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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
C(2009)

final

Draft

COMMISSION REGULATION

of

**on substances that may be added for specific nutritional purposes in foods for particular
nutritional uses**

(Text with EEA relevance)

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard 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 uses¹, and in particular Article 4(2) thereof,

After consulting the European Food Safety Authority,

Whereas:

- (1) A number of nutritional substances such as vitamins, minerals, amino acids and others may be added to foods for particular nutritional uses in order to ensure that the particular nutritional requirements of the persons for whom those foods are intended are fulfilled and/or in order to satisfy legal requirements laid down in specific directives adopted pursuant to Article 4(1) of Directive 89/398/EEC. The list of those substances had been established by Commission Directive 2001/15/EC of 15 February 2001 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses² and, following requests submitted by interested parties, new substances have been evaluated by the European Food Safety Authority, and consequently, that list should be completed and updated. Furthermore, it is appropriate to introduce specifications for some vitamin and mineral substances for their identification.
- (2) It is neither possible to define nutritional substances as a distinct group for the purpose of this Regulation nor to draw up at this stage an exhaustive list of all categories of nutritional substances that may be added in foodstuffs for particular nutritional uses.
- (3) The range of foods for particular nutritional uses is very wide and diversified and the technological processes used for their manufacture are varied. For this reason, the widest possible choice of substances that can be safely used in the manufacture of foods for particular nutritional uses should be available for the categories of nutritional substances to be listed in this Regulation.
- (4) The choice of substances should be based primarily on their safety and subsequently on their availability for use by humans and on their organoleptic and technological

¹ OJ L 186, 30.6.1989, p. 27.

² OJ L 52, 22.2.2001, p. 19.

properties. Unless otherwise specified in provisions applicable to specific categories of foodstuffs, the inclusion of substances in the list of those that may be used in the manufacture of foodstuffs for particular nutritional uses does not mean that their addition to those foodstuffs is necessary or desirable.

- (5) Where the addition of a nutritional substance has been judged necessary, this has been stipulated by specific rules in the relevant specific directives together with the appropriate quantitative conditions, as the case may be.
- (6) In the absence of any specific rules or in the case of foodstuffs for particular nutritional uses not covered by specific directives, nutritional substances should be used in order to manufacture products that are in conformity with the definition of such products and fulfil the particular nutritional requirements of the persons for whom they are intended. The products in question must also be safe when used as instructed by the manufacturer.
- (7) The provisions concerning the list of the nutritional substances that may be used in the manufacture of infant formulae and follow-on formulae and of processed cereal-based foods and baby foods for infants and young children are laid down in Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae³, and Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children⁴. Therefore those provisions need not be repeated in this Regulation.
- (8) A number of the nutritional substances may be added for technological purposes as additives, colourings, flavourings or other such uses including authorised oenological practices and processes provided for by relevant Community legislation. In this context specifications are adopted for them at Community level. It is appropriate that those specifications should be applicable for the substances whatever the purpose of their use in foodstuffs.
- (9) Pending the adoption of purity criteria for the rest of the substances at Community level, and in order to ensure a high level of protection for public health, generally acceptable purity criteria recommended by international organisations or agencies including but not limited to the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and EUP (European Pharmacopoeia) should apply. Member States should be permitted to maintain national rules setting stricter purity criteria, without prejudice to the rules set out in the Treaty.
- (10) Some specific nutrients or their derivatives have been identified as specifically necessary for the manufacture of some foodstuffs belonging to the group of foodstuffs for special medical purposes and their potential use should be reserved to the manufacture of these products.
- (11) For the sake of clarity, Directive 2001/15/EC and Directive 2004/6/EC derogating from Directive 2001/15/EC to postpone the application of the prohibition of trade to certain products⁵ should be repealed and replaced by this Regulation.
- (12) The measures provided in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

³ OJ L 401, 30.12.2006, p. 1.

⁴ OJ L 339, 6.12.2006, p. 16.

⁵ OJ L 15, 22.1.2004, p. 31.

HAS ADOPTED THIS REGULATION:

Article 1
Scope

This Regulation shall apply to foods for particular nutritional uses, excluding those covered by Directive 2006/125/EC and Directive 2006/141/EC.

Article 2
Eligible substances

1. Among the substances belonging to the categories appearing in Annex to this Regulation, only those listed in that Annex, complying with the relevant specifications as necessary may be added for specific nutritional purposes in the manufacture of foodstuffs for particular nutritional uses covered by Directive 89/398/EEC.
2. Without prejudice to Regulation (EC) No 258/97 of the European Parliament and of the Council⁶, also substances not belonging to the categories appearing in the Annex to this Regulation may be added for specific nutritional purposes in the manufacture of foods for particular nutritional uses.

Article 3
General requirements

1. The use of substances added for specific nutritional purposes 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.
2. Upon request by the competent authorities referred to in Article 9 of Directive 89/398/EEC, the manufacturer or, where appropriate, the importer shall produce the scientific work and the data establishing that the use of the substances complies with paragraph 1. If such work and data are contained in a readily available publication, a mere reference to that publication shall suffice.

Article 4
Specific requirements for substances listed in the Annex

1. The use of the substances listed in the Annex to this Regulation shall comply 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.
2. Purity criteria established by Community legislation which apply to the substances listed in the Annex when they are used in the manufacture of foodstuffs for purposes other than those covered by this Regulation shall also apply to those substances when they are used for purposes covered by this Regulation.
3. For substances listed in the Annex for which purity criteria are not established by Community legislation, and until the adoption of such specifications, generally

⁶ OJ L 43, 14.2.1997, p. 1.

acceptable purity criteria recommended by international bodies shall apply. National rules setting stricter purity criteria may be maintained.

Article 5

Repeals

Directive 2001/15/EC and Directive 2004/6/EC are repealed with effect from 31 December 2009.

Article 6

Entry into force and application

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

It shall apply as from 1 January 2010.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission

Androulla VASSILIOU

Member of the Commission

ANNEX

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

For the purpose of this table:

- 'Dietetic foods' means foods for particular nutritional uses including foods for special medical purposes but excluding infant formulae, follow-on formulae, processed cereal-based foods and baby foods intended for infants and young children,
- 'Foods for special medical purposes' means dietary foods for special medical purposes as defined in Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes⁷.

Substance	Condition of use	
	Dietetic foods	Foods for special medical purposes
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	
D-alpha-tocopheryl polyethylene glycol-1000 succinate (TPGS)		x
VITAMIN K		
phylloquinone (phytomenadione)	x	
menaquinone ⁸	x	
VITAMIN B1		
thiamin hydrochloride	x	

⁷ OJ L 91, 7.4.1999, p. 29–36.

⁸ Menaquinone occurring principally as menaquinone-7 and, to a minor extent, menaquinone-6.

thiamin mononitrate	x	
VITAMIN B2		
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 B6		
pyridoxine hydrochloride	x	
pyridoxine 5'-phosphate	x	
pyridoxine dipalmitate	x	
FOLATE		
pteroylmonoglutamic acid	x	
calcium-L-methylfolate	x	
VITAMIN B12		
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		
calcium carbonate	x	
calcium chloride	x	
calcium salts of citric acid	x	
calcium gluconate	x	
calcium glycerophosphate	x	
calcium lactate	x	
calcium salts of orthophosphoric acid	x	
calcium hydroxide	x	

calcium oxide	x	
calcium sulphate	x	
calcium bisglycinate	x	
calcium citrate malate	x	
calcium malate	x	
calcium L-pidolate	x	
MAGNESIUM		
magnesium acetate	x	
magnesium carbonate	x	
magnesium chloride	x	
magnesium salts of citric acid	x	
magnesium gluconate	x	
magnesium glycerophosphate	x	
magnesium salts of orthophosphoric acid	x	
magnesium lactate	x	
magnesium hydroxide	x	
magnesium oxide	x	
magnesium sulphate	x	
magnesium L-aspartate		x
magnesium bisglycinate	x	
magnesium L-pidolate	x	
magnesium potassium citrate	x	
IRON		
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	
ferrous bisglycinate	x	

ferrous L-pidolate	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		
zinc acetate	x	
zinc chloride	x	
zinc citrate	x	
zinc gluconate	x	
zinc lactate	x	
zinc oxide	x	
zinc carbonate	x	
zinc sulphate	x	
zinc bisglycinate	x	
MANGANESE		
manganese carbonate	x	
manganese chloride	x	
manganese citrate	x	
manganese gluconate	x	
manganese glycerophosphate	x	
manganese sulphate	x	
SODIUM		
sodium bicarbonate	x	
sodium carbonate	x	
sodium chloride	x	
sodium citrate	x	
sodium gluconate	x	
sodium lactate	x	
sodium hydroxide	x	
sodium salts of orthophosphoric acid	x	

POTASSIUM		
potassium bicarbonate	x	
potassium carbonate	x	
potassium chloride	x	
potassium citrate	x	
potassium gluconate	x	
potassium glycerophosphate	x	
potassium lactate	x	
potassium hydroxide	x	
potassium salts of orthophosphoric acid	x	
magnesium potassium citrate	x	
SELENIUM		
sodium selenate	x	
sodium hydrogen selenite	x	
sodium selenite	x	
selenium enriched yeast ⁹	x	
CHROMIUM (III)		
chromium (III) chloride and its hexahydrate	x	
chromium (III) sulphate and its hexahydrate	x	
MOLYBDENUM (VI)		
ammonium molybdate	x	
sodium molybdate	x	
FLUORINE		
potassium fluoride	x	
sodium fluoride	x	
BORON		
sodium borate	x	
boric acid	x	
Category 3. Amino acids		
L-alanine	x	
L-arginine	x	

⁹ Selenium-enriched yeasts produced by culture in the presence of sodium selenite as selenium source and containing, in the dried form as marketed, not more than 2.5 mg Se/g. The predominant organic selenium species present in the yeast is selenomethionine (between 60 and 85% of total extracted selenium in the product). The content of other organic selenium compounds including selenocysteine shall not exceed 10% of total extracted selenium. Levels of inorganic selenium normally shall not exceed 1% of total extracted selenium.

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 amino 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	
inosine 5'-phosphoric acid (IMP)	x	
sodium 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	