STATUTORY INSTRUMENTS

2003 No. 3207

FOOD, ENGLAND

The Processed Cereal-based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003

Made - - - - 8th December 2003 22nd December Laid before Parliament 2003 Coming into force - - 6th March 2005

The Secretary of State, in exercise of the powers conferred by sections 16(1)(a), (e) and (f), 17(1), 26(1)(a) and (3) and 48(1) of the Food Safety Act 1990(1) and now vested in him(2), having had regard in accordance with section 48(4A) of that Act to relevant advice given by the Food Standards Agency and after consultation as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council(3) 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 and in accordance with section 48(4) and (4B) of that Act, makes the following Regulations:

Title, application and commencement

1. These Regulations may be cited as the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (England) Regulations 2003; they apply in relation to England only and come into force on 6th March 2005.

Interpretation

2.—(1) In these Regulations—

⁽**1**) 1990 c. 16

⁽²⁾ Functions formerly exercisable by "the Ministers" (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the Food Standards Act 1999 (1999 c. 28), and paragraphs 12 and 21 of that Schedule amend respectively sections 17 and 48 of the 1990 Act. Functions of "the Ministers" so far as exercisable in relation to Wales were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I.1999/672), as read with section 40(3) of the 1999 Act, and those functions so far as exercisable in relation to Scotland were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46), as read with section 40(2) of the 1999 Act. Regulation 13(4) of S.I. 2000/656 expressly authorises the Secretary of State to amend or revoke existing Regulations made or having effect as if made by the Minister of Agriculture, Fisheries and Food (whether with others or not) under the 1990 Act.

⁽³⁾ OJ No. L31, 1.2.2002, p.1.

"the Act" means the Food Safety Act 1990;

"baby foods" means 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, but excludes processed cereal-based foods;

"the Directive" means Commission Directive 96/5/EC(4) on processed cereal-based foods and baby foods for infants and young children, as amended by Commission Directive 1998/36/ EC(5), Commission Directive 1999/39/EC(6) and Commission Directive 2003/13/EC(7);

"EEA Agreement" means the Agreement on the European Economic Area(8) signed at Oporto on 2nd May 1992 as adjusted by the Protocol(9) signed at Brussels on 17th March 1993;

"EEA State" means a State which is a Contracting Party to the EEA Agreement;

"food authority" does not include-

- the council of a district of a non-metropolitan county except where the county functions have been transferred to that council pursuant to a structural change; or
- the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner Temple and the Middle Temple);

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

"pesticide residue" means the residue in processed cereal-based foods or baby foods of a plant protection product as defined in point 1 of Article 2 of Council Directive 91/414/EEC(10) concerning the placing of plant protection products on the market, including its metabolites and products resulting from its degradation or reaction;

"processed cereal-based foods" means foods for particular nutritional use within the categories specified in Part I of Schedule 1 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;

"sell" includes possess for sale and offer, expose or advertise for sale; and

"young children" means children aged between one and three years.

- (2) Other expressions used in these Regulations and in the Directive have the same meaning in these Regulations as they have in the Directive.
- (3) Where any Schedule contains any note, the provisions of that Schedule shall be interpreted and applied in accordance with such note.

Exemption

3. These Regulations shall not apply to any baby food which is a milk intended for young children.

Restrictions on the sale of processed cereal-based foods and baby foods

- 4. No person shall sell any processed cereal-based food or baby food unless—
 - (a) it complies with the requirements of regulations 5 to 7 as to manufacture and composition; and

⁽⁴⁾ OJ No. L49, 28.2.96, p.17.

⁽⁵⁾ OJ No. L167, 12.6.98, p.23.

⁽⁶⁾ OJ No. L124, 18.5.1999, p.8.

⁽⁷⁾ OJ No. L41, 14.2.2003, p.33.

⁽⁸⁾ OJ No. L1, 3.1.94, p.1.

⁽⁹⁾ OJ No. L1, 3.1.94, p.571.

⁽¹⁰⁾ OJ No. L230, 19.8.91, p.1.

(b) it is labelled in accordance with regulation 8.

General requirements as to manufacture and composition

- **5.**—(1) No processed cereal-based food or baby food shall be manufactured from any ingredient other than those whose suitability for particular nutritional use by infants and young children has been established by generally accepted scientific data.
- (2) No processed cereal-based food or baby food shall contain any substance in such quantity as to endanger the health of infants or young children.
- (3) The composition of a processed cereal-based food shall comply with the criteria specified in Part II of Schedule 1 as read with Schedule 2.
 - (4) The composition of a baby food shall comply with the criteria specified in Schedule 3.

Added nutritional substances and nutrients

- **6.**—(1) In the manufacture of any processed cereal-based food or baby food, no nutritional substance shall be added other than a nutritional substance specified in Schedule 4.
- (2) No processed cereal-based food or baby food shall contain any added nutrient specified in column 1 of Part I of Schedule 5 in an amount exceeding the maximum limit specified opposite that nutrient in column 2 of that Part.
- (3) No processed cereal-based food or baby food specified in column 1 of Part II of Schedule 5 shall contain any added nutrient specified opposite that food in column 2 of that Part in an amount exceeding the maximum limit specified opposite that food in column 3 of that Part.

Pesticide residues

- 7.—(1) No processed cereal-based food or baby food shall contain—
 - (a) any pesticide residue of a pesticide specified in Schedule 6; or
 - (b) any omethoate, where it is a metabolite of a pesticide not specified in Schedule 6, or any product resulting from degradation or reaction of that metabolite,

at a level exceeding 0.003 mg/kg.

- (2) No processed cereal-based food or baby food shall contain any pesticide residue of a pesticide specified in column 1 of Schedule 7 at a level exceeding that specified in column 2 of that Schedule in relation to that pesticide.
- (3) No processed cereal-based food or baby food shall contain any pesticide residue of any individual pesticide which is not specified in Schedule 6 or column 1 of Schedule 7 at a level exceeding 0.01 mg/kg.
- (4) The levels referred to in paragraphs (1) to (3) apply to the processed cereal-based food or baby food—
 - (a) manufactured as ready for consumption, or
 - (b) if it is not so manufactured, as reconstituted according to its manufacturer's instructions.
- (5) Analytical methods for determining levels of pesticide residues for the purposes of this regulation shall be generally acceptable standardised methods.

Labelling

- **8.**—(1) Without prejudice to the generality of Part II of the Food Labelling Regulations 1996(**11**), processed cereal-based foods and baby foods shall be labelled with the following particulars—
 - (a) a statement as to the appropriate age (which shall be not less than four months) from which the food may be used, regard being had to its composition, texture or other particular properties;
 - (b) information as to the presence or absence of gluten if the age stated pursuant to sub-paragraph (a) is less than six months;
 - (c) the available energy value expressed in kJ and kcal, and the protein, carbohydrate and fat content, expressed in numerical form, per 100 g or 100 ml of the food as sold and, where appropriate, per specified quantity of the food as proposed for consumption;
 - (d) the average quantity, expressed in numerical form, per 100 g or 100 ml of the food as sold and, where appropriate, per specified quantity of the food as proposed for consumption, of each mineral substance and of each vitamin in respect of which a maximum or a minimum compositional requirement is specified in—
 - (i) Part II of Schedule 1 in the case of processed cereal-based foods; and
 - (ii) Schedule 3 in the case of baby foods; and
 - (e) if preparation of the food is necessary, appropriate instructions for preparation and a statement as to the importance of following those instructions.
- (2) Subject to paragraph (1)(d), no processed cereal-based food or baby food shall be labelled with the average quantity of any nutrient specified in Schedule 4 unless—
 - (a) that average quantity is expressed in numerical form, per 100 g or 100 ml of the food as sold and, where appropriate, per specified quantity of the food as proposed for consumption; and
 - (b) in the case of a mineral substance or vitamin, it is a mineral substance or vitamin other than one referred to in paragraph (1)(d).
- (3) Where, pursuant to paragraph (1)(d) or paragraph (2), any processed cereal-based food or baby food is labelled with the average quantity, per 100 g or 100 ml of the food as sold and, where appropriate, per specified quantity of the food as proposed for consumption, of any vitamin or mineral which is specified in column 1 of Schedule 8, the labelling of the food shall not express that average quantity as a percentage of the reference value specified in column 2 of Schedule 8 in relation to that vitamin or mineral unless the quantity present is equal to 15 per cent or more of the reference value.

Enforcement

- **9.**—(1) Except where paragraph (2) applies, each food authority shall enforce and execute these Regulations in its area.
- (2) Each port health authority shall enforce and execute these Regulations in its district in relation to imported food.

Offence and penalty

10. If any person contravenes regulation 4 he shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

⁽¹¹⁾ S.I. 1996/1499, relevant amending instruments are S.I. 1998/141, 1398, 2424, 1999/747, 1136, 1483, 1540, 2000/768, 2254, 3323, 2001/2294, 3442, 3775, 2002/379, 2003/461, 474, 1008, 1182, 1563, 1596, 1659, 2075, 2243, 2647.

Defence in relation to exports

- 11. In any proceedings for an offence under these Regulations it shall be a defence for the accused to prove—
 - (a) that the food in respect of which the offence is alleged to have been committed was intended for export to a country which has legislation analogous to these Regulations and that the food complies with that legislation; and
 - (b) in the case of export to an EEA State, that the legislation complies with the provisions of the Directive(12).

Application of various provisions of the Act

- 12. The following provisions of the Act shall apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or Part thereof shall be construed as a reference to these Regulations—
 - (a) section 2 (extended meaning of "sale" etc.);
 - (b) section 3 (presumptions that food is intended for human consumption);
 - (c) section 20 (offences due to fault of another person);
 - (d) section 21 (defence of due diligence) as it applies for the purposes of section 8, 14 or 15;
 - (e) section 22 (defence of publication in the course of a business);
 - (f) section 30(8) (which relates to documentary evidence);
 - (g) section 33(1) (obstruction etc. of officers);
 - (h) section 33(2), with the modification that the reference to "any such requirement as is mentioned in subsection (1)(b) above" shall be deemed to be a reference to any such requirement as is mentioned in that subsection as applied by paragraph (g) above;
 - (i) section 35(1) (punishment of offences) in so far as it relates to offences under section 33(1) as applied by paragraph (g) above;
 - (j) section 35(2) and (3) in so far as it relates to offences under section 33(2) as applied by paragraph (h) above;
 - (k) section 36 (offences by bodies corporate); and
 - (1) section 44 (protection of officers acting in good faith).

Revocations

- **13.**—(1) The Processed Cereal-based Foods and Baby Foods for Infants and Young Children Regulations 1997(**13**) and the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (Amendment) Regulations 1999(**14**) are revoked in relation to England.
- (2) The Processed Cereal-based Foods and Baby Foods for Infants and Young Children (Amendment) (England) Regulations 2000(15) are revoked.

Amendment

14.—(1) The Tryptophan in Food Regulations 1990(**16**) shall be amended (in so far as they apply in relation to England) in accordance with paragraph (2).

⁽¹²⁾ As adopted by the EEA Joint Committee Decisions No. 32/2002 (OJ No. L154, 13.6.2002, p.12) and 107/2003.

⁽¹³⁾ S.I. 1997/2042.

⁽¹⁴⁾ S.I. 1999/275.

⁽¹⁵⁾ S.I. 2000/1510.

⁽¹⁶⁾ S.I. 1990/1728; the relevant amending instrument is S.I. 2002/1817.

(2) In regulation 2(7) (prohibition on sale etc. of food containing tryptophan), in the definitions of "processed cereal-based food" and "baby food" there shall be substituted for the words "the Processed Cereal-based Foods and Baby Foods for Infants and Young Children Regulations 1997" the words "the Processed Cereal-based Foods and Baby Foods for Infants and Young Children (England) Regulations 2004".

Signed by authority of the Secretary of State for Health

Melanie Johnson
Parliamentary Under Secretary of State,
Department of Health

8th December 2003

SCHEDULE 1

Regulations 2(1), 5(3) and 8(1)(d)

PROCESSED CEREAL-BASED FOODS

PART I

Categories of processed cereal-based foods

- 1. Simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids.
- **2.** Cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid.
 - 3. Pastas which are to be used after cooking in boiling water or other appropriate liquids.
- **4.** Rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids.

PART II

Essential composition of 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.

Cereal content

- **1.**—(1) Processed cereal-based foods are prepared primarily from one or more milled cereals and/or starchy root products.
- (2) The amount of cereal and/or starchy root shall not be less than 25 per cent of the final mixture on a dry weight for weight basis.

Protein

- **2.**—(1) For products mentioned in paragraphs 2 and 4 of Part I, the protein content shall not exceed 1.3 g / 100 kJ (5.5 g / 100 kcal).
- (2) For products mentioned in paragraph 2 of Part I, the added protein shall not be less than 0.48 g / 100 kJ (2 g / 100 kcal).
- (3) For biscuits mentioned in paragraph 4 of Part I made with the addition of a high protein food, and presented as such, the added protein shall not be less than 0.36 g / 100 kJ (1.5 g / 100 kcal).
- (4) The chemical index of the added protein shall be equal to at least 80 per cent of that of the reference protein (casein as defined in Schedule 2), or the protein efficiency ratio (PER) of the protein in the mixture shall be equal to at least 70 per cent 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.

Carbohydrates

3.—(1) If sucrose, fructose, glucose, glucose syrups or honey are added to products mentioned in paragraphs 1 and 4 of Part I—

- (a) the amount of added carbohydrates from these sources shall not exceed 1.8 g / 100 kJ (7.5 g / 100 kcal);
- (b) the amount of added fructose shall not exceed 0.9 g / 100 kJ (3.75 g / 100 kcal).
- (2) If sucrose, fructose, glucose syrups or honey are added to products mentioned in paragraph 2 of Part I—
 - (a) the amount of added carbohydrates from these sources shall not exceed 1.2 g / 100 kJ (5 g / 100 kcal);
 - (b) the amount of added fructose shall not exceed 0.6 g / 100 kJ (2.5 g / 100 kcal).

Fat

- **4.**—(1) For products mentioned in paragraphs 1 and 4 of Part I, the fat content shall not exceed 0.8 g / 100 kJ (3.3 g / 100 kcal).
- (2) For products mentioned in paragraph 2 of Part I, the fat content shall not exceed 1.1 g / 100 kJ (4.5 g / 100 kcal). If the fat content exceeds 0.8 g / 100 kJ (3.3 g / 100 kcal)—
 - (a) the amount of lauric acid shall not exceed 15 per cent of the total fat content;
 - (b) the amount of myristic acid shall not exceed 15 per cent of the total fat content;
 - (c) the amount of linoleic acid (in the form of glycerides = linoleates) shall not be less than 70 mg / 100 kJ (300 mg / 100 kcal) and shall not exceed 285 mg / 100 kJ (1200 mg / 100 kcal).

Minerals

5.—(1) **Sodium**

- (i) Sodium salts may only be added to processed cereal-based foods for technological purposes.
- (ii) The sodium content of processed cereal-based foods shall not exceed 25 mg /100 kJ (100 mg / 100 kcal).

(2) Calcium

- (i) For products mentioned in paragraph 2 of Part I, the amount of calcium shall not be less than 20 mg / 100 kJ (80 mg / 100 kcal).
- (ii) For products mentioned in paragraph 4 of Part I manufactured with the addition of milk (milk biscuits) and presented as such, the amount of calcium shall not be less than 12 mg / 100 kJ (50 mg / 100 kcal).

Vitamins

- **6.**—(1) For processed cereal-based foods the amount of thiamin shall not be less than 25 μ g / 100 kJ (100 μ g / 100 kcal).
 - (2) For products mentioned in paragraph 2 of Part I:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A (μg RE) ⁽¹⁾	14	43	60	180

- (1) RE = all trans retinol equivalents
- (2) In the form of cholecalciferol, of which $10 \mu g = 400 i.u.$ of Vitamin D

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

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin D (μg) ⁽²⁾	0.25	0.75	1	3

⁽¹⁾ RE = all trans retinol equivalents

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

SCHEDULE 2

Regulation 5(3) and Schedule 1, Part II, paragraph 2.4

AMINO ACID COMPOSITION OF CASEIN

Amino acid	(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 3

Regulations 5(4) and 8(1)(d)

ESSENTIAL COMPOSITION OF BABY FOODS

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

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—
 - (a) the named meat, poultry, fish, offal or other traditional protein source, in total, shall constitute not less than 40 per cent by weight of the total product;
 - (b) each named meat, poultry, fish, offal or other traditional source of protein shall constitute not less than 25 per cent, by weight, of total named protein sources;

⁽²⁾ In the form of cholecalciferol, of which $10 \mu g = 400 \text{ i.u.}$ of Vitamin D

- (c) the total protein from the named sources shall not be less than 1.7 g/100 kJ (7 g/100 kcal).
- (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—
 - (a) the named poultry, fish, offal or other traditional protein source, in total, shall constitute not less than 10 per cent by weight of the total product;
 - (b) each named meat, poultry, fish, offal or other traditional source of protein shall constitute not less than 25 per cent by weight, of total named protein sources;
 - (c) the protein from the named sources shall not be less than 1 g / 100 kJ (4 g / 100 kcal).
- (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—
 - (a) the named meat, poultry, fish, offal or other traditional protein source, in total, shall constitute not less than 8 per cent by weight of the total product;
 - (b) each named meat, poultry, fish, offal or other traditional source of protein shall constitute not less than 25 per cent, by weight, of total named protein sources;
 - (c) the total protein from the named sources shall not be less than 0.5 g / 100 kJ (2.2 g / 100 kcal);
 - (d) the total protein in the product from all sources shall not be less than 0.7 g / 100 kJ (3 g / 100 kcal).
- (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—
 - (a) the protein from the dairy sources shall not be less than 0.5 g / 100 kJ (2.2 g / 100 kcal);
 - (b) the total protein in the product from all sources shall not be less than 0.7 g / 100 kJ (3 g / 100 kcal).
- (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 0.7 g / 100 kJ (3 g /100 kcal).
- (6) Sauces presented as an accompaniment to a meal are exempt from the requirements of subparagraphs (1) to (5).
- (7) Sweet dishes that mention dairy products as the first or only ingredient in the name shall contain not less than 2.2 g dairy protein / 100 kcal. All other sweet dishes are exempt from the requirements in sub-paragraphs (1) to (5).
- (8) 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.

Carbohydrates

- **2.** The quantities of total carbohydrates present in fruit and vegetable juices and nectars, fruit-only dishes, and desserts or puddings shall not exceed—
 - (a) 10 g / 100 ml for vegetable juices and drinks based on them;
 - (b) 15 g / 100 ml for fruit juices and nectars and drinks based on them;
 - (c) 20 g / 100 g for fruit-only dishes;
 - (d) 25 g / 100 g for desserts and puddings;
 - (e) 5 g / 100 g for other non-milk-based drinks.

Fat

- 3.—(1) For products referred to in paragraph 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 1.4 g / 100 kJ (6g / 100 kcal).
- (2) For all other products the total fat in the product from all sources shall not exceed 1.1 g / 100 kJ (4.5 g / 100 kcal).

Sodium

- **4.**—(1) The final sodium content in the product shall be either not more than 48 mg / 100 kJ (200 mg / 100 kcal) or not more than 200 mg per 100 g. 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 70 mg / 100 kJ (300 mg / 100 kcal).
- (2) Sodium salts may not be added to products based on fruit, nor to desserts or puddings except for technological purposes.

Vitamins

5.—(1) 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 6 mg / 100 kJ (25 mg / 100 kcal) or not less than 25 mg per 100 g.

- (2) Vitamin A—
- (i) In vegetable juices, the final content of vitamin A in the product shall be not less than 25 μ g RE/100 kJ (100 μ g RE/100 kcal) and, for the purposes of this paragraph, RE = all trans retinol equivalents.
- (ii) Vitamin A shall not be added to other baby foods.
- (3) Vitamin D—

Vitamin D shall not be added to baby foods.

SCHEDULE 4

Regulations 6(1) and 8(2)

NUTRITIONAL SUBSTANCES

Vitamins

1. Vitamin A

Retinol

Retinyl acetate

Retinyl palmitate

Beta-carotene

Vitamin D

Vitamin D_2 (= ergocalciferol)

Vitamin D₃ (= cholecalciferol)

Vitamin B₁

Thiamin hydrochloride

Thiamin mononitrate

Vitamin B₂

Riboflavin

Riboflavin-5'-phosphate, sodium

Niacin

Nicotinamide

Nicotinic acid

Vitamin B_6

Pyridoxine hydrochloride

Pyridoxine-5-phosphate

Pyridoxine dipalmitate

Pantothenic acid

D-pantothenate, calcium

D-pantothenate, sodium

Dexpanthenol

Folate

Folic acid

Vitamin B_{12}

Cyanocobalamin

Hydroxocobalamin

Biotin

D-biotin

Vitamin C

L-ascorbic acid

Sodium L-ascorbate

Calcium L-ascorbate

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

Potassium ascorbate

Vitamin K

Phylloquinone (phytomenadione)

Vitamin E

D-alpha tocopherol

DL-alpha tocopherol

D-alpha tocopherol acetate

DL-alpha tocopherol acetate

Amino acids

2. L-arginine}

L-cystine}

L-histidine} and their hydrochlorides

- L-isoleucine}
- L-leucine}
- L-lysine}
- L-cysteine}
- L-methionine
- L-phenylalanine
- L-threonine
- L-tryptophan
- L-tyrosine
- L-valine

Others

- 3. Choline
 - Choline chloride
 - Choline citrate
 - Choline bitartrate
 - Inositol
 - L-carnitine
 - L-carnitine hydrochloride

Salts of minerals and trace elements

- 4. 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

SCHEDULE 5

Regulation 6(2) and (3)

MAXIMUM LIMITS FOR VITAMINS, MINERALS AND TRACE ELEMENTS, IF ADDED, IN PROCESSED CEREAL-BASED FOODS AND BABY FOODS

PART I

General

Column 1	Column 2
Nutrient	Maximum limit per 100 kcal(1)
Vitamin E	3 mg α-TE
Riboflavin	0.4 mg
Niacin	4.5 mg NE
Vitamin B ₆	0.35 mg
Folic acid	50 μg
Vitamin B ₁₂	0.35 μg
Pantothenic acid	1.5 mg
Biotin	10 μg
Potassium	160 mg (of the food as sold)
Magnesium	40 mg
Iron	3 mg
Zine	2 mg
Copper	40 μg
Iodine	35 μg
Manganese	0.6 mg

PART II
Specified foods

Column I Food	Column 2 Nutrient	Column 3 Maximum limit per 100 kcal ⁽¹⁾
1. Vegetable juices which are baby foods		180 μg RE ⁽²⁾
2. Food fortified with iron	Vitamin C	25 mg
3. Fruit-based dishes, fruit juices, nectars or vegetable juices	Vitamin C	125 mg
4. Food other than that within entry number 2 or 3 above	Vitamin C	12.5 mg
5. Processed cereal-based food	Thiamin	0.5 mg
6. Baby food	Thiamin	0.25 mg
7. Food within paragraph 1 or 2 of Part I of Schedule 1	Calcium	180 mg (of the food as sold)
8. Food within paragraph 4 of Part I of Schedule 1	Calcium	100 mg (of the food as sold)
9. Food other than that within entry number 7 or 8 above	Calcium	80 mg (of the food as sold)

⁽¹⁾ Unless otherwise stated in column 2 of Part I or column 3 of Part II, the maximum limits specified in those columns apply to food ready for use, whether marketed as such or reconstituted as instructed by the manufacturer.

SCHEDULE 6

Regulation 7(1) and (3)

PESTICIDES WHOSE RESIDUES MUST NOT BE PRESENT IN PROCESSED CEREAL-BASED FOODS OR BABY FOODS AT A LEVEL EXCEEDING $0.003~\rm mg/kg$

Chemical name

Aldrin and dieldrin, expressed as dieldrin

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

Endrin

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

Fentin, expressed as triphenyltin cation

⁽²⁾ RE = all trans retinol equivalents.

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)

SCHEDULE 7

Regulation 7(2) and (3)

SPECIFIC MAXIMUM RESIDUE LEVELS OF CERTAIN PESTICIDES IN PROCESSED CEREAL-BASED FOODS OR BABY FOODS

Column 1	Column 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

SCHEDULE 8

Regulation 8(3)

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

Column 1	Column 2
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

Column 1	Column 2	
Nutrient	Labelling reference value	
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	

EXPLANATORY NOTE

(This note is not part of the Regulations)

- 1. These Regulations provide for the continued implementation in England of Commission Directive 96/5/EC on processed cereal-based foods and baby foods for infants and young children, as amended by Commission Directives 1998/36/EC and 1999/39/EC and now as further amended by Commission Directive 2003/13/EC. These Regulations revoke and replace in relation to England the Processed Cereal-based Foods and Baby Foods for Infants and Young Children Regulations 1997, as amended.
 - 2. These Regulations come into force on 6th March 2005. They—
 - (a) prohibit the sale of processed cereal-based foods and baby foods for infants and young children unless they comply with the manufacturing and compositional requirements in regulations 5 to 7 and the labelling requirements in regulation 8 (regulation 4);
 - (b) exempt from their application any baby food which is a milk intended for young children (regulation 3);
 - (c) specify the enforcement authorities (regulation 9);
 - (d) create an offence and prescribe a penalty (regulation 10);
 - (e) provide a defence in relation to exports in accordance with Articles 2 and 3 of Council Directive 89/397/EEC (OJ No. L186, 30.6.89, p.23) on the official control of foodstuffs (regulation 11);
 - (f) apply certain provisions of the Food Safety Act 1990 (regulation 12); and
 - (g) contain a revocation provision (regulation 13) and make a consequential amendment (regulation 14).
- **3.** In implementation of Directive 2003/13/EC these Regulations prohibit the sale of processed cereal-based foods and baby foods for infants and young children if those foods contain pesticide residues above certain levels. Different levels are set depending on the pesticide in question (regulation 7 and Schedules 6 and 7). In implementation of the final sentence of Article 6(2) of Directive 96/5/EC as substituted by Directive 1999/39/EC, provision is made as to analytical methods (regulation 7(5)).

- **4.** These Regulations also make some minor, drafting and technical changes, particularly to the provision applying certain provisions of the 1990 Act (regulation 12). Port health authorities now have a role in enforcement (regulation 9). The offence provision now relates only to a contravention of the restrictions on sale in regulation 4 (regulation 10).
- **5.** A full regulatory impact assessment of the effect that this instrument will have on the costs of business has been prepared and placed in the Library of each House of Parliament together with a Transposition Note setting out how the main elements of Directive 2003/13/EC are transposed in these Regulations. Copies may be obtained from the Food Labelling and Standards Division of the Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH.