S.I. No. 579/2006 — European Communities (Foodstuffs Intended for Particular Nutritional Uses) Regulations 2006

S.I. No. 579 of 2006

European Communities (Foodstuffs Intended for Particular Nutritional Uses) Regulations 2006

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 further effect 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 for the purpose of giving further effect to Commission Directive 2001/15/EC[4] of 15 February 2001 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses, as amended by Commission Directive 2004/5/EC[5] of 20 January 2004, and for the purpose of giving effect to Commission Directive 2006/34/EC[6] of 21 March 2006 amending the Annex to Directive 2001/15/EC[4] as regards the inclusion of certain substances, hereby make the following regulations:

PART 1

Preliminary

1. (1) These Regulations may be cited as the European Communities (Foodstuffs Intended for Particular Nutritional Uses) Regulations 2006.

(2) These Regulations come into operation on 31 December 2006.

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 Deputy Public Analyst located at a Public Analyst's Laboratory,

(b) an Executive Analytical Chemist located at a Public Analyst's Laboratory; or

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

"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;

"Directives" mean 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 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses, as amended by Commission Directive 2004/5/EC[5] of 20 January 2004 and Commission Directive 2006/34/EC[6] of 21 March 2006;

"foodstuffs for particular nutritional uses" has the meaning assigned to it by Regulation 3(2);

"General Food Law Regulation" means Regulation (EC) No. 178/2002[7] 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;

"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;

"Minister" means the Minister for Health and Children;

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

"Official Controls Regulation" means Regulation (EC) No. 882/2004[8] of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;

"official laboratory" means -

(a) the Public Analyst's Laboratory, Cork,

(b) the Public Analyst's Laboratory, Dublin, or

(c) the Public Analyst's Laboratory, Galway;

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

"specific Directive" means a Directive adopted pursuant to Article 4 of Council Directive 89/398/EEC[1] of 3 May 1989, as amended, for the purposes of setting down specific provisions applicable to the groups of foods for particular nutritional uses listed in Schedule 1 to these Regulations;

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

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

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

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

PART 2

General Provisions

3. (1) These Regulations concern foodstuffs intended for particular nutritional uses.

(2) "Foodstuffs for particular nutritional uses" are those foodstuffs which -

(a) are clearly distinguishable from foodstuffs for normal consumption, owing to their special composition or manufacturing process, and

(b) are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability.

(3) A particular nutritional use must fulfil the particular nutritional requirements of -

(a) certain categories of persons whose digestive processes or metabolism are disturbed, or

(b) certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs, or

(c) infants or young children in good health.

4. A person shall not manufacture or place on the market foodstuffs intended for particular nutritional uses unless that person complies with the provisions laid down in these Regulations and in the Directives.

5. (1) The nature or composition of the foodstuffs for particular nutritional uses referred to in Regulation 3 must be such that the foodstuffs are appropriate for the particular nutritional use intended.

(2) The foodstuffs for particular nutritional uses referred to in Regulation 3 must also comply with any mandatory provisions applicable to foodstuffs for normal consumption, save as regards changes made to them to ensure their conformity with the requirements of Regulation 3.

(3) For the categories of substances added for specific nutritional purposes in foodstuffs for particular nutritional uses listed in Schedule 2, only the chemical substances mentioned under each category may be used in the manufacture of foodstuffs for particular nutritional uses covered by Directive 89/398/EEC[1] of 3 May 1989, as amended.

(4) The use of those substances referred to at paragraph (3) shall be in conformity with any specific provisions concerning those substances that may be laid down in specific Directives provided for in Article 4(1) of Directive 89/398/EEC[1] of 3 May 1989, as amended.

(5) Without prejudice to European Parliament and Council Regulation (EC) No. 258/97[9] other substances added for specific nutritional purposes, not belonging to one of the categories listed in Schedule 2 may be used in the manufacture of foodstuffs for particular nutritional uses.

(6) The use of nutritional substances in foodstuffs for particular nutritional uses shall result in the manufacture of safe products that fulfil the particular nutritional requirements of the persons for whom they are intended as established by generally accepted scientific data.

6. (1) Purity criteria for substances listed in Schedule 2, and specified by Community legislation for their use in the manufacture of foodstuffs for purposes other than those covered by Directive 2001/15/EC[4] of 15 February 2001, as amended, shall apply.

(2) For those substances listed in Schedule 2, for which purity criteria are not specified by Community legislation, and until the adoption of such specifications, generally acceptable purity criteria recommended by international bodies shall apply.

7. (1) Foodstuffs for particular nutritional uses referred to in subparagraphs (a) and (b) of Regulation 3(3) may be characterised as ‘dietetic’ or ‘dietary’.

(2) Directive 2000/13/EC[10] 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, shall apply to the foodstuffs for particular nutritional uses referred to in Regulation 3, subject to the additional requirements set out below -

(a) the designation under which any such foodstuff is sold shall be accompanied by an indication of its particular nutritional characteristics, save in the case of foodstuffs which fulfil the particular nutritional requirements referred to at Regulation 3 (3) (c);

(b) the designation under which any such foodstuff is sold shall be accompanied by an indication of its particular nutritional characteristics, save in the case of foodstuffs which fulfil the particular nutritional requirements referred to at Regulation 3 (3) (c);

(c) in the case of the labelling of foodstuffs for particular nutritional uses for which no specific Directive has been adopted in accordance with Article 4 of Directive 89/398/EEC[1] of 3 May 1989, as amended, the labelling of such foodstuffs shall also include -

(i) the particular elements of the qualitative and quantitative composition or the special manufacturing process which gives the foodstuff its particular nutritional characteristics;

(ii) the carbohydrate, protein and fat content per100 grams or 100 millilitres of the foodstuff as marketed and, where appropriate, per specified quantity of the foodstuff as proposed for consumption;

(iii) the available energy value expressed in kilojoules and kilocalories per 100 grams or 100 millilitres of the foodstuff as marketed, and where appropriate, per specified quantity of the foodstuff as proposed for consumption;

(iv) where the energy value is less than 50 kilojoules (12 kilocalories) per 100 grams or 100 millilitres of the foodstuff as marketed, these particulars may be replaced either by the words ‘energy value less than 50 kilojoules (12 kilocalories) per 100 grams’ or by the words ‘energy value less than 50 kilojoules (12 kilocalories) per 100 millilitres’.

8. (1) The foodstuffs for particular nutritional uses referred to at Regulation 3 shall only be allowed on the retail market in pre-packaged form, and the packaging shall completely cover the foodstuffs.

(2) Without prejudice to paragraph (1), the Minister, after consultation with the Authority, may permit derogations from these provisions for the purposes of the retail trade provided that the foodstuff is accompanied by the particulars provided for in Regulation 7(2) at the time when it is put on sale.

9. (1) The labelling, and the labelling methods used, the presentation and the advertising of the foodstuffs for particular nutritional uses referred to in Regulation 3 must not attribute properties for the prevention, treatment or

cure of human disease to such foodstuffs or imply such properties.

(2) Paragraph (1) shall not prevent the dissemination of any useful information or recommendations exclusively intended for persons having qualifications in medicine, nutrition or pharmacy.

10. The following shall be prohibited in the labelling, presentation and advertising of foodstuffs for normal consumption -

(a) the use of the adjectives ‘dietetic’ or ‘dietary’, whether alone or in conjunction with other words, to designate these foodstuffs;

(b) all other markings or any presentation likely to give the impression that such foodstuffs referred to in Regulation 3 are involved.

11. (1) Where a foodstuff for a particular nutritional use, which does not belong to one of the groups listed in Schedule 1 to these Regulations, is to be placed on the market for the first time in the State, the manufacturer, or where the foodstuff is manufactured in a third country, the importer, shall notify the Authority before the foodstuff is placed on the market. Such notification shall be accompanied by -

(i) a model of the label used for the foodstuff, and

(ii) an indication as to whether or not the foodstuff has been on the market in another Member State and, if so, the name of such Member State and the name of the competent authority which first received a notification pursuant to Article 9 of Directive 89/398/EEC[1] of 3 May 1989, as amended.

(2) Where necessary, the Authority may require the manufacturer or, where appropriate, the importer, to produce the scientific work and the data establishing the foodstuff's compliance with paragraphs (2) and (3) of Regulation 3 together with the information provided for in Regulation 7(2)(c)(i). If such work is contained in a readily available publication, a mere reference to this publication shall suffice.

(3) The Authority may require the manufacturer or, where appropriate, the importer, to produce the scientific work and the data establishing the use of substances added for specific nutritional purposes in compliance with Regulation 5(6). If such work is contained in a readily available publication, a mere reference to this publication shall suffice.

12. (1) The Minister, after consultation with the Authority, may by order impose temporary suspensions or restrictions on trade in a foodstuff intended for a particular nutritional use where he or she has detailed grounds for establishing that the foodstuff, not belonging to any of the groups listed in Schedule 1, does not comply with paragraph (2) or (3) of Regulation 3 or endangers human health, albeit freely circulating in one or more of the Member States.

(2)The Minister, after consultation with the Authority, may by order temporarily suspend or restrict the application of the provisions of a specific Directive, where, as a result of new information or of a reassessment of existing information made since the relevant specific

Directive was adopted, he or she has detailed grounds for establishing that foodstuffs intended for particular nutritional uses endanger human health even though they comply with the relevant specific Directive.

PART 3

Enforcement

13. The enforcement of these Regulations, and of the Directives, shall be carried out in accordance with the provisions of these Regulations.

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

15. 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 Regulation 13, the enforcement provisions contained in the Act of 1998 shall apply for the purposes of ensuring compliance with the requirements of these Regulations.

16. (1) An authorised officer may, for the purposes of these Regulations, purchase or take without payment a sample of foodstuffs or of another relevant article or substance.

(2) An authorised officer may, for the purpose of taking a sample of foodstuffs or of another relevant article or substance, open any receptacle.

(3) Where an authorised officer purchases or takes without payment, with the intention of having it analysed, a sample of foodstuffs 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 foodstuffs, prohibit the removal of the foodstuffs 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 foodstuffs or of another relevant article or substance, 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 foodstuffs or of another relevant article or substance, of his or her intention of having the sample analysed.

17. (1) Where a sample of foodstuffs or of another relevant article or substance, is taken pursuant to these Regulations for the purposes of analysis and where the division of the sample is reasonably practicable, the authorised officer concerned shall divide the sample into 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 foodstuffs or of another relevant article or substance, and retain the third part.

(2) Where an authorised officer takes a sample consisting of foodstuffs or of

another relevant article or 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) 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 foodstuffs or of another relevant article or substance, taken for the purposes of analysis 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 made available for inspection by the court if the court so requires.

18. (1) The approved examiner or a person under his or her direction shall analyse as soon as possible any sample of foodstuffs or of another relevant article or 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 4 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.

19. Where a sample of foodstuffs or of another relevant article or substance is taken by an authorised officer in pursuance of these Regulations for analysis by an approved examiner, and where the certificate given in accordance with Regulation 18 indicates that there has been non-compliance with these Regulations, 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, and shall provide the food business operator with a copy of the report.

20. An authorised officer may, for the purposes of these Regulations, inspect and take copies, or samples, of labels used on foodstuffs.

21. (1) An authorised officer may, for the purposes of these Regulations, seize, remove, detain or direct the withdrawal from the market of any foodstuffs 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 foodstuffs 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 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, foodstuffs 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 foodstuffs of his or her intention to do so, apply to a judge of the District Court for an order directing that such foodstuffs 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 foodstuffs 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.

22. (1) A person who fails to comply with these Regulations is 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.

(3) A person who -

(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 requirement under these Regulations,

(c) fails to comply with a request 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 requirement under these Regulations a name, address or corroborative evidence which is false or misleading,

is guilty of an offence.

23. 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.

24. (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 documents 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 purport 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.

25. (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 €5,000 or at the discretion of the Court to imprisonment for a term not exceeding 12 months or both.

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

(a) the Authority, or

(b) an official agency.

PART 4

Revocations

27. (1) The European Communities (Foodstuffs Intended for Particular Nutritional Uses) Regulations 2005 (S.I. No. 66 of 2005) 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

Annex I of Council Directive 89/398/EEC[1] as amended by Directive 1999/41/EC[3]

- Groups of foodstuffs for particular nutritional uses for which specific provisions will be laid down by specific Directives:

1. Infant formulae and follow-on formulae.

2. Processed cereal-based foods and baby foods for infants and young children.

3. Food intended for use in energy-restricted diets for weight reduction.

4. Dietary foods for special medical purposes.

5. Foods intended to meet the expenditure of intense muscular effort, especially for sports-men and sports-women.

- Groups of foodstuffs for particular nutritional uses for which specific provisions will be laid down by a specific Directive dependent on the outcome of the procedure described in Article 4(b) of Directive 89/398/EEC[1] of 3 May 1989, as amended.

6. Foods for persons suffering from carbohydrate-metabolism disorders (diabetes)

Schedule 2

SUBSTANCES THAT MAY BE ADDED FOR SPECIFIC NUTRITIONAL PURPOSES IN FOODS FOR PARTICULAR NUTRITIONAL USES

For the purpose of this table:

- 'FSMP' means foods for particular nutritional uses intended for special medical purposes

- 'All FPNU' means dietary foods for particular nutritional uses including FSMPs but excluding infant formulae, follow-on formulae, processed cereal-based foods and baby foods intended for infants and young children

Substance	Conditions of use	
	All FPNU	FSMP
Category 1. Vitamins		
VITAMIN A		

- retinol	x
- retinyl acetate	x
- retinyl palmitate	x
- beta-carotene	x
VITAMIN D	
- cholecalciferol	x
- ergocalciferol	x
VITAMIN E	
- D-alpha-tocopherol	x
- DL-alpha-tocopherol	x
- D-alpha-tocopheryl acetate	x
- DL-alpha-tocopheryl acetate	x
- D-alpha-tocopheryl acid succinate	x
VITAMIN K	
- phylloquinone (phytomenadione)	x
VITAMIN B_1	
- thiamin hydrochloride	x
- thiamin mononitrate	x
VITAMIN B_2	
- riboflavin	x
- riboflavin 5′-phosphate, sodium	x
NIACIN	
- nicotinic acid	x

- nicotinamide	x
PANTOTHENIC ACID	
- D-pantothenate, calcium	x
- D-pantothenate, sodium	x
- dexpanthenol	x
VITAMIN B_6	
- pyridoxine hydrochloride	x
- pyridoxine 5′-phosphate	x
- pyridoxine dipalmitate	x
FOLATE	
- pteroylmonoglutamic acid	x
- calcium-L-methylfolate	x
VITAMIN B_{12}	
- cyanocobalamin	x
- hydroxocobalamin	x
BIOTIN	
- D-biotin	x
VITAMIN C	
- L-ascorbic acid	x
- sodium-L-ascorbate	x
- calcium-L-ascorbate	x
- potassium-L-ascorbate	x

- L-ascorbyl 6-palmitate	x	

Category 2. Minerals

CALCIUM

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

MAGNESIUM

- acetate	x	
- carbonate	x	
- chloride	x	
- salts of citric acid	x	
- magnesium L-aspartate		x
- gluconate	x	
- glycerophosphate	x	
- salts of orthophosphoric acid	x	
- lactate	x	

- hydroxide	x
- oxide	x
- sulphate	x
IRON	
- ferrous bisglycinate	x
- ferrous carbonate	x
- ferrous citrate	x
- ferric ammonium citrate	x
- ferrous gluconate	x
- ferrous fumarate	x
- ferric sodium diphosphate	x
- ferrous lactate	x
- ferrous sulphate	x
- ferric diphosphate (ferric pyrophosphate)	x
- ferric saccharate	x
- elemental iron (carbonyl + electrolytic + hydrogen reduced)	x
COPPER	
- cupric carbonate	x
- cupric citrate	x
- cupric gluconate	x
- cupric sulphate	x
- copper lysine complex	x

IODINE	
- potassium iodide	x
- potassium iodate	x
- sodium iodide	x
- sodium iodate	x
ZINC	
- acetate	x
- chloride	x
- citrate	x
- gluconate	x
- lactate	x
- oxide	x
- carbonate	x
- sulphate	x
MANGANESE	
- carbonate	x
- chloride	x
- citrate	x
- gluconate	x
- glycerophosphate	x
- sulphate	x
SODIUM	

- bicarbonate	x
- carbonate	x
- chloride	x
- citrate	x
- gluconate	x
- lactate	x
- hydroxide	x
- salts of orthophosphoric acid	x
POTASSIUM	
- bicarbonate	x
- carbonate	x
- chloride	x
- citrate	x
- gluconate	x
- glycerophosphate	x
- lactate	x
- hydroxide	x
- salts of orthophosphoric acid	x
SELENIUM	
- sodium selenate	x
- sodium hydrogen selentine	x
- sodium selenite	x
CHROMIUM (III) and their hexahydrates	

- chloride	x	
- sulphate	x	
MOLYBDENUM (VI)		
- ammonium molybdate	x	
- sodium molybdate	x	
FLUORINE		
- potassium fluoride	x	
- sodium fluoride	x	
Category 3. Amino acids		
- L-alanine	x	
- L-arginine	x	
- L-aspartic acid		x
- L-citrulline		x
- L-cysteine	x	
- Cystine	x	
- L-histidine	x	
- L-glutamic acid	x	
- L-glutamine	x	
- glycine	x	
- L-isoleucine		x
- L-leucine	x	
- L-lysine	x	

- L-lysine acetate	x		
- L-methionine	x		
- L-ornithine	x		
- L-phenylalanine	x		
- L-proline		x	
- L-threonine	x		
- L-tryptophan	x		
- L-tyrosine	x		
- L-valine	x		
- L-serine			x
- L-arginine-L-aspartate			x
- L-lysine-L-aspartate			x
- L-lysine-L-glutamate			x
- N-acetyl-L-cysteine			x
- N-acetyl-L-methionine		x in products intended for persons over 1 year of age	

For animo acids, as far as applicable, also the sodium, potassium calcium and magnesium salts as well as their hydrochlorides may be used

Category 4. Carnitine and taurine

- L-carnitine	x
- L-carnitine hydrochloride	x
- taurine	x
- L-carnitine-L-tartrate	x

Category 5. Nucleotides

- adenosine 5′-phosphoric acid (AMP)	x
- sodium salts of AMP	x
- cytidine 5′-monophosphoric acid (CMP)	x
- sodium salts of CMP	x
- guanosine 5′-phosphoric acid (GMP)	x
- sodium salts of GMP	x
- insosine 5′-phosphoric acid (IMP)	x
- sodim salts of IMP	x
- uridine 5′-phosphoric acid (UMP)	x
- sodium salts of UMP	x

Category 6. Choline and inositol

- choline	x
- choline chloride	x
- choline bitartrate	x
- choline citrate	x
- inositol	x

Schedule 3

SUBSTANCES THAT MAY BE ADDED FOR SPECIFIC NUTRITIONAL PURPOSES TO FOODS FOR PARTICULAR NUTRITIONAL USES COVERED BY DIRECTIVE 2001/15/EC[4]

Category 1. Vitamins

VITAMIN E

- D-alpha-tocopheryl polyethylene glycol 1000 succinate

Category 2. Minerals

BORON

- boric acid
- sodium borate

CALCIUM

- amino acid chelate
- pidolate

CHROMIUM

- amino acid chelate

COPPER

- amino acid chelate

IRON

- ferrous hydroxide
- ferrous pidolate
- amino acid chelate

SELENIUM

- enriched yeast

MAGNESIUM

- amino acid chelate

- pidolate

MANGANESE

- amino acid chelate

ZINC

- amino acid chelate

Schedule 4

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

European Communities

(Foodstuffs Intended for Particular Nutritional Uses) Regulations 2006

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

This 21 day of November 2006.

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 concern foodstuffs intended for particular nutritional uses. They revoke the European Communities (Foodstuffs Intended for Particular Nutritional Uses) Regulations 2005 (S.I. No. 66 of 2005) and bring into effect new Regulations.

These Regulations give further effect to Council Directive 89/398/EEC 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 of the European Parliament and of the Council of 19 December 1996, and Directive 1999/41/EC of the European Parliament and of the Council of 7 June 1999, and give further effect to Commission Directive 2001/15/EC of 15 February 2001, as amended by Commission Directive 2004/5/EC of 20 January 2004.

These Regulations give effect to Commission Directive 2006/34/EC of 21 March 2006 amending the Annex to Directive 2001/15/EC as regards the inclusion of certain substances.

These Regulations may be cited as the European Communities (Foodstuffs Intended for Particular Nutritional Uses) Regulations 2006.

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

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

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

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

[5] OJ L 14, 21.1.2004, p. 19.

[6] OJ L 83, 22.3.2006, p.14

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

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

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

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

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

[5] OJ L 14, 21.1.2004, p. 19.

[6] OJ L 83, 22.3.2006, p.14

[7] OJ L31, 1.2.2002, p. 1

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

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

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

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

[9] OJ L 43, 14.2.1997 p. 1

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

[10] OJ L 109, 6.5.2000, p. 29, as affected by Corrigendum to Directive 2000/13/EC, OJ L 124, 25.5.2000, p. 66.

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

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

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

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

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

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