled cereals and/or starchy root products.

The amount of cereal and/or starchy root shall not be less than 25% of the final mixture on a dry weight for weight basis.

2. Protein

2.1 For products mentioned in subparagraphs (b) and (d) of the definition of processed cereal-based foods in paragraph (1) of Regulation 2, the protein content shall not exceed 1.3g/100 kJ (5.5g/100 kcal).

2.2 For products mentioned in subparagraph (b) of the definition of processed cereal-based foods in paragraph (1) of Regulation 2, the added protein shall not be less than 0.48g/100 kJ (2g/100 kcal).

2.3 For biscuits mentioned in subparagraph (d) of the definition of processed cereal-based foods in paragraph (1) of Regulation 2, made with the addition of a high protein food, and presented as such, the added protein shall not be less than 0.36g/100 kJ (1.5/100 kcal).

2.4 The chemical index of the added protein shall be equal to at least 80% of that of the reference protein (casein as defined in Schedule 3), or the protein energy ratio (PER) of the protein in the mixture shall be equal to at least 70% of that of the reference protein. In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the protein mixture, and only in the proportions necessary for that purpose.

3. Carbohydrates

3.1 If sucrose, fructose, glucose, glucose syrups or honey are added to products mentioned in subparagraphs (a) and (d) of the definition of processed cereal-based foods in paragraph (1) of Regulation 2:

- the amount of added carbohydrates from these sources shall not exceed 1.8g/100 kJ (7.5g/100 kcal).
- the amount of added fructose shall not exceed 0.9g/100 kJ (3.75g/100 kcal).

3.2 If sucrose, fructose, glucose syrups or honey are added to products mentioned in subparagraph (b) of the definition of processed cereal-based foods in paragraph (1) of Regulation 2,

- the amount of added carbohydrates from these sources shall not exceed 1.2g/100 kJ (5g/100 kcal).
- the amount of added fructose shall not exceed 0.6g/100 kJ (2.5g/100 kcal).

4. Lipids

4.1 For products mentioned in subparagraphs (a) and (d) of the definition of processed cereal-based foods in paragraph (1) of Regulation 2, the lipid content shall not exceed 0.8g/100 kJ (3.3g/100 kcal).

4.2 For products mentioned in subparagraph (b) of the definition of processed cereal-based foods in paragraph (1) of Regulation 2, the lipid content shall not exceed 1.1g/100 kJ (4.5g/100 kcal). If the lipid content exceeds 0.8g/100 kJ (3.3g/100 kcal):

- (a) the amount of lauric acid shall not exceed 15% of the total lipid content;
- (b) the amount of myristic acid shall not exceed 15% of the total lipid content;
- (c) the amount of linoleic acid (in the form of glycerides = linoleates) shall not be less than 70mg/100 kJ (300mg/ 100 kcal) and shall not exceed 285mg/100 kJ (1,200mg/ 100 kcal).

5. Minerals

5.1 Sodium

- Sodium salts may only be added to processed cereal-based foods for technological purposes,

- the sodium content of processed cereal-based foods shall not exceed 25mg / 100 kJ (10 mg/ 100 kcal).

5.2. Calcium

5.2.1 For products mentioned in subparagraph (b) of the definition of processed cereal-based foods in paragraph (1) of Regulation 2, the amount of calcium shall not be less than 20mg/ 100 kJ (80mg/ 100 kcal).

5.2.2 For products mentioned in subparagraph (d) of the definition of processed cereal-based foods in paragraph (1) of Regulation 2, manufactured with the addition of milk (milk biscuits) and presented as such, the amount of calcium shall not be less than 12mg/ 100 kJ (50mg/ 100 kcal).

6. Vitamins

6.1 For processed cereal-based foods the amount of thiamin shall not be less than 2.5 µg/ 100 kJ (100µg/100 kcal).

6.2 For products mentioned in subparagraph (b) of the definition of processed cereal-based foods in paragraph (1) of Regulation 2:

	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

¹ RE = all trans retinol equivalents

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

These limits are also applicable if vitamins A and D are added to other processed cereal-based foods.

The requirements concerning nutrients refer to the products ready for use, marketed as such or reconstituted as instructed by the manufacturer.

1. Protein

1.1 If meat, poultry, fish, offal or other traditional source of protein, are the only ingredients mentioned in the name of the product, then:

- the named meat, poultry, fish, offal or other traditional protein source, in total, shall constitute not less than 40% by weight of the total product,
- each named meat, poultry, fish, offal or other traditional source of protein shall constitute not less than 25%, by weight, of total named protein sources,
- the total protein from the named sources shall not be less than 1.7g/100kJ (7g/100 kcal).

1.2 If meat, poultry, fish, offal or other traditional source of protein, singly or in combination, are mentioned first in the name of the product, whether or not the product is presented as a meal, then:

- the named meat, poultry, fish, offal or other traditional protein source, in total, shall constitute not less than 10% by weight of the total product,
- each named meat, poultry, fish, offal or other traditional source of protein shall constitute not less than 25% by weight, of total named protein sources,
- the protein from the named sources shall not be less than 1 g/ 100 kJ (4g / 100 kcal).

1.3 If meat, poultry, fish, offal or other traditional source of protein singly or in combination are mentioned, but not first, in the name of the product, whether or not the product is presented as a meal, then:

- the named meat, poultry, fish, offal or other traditional protein source, in total, shall constitute not less than 8% by weight of the total product,
- each named meat, poultry, fish, offal or other traditional source of protein shall constitute not less than 25%, by weight, of total named protein sources,
- the protein from the named sources shall not be less than 0.5g/ 100 kJ (2.2g/ 100 kcal),
- the total protein in the product from all sources shall not be less than 0.7g/ 100 kJ (3g/ 100 kcal).

1.3a If cheese is mentioned together with other ingredients in the name of a savoury product, whether or not the product is presented as a meal, then:

- the protein from the dairy sources shall not be less than 0.5g/100kJ (2.2g/100 kcal)

- the total protein in the product from all sources shall not be less than 0.7g/100kJ (3g/100 kcal)

1.4 If the product is designated on the label as a meal, but does not mention meat, poultry, fish, offal or other traditional source of protein in the name of the product, then the total protein in the product from all sources shall not be less than 0.7g/ 100 kJ (3g/ 100 kcal).

1.4a Sauces presented as an accompaniment to a meal are exempt from the requirements of sections 1.1 to 1.4 inclusive.

1.4b Sweet dishes that mention dairy products as the first or only ingredient in the name shall contain not less than 2.2g dairy protein/100kcal. All other sweet dishes are exempt from the requirements in 1.1 to 1.4.

1.5 The addition of amino acids is permitted solely for the purpose of improving the nutritional value of the protein present, and only in the proportions necessary for that purpose.

2. Carbohydrates

The quantities of total carbohydrates present in fruit and vegetable juices and nectars, fruit-only dishes, and desserts or puddings shall not exceed:

- 10g/ 100 ml for vegetable juices and drinks based on them,
- 15g/ 100 ml for fruit juices and nectars and drinks based on them,
- 20g/ 100 g for fruit-only dishes,
- 25g/ 100 g for desserts and puddings,
- 5g/ 100 g for other non-milk-based drinks.

3. Fat

3.1 For products referred to in point 1.1 of this Schedule, if meat or cheese are the only ingredients or are mentioned first in the name of a product, then the total fat in the product from all sources should not exceed 1.4g/ 100 kJ (6g/ 100 kcal).

3.2 For all other products the total fat in the product from all sources should not exceed 1.1g / 100 kJ (4.5g/ 100 kcal).

4. Sodium

4.1 The final sodium content in the product should be either not more than 48mg/ 100 kJ (200mg/ 100 kcal) or not more than 200 mg per 100g. However, if cheese is the only ingredient mentioned in the name of the product, the final sodium content in the product should not be more than 70mg/ 100 kJ (300mg/ 100 kcal).

4.2 Sodium salts may not be added to products based on fruit, nor to desserts, puddings except for technological purposes.

5. Vitamins

Vitamin C

In a fruit juice, nectar, or vegetable juice the final content of vitamin C in the product should be either not less than 6mg/ 100 kJ (25mg/ 100 kcal) or not less than 25mg per 100g.

Vitamin A

In vegetable juices, the final content of vitamin A in the product should be not less than 25µg RE/ 100 kJ (100µg RE/ 100 kcal)¹

¹ RE = all trans retinol equivalents

Vitamin A shall not be added to other baby foods.

Vitamin D

Vitamin D shall not be added to baby foods.

(g per 100 g of protein)

Arginine	3.7
Cystine	0.3
Histidine	2.9
Isoleucine	5.4
Leucine	9.5
Lysine	8.1
Methionine	2.8
Phenylalanine	5.2
Threonine	4.7
Tryptophan	1.6
Tyrosine	5.8
Valine	6.7

1. Vitamins

Vitamin A

Retinol

Retinyl acetate
Retinyl palmitate
beta carotene
Vitamin D
Vitamin D₂ (= ergocalciferol)
Vitamin D₃ (= cholecalciferol)
Vitamin B₁
Thiamin hydrochloride
Thiamin mononitrate
Vitamin B₂
Riboflavin
Riboflavin-5'-phosphate, sodium
Niacin
Nicotinamide
Nicotinic acid
Vitamin B₆
Pyridoxine hydrochloride
Pyridoxine-5-phosphate
Pyridoxine dipalmitate
Pantothenic Acid
D-pantothenate, calcium
D-pantothenate, sodium
Dexpanthenol
Folate
Folic acid
Vitamin B₁₂
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 K
Phylloquinone (Phytomenadione)
Vitamin E
D-alpha tocopherol
DL-alpha tocopherol
D-alpha tocopherol acetate
DL-alpha tocopherol acetate
2. Amino acids
 L-arginine

)

L-cystine

)

L-histidine

)

L-isoleucine

)

and their hydrochlorides

L-leucine

)

L-lysine

)

L-cysteine

)

L-methionine

L-phenylalanine

L-threonine

L-tryptophan

L-tyrosine

L-valine

3. Others

Choline
Choline chloride
Choline citrate
Choline bitartrate
Inositol
L-Carnitine
L-carnitine hydrochloride

4. Salts of minerals and trace elements

Calcium

Calcium carbonate
Calcium chloride
Calcium salts of citric acid
Calcium gluconate
Calcium glycerophosphate
Calcium lactate
Calcium oxide
Calcium hydroxide
Calcium salts of orthophosphoric acid

Magnesium

Magnesium carbonate
Magnesium chloride
Magnesium salts of citric acid
Magnesium gluconate
Magnesium oxide
Magnesium hydroxide
Magnesium salts of orthophosphoric acid
Magnesium sulphate
Magnesium lactate
Magnesium glycerophosphate

Potassium

Potassium chloride
Potassium salts of citric acid
Potassium gluconate
Potassium lactate
Potassium glycerophosphate

Iron

Ferrous citrate
Ferric ammonium citrate
Ferrous gluconate
Ferrous lactate
Ferrous sulphate
Ferrous fumarate
Ferric diphosphate (Ferric pyrophosphate)
Elemental iron (carbonyl + electrolytic + hydrogen-reduced)

Ferric saccharate
 Sodium ferric diphosphate
 Ferrous carbonate
Copper
 Copper-lysine complex
 Cupric carbonate
 Cupric citrate
 Cupric gluconate
 Cupric sulphate
Zinc
 Zinc acetate
 Zinc citrate
 Zinc lactate
 Zinc sulphate
 Zinc oxide
 Zinc gluconate
Manganese
 Manganese carbonate
 Manganese chloride
 Manganese citrate
 Manganese gluconate
 Manganese sulphate
 Manganese glycerophosphate
Iodine
 Sodium iodide
 Potassium iodide
 Potassium iodate
 Sodium iodate

**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

The requirements concerning nutrients refer to the products ready for use, marketed as such or reconstituted as instructed by the manufacturer, except for potassium and calcium for which the requirements refer to the product as sold.

Nutrient
Maximum per 100 kcal

Vitamin A (μg RE)	180 ¹
Vitamin E (mg a —TE)	

3

Vitamin C (mg)

12.5/25²/125³

Thiamin (mg)

0.25/0.5⁴

Riboflavin (mg)

0.4

Niacin (mg NE)

4.5

Vitamin B₆ (mg)

0.35

Folic acid (μg)

50

Vitamin B₁₂ (μg)

0.35

Pantothenic acid (mg)

1.5

Biotin (μg)

10

Potassium (mg)

160

Calcium (mg)

80/180⁵/100⁶

Magnesium (mg)

40

Iron (mg)

3

Zinc (mg)

	2
Copper (µg)	40
Iodine (µg)	35
Manganese (mg)	0.6

¹ In accordance with the provisions of Schedules 1 and 2.

² Limit applicable to products fortified with iron.

³ Limit applicable to fruit-based dishes, fruit juices, nectars and vegetable juices.

⁴ Limit applicable to processed cereal-based foods.

⁵ Limit applicable to products mentioned in subparagraphs (a) and (b) of the definition of processed cereal-based foods in paragraph (1) of Regulation 2.

⁶ Limit applicable to products mentioned in subparagraph (d) of the definition of processed cereal-based foods in paragraph (1) of Regulation 2.

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

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

Haloxyfop (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

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

European Communities (Processed Cereal-Based Foods and Baby Foods for Infants and Young Children) 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

theday 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 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
this 13th day of July 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 96/5/EC, Euratom of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children, as amended by Commission Directive 98/36/EC of 2 June 1998, and Commission Directive 1999/39/EC of 6 May 1999, and Commission Directive 2003/13/EC of 10 February 2003.

These Regulations revoke the European Communities (Processed Cereal-Based Foods and Baby Foods for Infants and Young Children) Regulations 2000 (S.I. No. 142 of 2000).

These Regulations may be cited as the European Communities (Processed Cereal-Based Foods and Baby Foods for Infants and Young Children) Regulations 2004.