

6/2007 — European Communities (Processed Cereal-Based Foods and Baby Foods for Infants and Young Children) Regulations 2007

S.I. No. 776 of 2007

EUROPEAN COMMUNITIES (PROCESSED CEREAL-BASED FOODS AND
BABY FOODS FOR INFANTS AND YOUNG CHILDREN) REGULATIONS 2007

Notice of the making of this Statutory Instrument was published in

“Iris Oifigiúil” of 30th November, 2007.

I, MARY HARNEY, Minister for Health and Children, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972), and for the purpose of giving effect to Commission Directive 2006/125/EC ¹ of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children, hereby make the following regulations:

PART 1 Preliminary

1. These Regulations may be cited as the European Communities (Processed Cereal-Based Foods and Baby Foods for Infants and Young Children) Regulations 2007.

2. (1) In these Regulations—

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

“approved examiner” means—

(a) a Chief Medical Scientist located at an official laboratory,

(b) a Consultant Microbiologist located at an official laboratory,

(c) a Deputy Public Analyst located at a Public Analyst’s Laboratory,

(d) an Executive Analytical Chemist located at a Public Analyst's Laboratory,

(e) a Public Analyst located at a Public Analyst's Laboratory,

(f) a person designated by the Minister pursuant to Regulation 15;

“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 2006/125/EC of 18 December 2006 on processed cereal-based foods and baby foods for infants and young children;

“General Food Law Regulation” means Regulation (EC) No. 178/2002² of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety;

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

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

“Minister” means the Minister for Health and Children;

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

“Official Controls Regulation” means Regulation (EC) No 882/2004³ of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;

“official laboratory” in these Regulations means—

- (a) the Public Analyst’s Laboratory, Cork,
- (b) the Public Analyst’s Laboratory, Dublin,
- (c) the Public Analyst’s Laboratory, Galway,
- (d) the Public Health Laboratory, HSE, Dublin Mid-Leinster,
- (e) the Public Health Laboratory, Sligo,
- (f) the Public Health Laboratory, Waterford,
- (g) the Public Health Microbiology Laboratory, Cork,
- (h) the Public Health Microbiology Laboratory, Galway,
- (i) the Public Health Microbiology Laboratory, Limerick, or
- (j) a laboratory designated by the Minister pursuant to Regulation 15;

“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/EEC ⁴, including its metabolites and products resulting from its degradation or reaction, 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 or in the General Food Law Regulation has, unless the context otherwise requires, the same meaning in these Regulations as it has in the Directive or in the General Food Law Regulation.

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

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

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

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

PART 2 General Provisions

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 manufacture or place on the market processed cereal-based foods or baby foods, or products presented as such, unless that person complies with the provisions laid down in these Regulations and in the Directive.

(5) 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) 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.

(6) Processed cereal-based foods and baby foods shall not contain residues of individual pesticides at levels exceeding 0.01mg per kg, except for those substances for which specific levels have been set in Schedule 6, in which case those specific levels shall apply.

(7) The levels referred to at paragraph (6) shall apply to the products 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) Those pesticides listed in Schedule 7 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 7 are considered not to have been used if their residues do not exceed a level of 0.003mg per kg.

(10) The levels referred to in paragraph (9) 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/EC ⁵ of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, the following mandatory particulars—

(a) a statement 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 100g or 100ml 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 as specified 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.

PART 3 Enforcement

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

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

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

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

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

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

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

8. (1) Where a sample of processed cereal-based foods, baby foods or other relevant substance is taken pursuant to these Regulations, for the purposes of official analysis and where the division of the sample is reasonably practicable, the authorised officer concerned may divide the sample into not more than three approximately equal parts, (enforcement, trade (defence) and referee), each of which he or she shall mark in such a way as to identify it as a part of the sample taken by the officer. The authorised officer shall, in the presence of the food business operator, or the person in apparent charge or control of such food—

(a) mark, seal and fasten each part in such a manner as its nature will permit, and in such a way that the integrity of the sample is not compromised;

(b) forward one part to the approved examiner in an official laboratory for analysis;

(c) give or send one part to the food business operator, and

(d) retain the third part.

(2) Where an authorised officer takes a sample consisting of processed cereal based foods, baby foods or other relevant substance contained in unopened containers and its division into parts—

(a) is not reasonably practicable, or

(b) might affect the composition or impede the proper analysis of the sample,

the provisions of paragraph (1) as regards the division of samples into parts shall be deemed to be complied with if the authorised officer divides the containers into three

lots and deals with each lot as if it were a sample as specified under paragraph (1).

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

9. (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, baby foods or other relevant substance submitted to him or her in pursuance of these Regulations and the approved examiner shall certify to the person who submitted the sample to him or her the result of such analysis. The form of certificate set out in Schedule 8 to these Regulations or a certificate in like form shall be used.

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

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

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

12. The provisions of Regulations 7, 8, 9, 10 and 11 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.

13. (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 other products, which are suspected by him or her to fail to comply with the provisions of these Regulations.

(2) An authorised officer may, with the consent in writing of the food business operator, or the person in apparent charge or control of such 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 food business operator of his or her intention to do so, apply to a judge of the District Court for an order directing that such products be destroyed or otherwise disposed of.

(4) A judge of the District Court, to whom an application is made for an order under paragraph (3), may, if satisfied that such 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.

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

15. 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.

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

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

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

(a) obstructs or interferes with an authorised officer in the exercise of the officer's powers under these Regulations,

(b) fails or refuses to state his or her name or address in compliance with a request under these Regulations,

(c) fails to comply with a request or notice from an authorised officer under these Regulations,

(d) makes a statement to an authorised officer which the person knows is false or misleading, or

(e) gives in purported compliance with a request under these Regulations a name, address or corroborative evidence which is false or misleading,

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

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

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

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

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

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

(b) tampers or interferes with any sample taken under these Regulations.

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

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

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

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

(b) on conviction on indictment, to a fine not exceeding €500,000, or imprisonment for a term not exceeding 3 years, or both.

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

(a) the Authority, or

(b) an official agency

or both.

PART 4 Revocation

21. (1) The European Communities (Processed Cereal-Based Foods and Baby Foods for Infants and Young Children) Regulations 2004 ([S.I. No. 433 of 2004](#)) 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.

SCHEDULE 1 ESSENTIAL COMPOSITION OF PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN

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 Article 1(2)(a)(ii) and (iv), the protein content shall not exceed 1.3g/100 kJ (5.5g/100 kcal).

2.2 For products mentioned in Article 1(2)(a)(ii), the added protein shall not be less than 0.48g/100 kJ (2g/100 kcal).

2.3 For biscuits mentioned in Article 1(2)(a)(ii) and (iv), 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 (1.5g/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 efficiency 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 shall be 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 Article 1(2)(a)(i) and (iv):

—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 Article 1(2)(a)(ii):

—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 Article 1(2)(a)(i) and (iv): the lipid content shall not exceed 0.8g/100 kJ (3.3g/100 kcal).

4.2 For products mentioned in Article 1(2)(a)(ii): 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):

—the amount of lauric acid shall not exceed 15% of the total lipid content,

—the amount of myristic acid shall not exceed 15% of the total lipid content,

—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 (1200mg/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 (100mg/100 kcal).

5.2. Calcium

5.2.1 For products mentioned in Article 1(2)(a)(ii), the amount of calcium shall not be less than 20mg/100 kJ (80mg/100 kcal).

5.2.2 For products mentioned in, Article 1(2)(a) and (iv), 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 25g/100 kJ (100g/100 kcal).

6.2 For products mentioned in Article 1(2)(a)(ii):

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

(1) RE = all trans retinol equivalents

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

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

7. Maximum limits for vitamins, minerals and trace elements, if added

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 (g RE) | 1803312.5/25 (2) |
| Vitamin E (mg a —TE)(1) | 0.50.44.50.35500.351.51016080/180 |
| Vitamin D (g)(4) | /100 (5)403240350.6 |
| Vitamin C (mg) | |
| Thiamin (mg) | |
| Riboflavin (mg) | |
| Niacin (mg NE) | |
| Vitamin B6 (mg)(3) | |
| Folic acid (g) | |
| Vitamin B12 (g) | |
| Pantothenic acid (mg) | |
| Biotin (g) | |
| Potassium (mg) | |
| Calcium (mg) | |
| Magnesium (mg) | |
| Iron (mg) | |
| Zinc (mg) | |
| Copper (g) | |
| Iodine (g) | |
| Manganese (mg) | |

- (1) -TE = d--tocopherol equivalent.
- (2) Limit applicable to products fortified with iron.
- (3) NE = Niacin equivalents = mg nicotinic acid + mg tryptophan/60.
- (4) Limit applicable to products mentioned in Article 1(2)(a)(i) and (ii).
- (5) Limit applicable to products mentioned in Article 1(2)(a)(iv).

SCHEDULE 2 ESSENTIAL COMPOSITION OF BABY FOODS FOR INFANTS AND YOUNG CHILDREN

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/100 kJ (7g/100 kcal).

1.2 If meat, poultry, fish, offal or other traditional source of protein, singularly 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 1g/100 kJ (4g /100 kcal).

1.3 If meat, poultry, fish, offal or other traditional source of protein singularly 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).

1.4 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)

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

1.6 Sauces presented as an accompaniment to a meal shall be exempt from the requirements of points 1.1 to 1.5 inclusive.

1.7 Sweet dishes that mention dairy products as the first or only ingredient in the name shall contain not less than 2.2g dairy protein/100 kcal. All other sweet dishes shall be exempt from the requirements in 1.1 to 1.5.

1.8 The addition of amino acids shall be 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/100ml for vegetable juices and drinks based on them,
- 15g/100ml for fruit juices and nectars and drinks based on them,
- 20g/100g for fruit-only dishes,
- 25g/100g for desserts and puddings,
- 5g/100g for other non-milk-based drinks.

3. Fat

3.1 For products referred to in point 1.1:

if meat or cheese are the only ingredients or are mentioned first in the name of a product, the total fat in the product from all sources shall not exceed 1.4g/100 kJ (6g/100 kcal).

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

4. Sodium

4.1 The final sodium content in the product shall be either not more than 48mg/100 kJ (200mg/100 kcal) or not more than 200mg per 100g. However, if cheese is the only ingredient mentioned in the name of the product, the final sodium content in the product shall 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 shall 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 shall be not less than 25g RE/100 kJ (100g RE/100 kcal).

Vitamin A shall not be added to other baby foods.

Vitamin D

Vitamin D shall not be added to baby foods.

6. Maximum limits for vitamins, minerals and trace elements, if added

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 (g RE) | 180(1)312.5/25 (2)/125(3) |
| Vitamin E (mg a — TE) | 0.250.44.50.35500.351.51016080403240350.6 |
| Vitamin C (mg) | |
| Thiamin (mg) | |
| Riboflavin (mg) | |
| Niacin (mg) | |
| Vitamin B6 (mg) | |
| Folic acid (g) | |
| Vitamin B12 (g) | |
| Pantothenic acid (mg) | |
| Biotin (g) | |
| Potassium (mg) | |
| Calcium (mg) | |
| Magnesium (mg) | |
| Iron (mg) | |

(mg)Zinc
(mg)Copper
(g)Iodine
(g)Manganese
(mg)

(1) In accordance with the provisions of point 5.

(2) Limit applicable to products fortified with iron.

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

SCHEDULE 3 AMINO ACID COMPOSITION OF CASEIN

(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 |

SCHEDULE 4 NUTRITIONAL SUBSTANCES

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 chloride

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

SCHEDULE 5 REFERENCE VALUES FOR NUTRITION LABELLING FOR
FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN

| Nutrient | Labelling Reference Value |
|-------------|---------------------------------|
| Vitamin A | (g) 400(g) |
| Vitamin D | |
| CThiamin | 10(mg) 25(mg) |
| Riboflavin | |
| Niacin | 0.5(mg) |
| equivalents | |
| Vitamin B6 | 0.8(mg) 9(mg) |
| Folate | |
| Vitamin B12 | 0.7(g) 100(g) |
| Calcium | 0.7(mg) |
| Iron | 400(mg) 6(mg) |
| Zinc | 4(g) 70(g) |
| Iodine | 10(mg) 0.4 |
| Selenium | |
| Copper | |

SCHEDULE 6 SPECIFIC MAXIMUM RESIDUE LEVELS OF PESTICIDES OR
METABOLITES OF PESTICIDES IN PROCESSED CEREAL-BASED FOODS AND
BABY FOODS

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

SCHEDULE 7 PESTICIDES WHICH SHALL NOT BE USED IN AGRICULTURAL
PRODUCTION INTENDED FOR THE PRODUCTION OF PROCESSED CEREAL-

BASED FOODS AND BABY FOODS

Table 1

Chemical name of the substance (residue definition)

Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone expressed as disulfoton)

Fensulfothion (sum of fensulfothion, its oxygen analogue and their sulfones, expressed as fensulfothion)

Fentin, expressed as triphenyltin cation

Haloxypop (sum of haloxypop, its salts and esters including conjugates, expressed as haloxypop)

Heptachlor and 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

SCHEDULE 8

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 2007

Certificate of Analysis

To ⁽¹⁾

I, the undersigned ⁽²⁾

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

the day of 20.....

a sample marked ⁽³⁾

Date

Number

Weight or Measure

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

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

Observations: ⁽⁶⁾

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

Certified by me this day of 20

at ⁽⁷⁾

Name in BLOCK LETTERS

Status

Signature

Official Stamp

NOTES

- (1) Insert the name and address of the person submitting the sample for analysis.
- (2) Insert description (e.g. Executive Analytical Chemist located at a Public Analyst 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,

28 November 2007

MARY HARNEY,

Minister for Health and Children.

EXPLANATORY NOTE

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

These Regulations give effect to Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children.

These Regulations revoke the European Communities (Processed Cereal-Based Foods and Baby Foods for Infants and Young Children) Regulations 2004 (S.I. No. 433 of 2004).

These Regulations may be cited as the European Communities (Processed Cereal-Based Foods and Baby Foods for Infants and Young Children) Regulations 2007.

1 OJ L 339, 6.12.2006, p. 16.

2 OJ L 31, 1.2.2002, p. 1.

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

4 OJ L 230, 19.8.1991, p. 1.

5 OJ L 109, 6.5.2000, p. 29.

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