



ISDI COMMENTS on

Advisory list of nutrient compounds for the use in foods for special dietary uses intended for use by infants and young children at step 3' CX/NSFSDU 05/27/8

General remark on the requested substances

In the table below, the substances ISDI wishes to be included in the advisory list are, for the great majority, defined and authorised already in supranational or national legislation specification.

The advisory list of vitamin formulations, mineral salts, amino acids and other substances should not be considered as a positive (e.g. closed) list for ingredients referred to in sections 3.2.1 and 3.2.2

Most of these substances are sources of nutrients that are mandatory in infant formulae, follow-on-formulae, processed cereal-based foods for infants and young children canned baby foods and Foods for Special Medical Purposes.

They have been shown to have good technological and nutritional characteristics. They allow flexibility in the formulation of the variety of foods specifically designed for infants and young children.

All dietetic foods, manufactured for infants and adults, contain additives and ingredients which are classified as food grade, often even pharmaceutical grade materials, which have been approved for use by international expert bodies. The materials used must comply with assigned specific purity criteria, to ensure that no lower or chemical grade materials can find their way into dietetic foods.

Specific remark on Foods for Special Medical Purposes

FSMPs play a vital part in the dietary management of those infants and young children who have special nutritional requirements. Products intended for infants and young children not in good health are highly specific and are designed to meet the particular nutritional requirements resulting from a disease, disorder or medical condition. They are designed to be used for the dietary management of infants suffering from a particular disease e.g. phenylketonuria, galactosemia and other inborn errors of metabolism, malabsorption, allergies.

In some medical conditions, protein requirements cannot be met using whole protein due to intolerance, inability to metabolise etc. To supply the protein requirements to such patients, a range of amino acids must be used, to provide the body protein in its simplest form, while satisfying the specific daily requirements.

In many cases, the products are used as the only source of nutrition and are, in fact, substitutes for normal food. Thus a full complement of nutrition in the form of carbohydrate, protein, fat, vitamins, minerals and trace elements must be supplied. It is vital that the vitamins and

minerals sources and sources of other nutrients requested by ISDI for use in FSMPs are accepted, to allow the formulation of these much needed products.

The following tables summarise ISDI proposals (addition in bold, deletion stroke out) and comments on the document prepared by Germany.

A: ADVISORY LIST OF MINERAL SALTS AND TRACE ELEMENTS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR USE BY INFANTS AND YOUNG CHILDREN

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children					ISDI Comments
	CAC ²	international and/or national bodies	IF	FOF	PCBF	CBF	FSMP	
1. Sources of Calcium								
New Zealand, Malaysia, ISDI: [1.13 Calcium sulphate]	√ (1979)	JECFA (1975), Ph Int, FCC, Ph Eur (dihydrate), DAB, MP	-	-	-	-	{√}	Authorised in EU (Directive 2001/15 amended by Directive 2004/5) following positive opinion from the European Food Safety Authority on this usage, 10 Dec. 2003
2. Source of Iron (Fe)								
2.13 Ferric orthophosphate		FCC, Affirmed GRAS (21CFR184.130 1)			√			
EU, ISDI: [2.14 Sodium ferric diphosphate]		FCC	-	-	{√}	{√}	{√}	Authorised in EU(Directive 2001/15), for this usage, following positive opinion from the EU Scientific Committee on Food dated 12 May 1999
ISDI: [2.15 Ferrous citrate]		FCC, , Affirmed GRAS (21CFR184.130 7c)	{√}	{√}	{√}	{√}	{√}	Martindale - The Extra Pharmacopoeia , 29 th edition, 1989, ed. JEF Reynolds, The Pharmaceutical Press, London, UK.
New Zealand: [2.16 Ferrous succinate]		MP, MI			√			ISDI supports the addition of ferric orthophosphate, sodium ferric diphosphate, ferrous succinate and ferrous bisglycinate as sources of iron in cereal products for children but not in infant formulas or FSMP products. These iron sources can have taste and stability advantages and have been shown to be bioavailable.
South Africa: [2.17 Ferrous bisglycinate]		JECFA (2003)			√			
4. Source of Sodium (Na)								
New Zealand: [4.11 Sodium chloride(iodised)]		USP, Ph Eur, BP, JP	?	?	?	?	?	Delete this section Iodine levels in foods for special dietary should be tightly controlled and should therefore be added specifically rather than through iodised salt.
8. Source of Zinc (Zn)								
EU, ISDI: [8.6 Zinc carbonate]		BP (hydroxide carbonate)	-	-	-	-	{√}	Authorised in EU(Directive 2001/15) for this usage, following positive opinion from the EU

								Scientific Committee on Food dated 12 May 1999
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13. Fluoride (F)

B: ADVISORY LIST OF VITAMIN COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR USE BY INFANTS AND YOUNG CHILDREN

2. Provitamin A								
ISDI: [2.2 Provitamin A other than beta-carotene: [2.2.1 apo-8-carotenal]	√ (1991)	JECFA (1984), FCC	{√}	{√}	{√}	{√}	{√}	Delete. ISDI had already withdrawn this request in 2004
4. Vitamin E								
ISDI, EU, New Zealand: [4.5 D-alpha-Tocopheryl acid succinate]		FCC, NF	-	-	-	-	{√}	Authorised in EU(Directive 2001/15) for this usage, following positive opinion from the EU Scientific Committee on Food dated 12 May 1999

C: ADVISORY LIST OF AMINO ACIDS AND OTHER NUTRIENTS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR USE BY INFANTS AND YOUNG CHILDREN

1. Amino acids ³								
1.1 L-Arginine		FCC, USP, Ph Eur, BP, DAB	_____				√	Arginine is no longer considered as an (semi) essential amino acids and therefore can be deleted except for FSMP. Glutamine is no longer considered as an (semi) essential amino acids and therefore can be deleted except for FSMP.
1.2 L-Arginine hydrochloride		FCC, USP, Ph Eur, BP, DAB	_____				√	
1.23 L- Glutamic acid		JECFA (1987), FCC, USP, Ph Eur	_____				√	
1.24 L- Glutamine		FCC, USP, DAB	_____				√	
2. Carnitine								
2.1 L-Carnitine		FCC, USP, Ph Eur	√		ISDI: {√}	ISDI: {√}	√	Authorised in EU(Directive 96/5) for this usage, following positive opinion from the EU Scientific Committee on Food dated 27 Oct. 1989
ISDI: [2.2 L-Carnitine tartrate]		FCC, Ph Eur	-		-	-	√	Authorised in EU (Directive 2001/15 amended by Directive 2004/5) following positive opinion from the European Food Safety Authority on this usage, 3 Nov 2003.

LIST OF NUTRIENT COMPOUNDS THAT LACK OFFICIAL PURITY REQUIREMENTS

LIST A:								
[Calcium citrate malate]	?	?	-	-	-	-	[√]	ISDI withdraws this request
[Calcium enriched yeast]	?	?	-	-	-	-	[√]	ISDI withdraws this request
[Calcium pyruvate monohydrate]	?	?	-	-	-	-	[√]	ISDI withdraws this request
[Cupric carbonate]	?	?	[√]	[√]	[√]	[√]	[√]	Although there are no purity criteria, these substances have been authorised and used in the European Union for many years.
[Cupric citrate]	?	?	[√]	[√]	[√]	[√]	[√]	USP
[Copper-lysine-complex]	?	?	[√]	[√]	[√]	[√]	[√]	
[Sodium iodate]	?	?	-	-	[√]	[√]	[√]	Martindale, 29 th edition, 1989
[Zinc citrate]	?	?	[√]	[√]	[√]	[√]	[√]	
[Zinc lactate]	?	?	[√]	[√]	[√]	[√]	[√]	
[Manganese(II) carbonate]	?	?	[√]	[√]	[√]	[√]	[√]	
[Potassium fluoride]	?	?	-	-	-	-	[√]	Although there are no purity criteria, these substances have been used for many years. Martindale, 29 th edition, 1989
LIST B:								
[DL-alpha-Tocopheryl acid succinate]	FC	?	-	-	-	-	[√]	Martindale, 29 th edition, 1989, USP
[DL-alpha-Tocopheryl polyethylene glycol 1000 succinate]		?	-	-	-	-	[√]	USP monograph
[Potassium-L-ascorbate]		?	[√]	[√]	[√]	[√]	[√]	Although there are no purity criteria, these substances have been used for many years. Martindale, 29 th edition, 1989
[Pyridoxal 5-phosphate]		?	[√]	[√]	[√]	[√]	[√]	Although there are no purity criteria, these substances have been used for many years. USP, Martindale
[Pyridoxal dipalmitate]		?	[√]	[√]	[√]	[√]	[√]	Although there are no purity criteria, these substances have been used for many years.
LIST C:								
[L-Isoleucine hydrochloride]		?					[√]	USP, Martindale, 29 th edition, 1989
[L-Leucine hydrochloride]	FC	?					[√]	allowed in USA (21CFR172.320) Martindale, 29 th edition, 1989 USP
[L-Lysine acetate]	FC	?					[√]	Martindale, 29 th edition, 1989 USP
[L-Lysine L-Aspartate]		?			-		[√]	Both lysine aspartate and lysine

[L-Lysine L-Glutamate dihydrate]	?	?			-		[√]	glutamate are produced from the salification individual monographed amino acids. These amino acid salts are permitted under EU legislation and detailed product specification data was submitted to the SCF to support inclusion of these amino acids in 2001/15/EC.
[L-Ornithine]	?	?			-		[√]	Martindale, 29 th edition, 1989
[L-Carnitine hydrochloride]	FC C	?	[√]	[√]	ISDI: [√]	ISDI: [√]	[√]	Martindale, 29 th edition, 1989
[Choline]	FC C	?	[√]	[√]	[√]	[√]	[√]	US GRAS (21CFR182.8252) Martindale, 29 th edition, 1989 USP
[Cytidine 5-monophosphate(CMP)]	?	?	[√]	ISDI: [√]	-	-	[√]	
[Cytidine 5-monophosphate sodium salt]	?	?	[√]	ISDI: [√]	-	-	[√]	
[Uridine 5-monophosphate(UMP)]	?	?	[√]	ISDI: [√]	-	-	[√]	
[Uridine 5-monophosphate sodium salt]	?	?	[√]	ISDI: [√]	-	-	[√]	
[Adenosine 5- monophosphate (AMP)]	?	?	[√]	ISDI: [√]	-	-	[√]	Martindale, 29 th edition, 1989
[Adenosine 5- monophosphate sodium salt]	?	?	[√]	ISDI: [√]	-	-	[√]	
[Guanosine 5- monophosphate sodium salt]	FC C	?	[√]	ISDI: [√]	-	-	[√]	
[Inosine 5-monophosphate sodium salt]	FC C	?	[√]	ISDI: [√]	-	-	[√]	
ISDI: [Creatine monohydrate]	?	?					[√]	Positive opinion from EFSA 17 Feb 2004

ISDI references:

- “Opinion on substances for nutritional purposes which have been proposed for use in the manufacture of foods for particular nutritional purposes ('Parnuts').” Expressed 12 May 1999 by the European Scientific Committee on Food (http://europa.eu.int/comm/food/fs/sc/scf/out31_en.pdf)
- Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a request from the Commission related to Calcium sulphate for use in foods for particular nutritional uses. Expressed 10 December 2003 (http://www.efsa.eu.int/science/afc/afc_opinions/193/opinion_afc_03_en1.pdf)
- Report on the essential requirements for weaning foods. Adopted 27 October 1989 and 30 March 1990 by the the European Scientific Committee on Food (http://europa.eu.int/comm/food/fs/sc/scf/reports/scf_reports_24.pdf)
- Commission Directive 2001/15/EC of 15 February 2001 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses, as amended by Directive 2004/5 (http://europa.eu.int/eur-lex/en/consleg/pdf/2001/en_2001L0015_do_001.pdf)
- Commission Directive of 16 February 1996 on processed cereal-based foods and baby foods for infants and young children (http://europa.eu.int/eur-lex/en/consleg/pdf/1996/en_1996L0005_do_001.pdf)

Abbreviations:

IF = infant formula
FUF = follow-up formula
PCBF = processed cereal based food
CBF = canned baby food
[FSMP] = food for special medical purposes

BP = British Pharmacopoeia
BPC = British Pharmaceutical Codex
DAB = Deutsches Arzneibuch
DAC = Deutscher Arzneimittel-Codex
FCC = Food Chemicals Codex
FU = Farmacopoea Ufficiale della Republica Italiana
JP = The Pharmacopeia of Japan
Jap Food Stan = Japanese Food Standard
NF = The National Formulary/USA
Ph Eur = Pharmacopoeia Europaea
Ph Franç = Pharmacopée Française
Ph Helv = Pharmacopoea Helvetica
Ph Int = International Pharmacopeia
USP = The United States Pharmacopeia

D: ADVISORY LIST OF FOOD ADDITIVES FOR SPECIAL NUTRIENT FORMS

ISDI maintains its request to amend the introductory paragraph as follows:

For reasons of stability and safe handling, some vitamins **and nutrients** have to be converted into suitable preparations, e.g. stabilised oily solutions, gelatine or gum arabic coated products, fat embedded preparations, dry rubbed preparations. For this purpose, the **following edible materials and the additives included substances permitted** in the ~~respective~~ **specific** Codex standard **respectively** may be used: