codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 7 **CX/NFSDU 05/27/8-Add. 1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Twenty-seventh Session
Bonn, Germany, 21- 25 November 2005

ADVISORY LIST OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR USE BY INFANTS AND YOUNG CHILDREN AT STEP 4[1]

- ***Comments at Step 3 –***

Comments from:

ARGENTINA
AUSTRALIA
MEXICO
NEW ZEALAND
UNITED STATES OF AMERICA

ISDI – International Special Dietary Foods Industries

[1] Prevously considered as the PROPOSED DRAFT REVISION OF THE ADVISORY LIST(S) OF MINERAL SALTS AND VITAMIN COMPOUNDS FOR THE USE IN FOODS FOR INFANTS AND CHILDREN (CAC/GL 10-1979, amended 1983, 1991).

ARGENTINA

2. CRITERIA FOR THE INCLUSION AND DELETION OF NUTRIENT COMPOUNDS FROM THE ADVISORY LISTS

As regards this issue, Argentina recommends replacing the phrase "*de nutrientes*" by "*nutritivos*" in the heading and the text, so that it is consistent with the title of the document, as it is a more appropriate translation from the original (applicable to Spanish version only).

2.1 (c)

Regarding this bullet point, Argentina agrees with the US proposal in considering Codex background first, then international specifications and, in the absence of these, national specifications.

2.1 (d)

Argentina believes that although is the manufacturer's responsibility to maintain the stability of nutrient compounds in the food(s) until the Use-by-Day of the product, the original wording of bullet point (d) should be retained, as it considers the criteria for the inclusion of nutrients in general rather than the specific inclusion of a given type of food.

2.1 (e)

With regard to this issue, Argentina believes that the term "*generalmente*" should be deleted, as the translation does not convey the intended meaning of the phrase (applicable to Spanish version only).

2.2

Argentina believes it is advisable to choose the DSM proposal, considering that it is more appropriate to refer to possible additions first and then to deletions.

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

1. Source of Calcium (Ca)

Argentina believes that sources of calcium used should include those with the highest solubility. Some sources such as phosphates, especially tribasic and pyrophosphate, would have low solubility according to the bibliography. This characteristic is a prerequisite for their bioavailability. *** (bibiliography)

2. Source of Iron (Fe)

Regarding the sources of elemental iron (reduced, electrolytic and carbonyl), Argentina is of the view that, given their very low bioavailability, their use in PCBF and FSMP would not be advisable. Their addition could be justified in CBF, as they could turn into ionic forms during the manufacturing process.

4. Source of Sodium (Na)

As there are other sources of iodine, Argentina believes that iodinated sodium chloride should not be accepted as a source of sodium, since it could create problems in the product design in respect of the iodine input.

8. Source of Zinc (Zn)

As regards the sources of zinc, Argentina believes that both carbonate and oxide are insoluble and not very absorbable. *** (bibliography)

1.13, 2.16, 2.17, 4.12, 13.3

With regard to the various nutrient sources under these items, Argentina believes – despite the lack of scientific background – that the choice of source should be made in a very restrictive and careful manner, circumscribing it only to those scientifically supported and with the highest bioavailability, due to the vulnerability of the age group to which these foods are intended.

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

2.2 and 4.5

As to these two nutrient sources, we would like to refer back to the above mentioned idea. Argentina believes that that the choice of source should be made in a very restrictive and careful manner, circumscribing it only to those scientifically supported and with the highest bioavailability, due to the vulnerability of the age group to which these foods are intended.

5.4
Argentina believes that the phrase "*L-Ascorbato cálcico*" should be replaced by "*L-Ascorbato sódico*", as *L-Ascorbato cálcico* is listed under 5.2 of the same list (applicable to Spanish version only).

6.1
Argentina recommends replacing "*Tiamina cloruro hidrocloruro*" by "*Tiamina clorhidrato*", as this is the appropriate term to name the compound in Spanish (applicable to Spanish version only).

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

LIST OF NUTRIENT COMPOUNDS THAT LACK OFFICIAL PURITY REQUIREMENTS
Argentina supports the withdrawal from the table of all the compounds of which there is no scientific background that supports their inclusion, due to the vulnerability of the age group to which these foods are intended.

D: ADVISORY LIST OF FOOD ADDITIVES FOR SPECIAL VITAMIN FORMS
Argentina agrees with the change in the heading of this section, replacing the term "vitamin" by "nutrient", and with the adoption of the paragraph proposed by ISDI and Switzerland, deleting the term "vitamins" since it would be included within "nutrients".
Argentina believes the word "respectively" should be deleted, as it is redundant and brings about confusion in connection with the phrase.

TABLE
The phrase that precedes the table reads: "…For this purpose, the following included substances permitted in the specific Codex standard respectively may be used:"
That is to say, the additives, their uses and maximum levels should match those permitted by the specific Codex standard for each category of food in particular.
Argentina believes that the purpose of the including this table in this general standard is not clear; neither is the inclusion of new additives requested by countries – many of which do not have maximum levels of use.
Because the technological justification for the request of the inclusions and the intended purpose of the inclusion of this table are unknown, it has not been possible to form an opinion and thus further clarification is requested.
Argentina believes the words "*Dióxido de silicona*" should be replaced by "*Dióxido de silicio*", since the translation from English into Spanish is not *Silicona* but *Silicio* (applicable to Spanish version only).

***** BIBLIOGRAPHY**
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-Special Issue on Recent Intervention Trials with Zinc: Implications for Programs and Research. Food and Nutrition Bulletin, vol. 22, no. 2, The United Nations University, 2001. United Nations University Press
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-Heaney, R. P., Dowell, S. D., Bierman, J., Hale, C. A. & Bendich, A. Absorbability and cost effectiveness in calcium supplementation. J Am Coll Nutr 2001; 20: 239–246.
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AUSTRALIA

1. Criteria for the Inclusion and Deletion of Nutrient Compounds from the Advisory List
Australia supports the use of national purity criteria requirements, where they exist, in the absence of internationally recognised purity requirements and agrees with amended 2.1 (c) as proposed by the USA. However for clarity purposes we suggest the following minor word change to reduce the duplication:

> (c) ~~the purity requirements of~~ the nutrient compounds conform with the applicable Specifications of Identity and Purity recommended by the Codex Alimentarius Commission, or in absence of such specifications, with another internationally recognised specification. If there is no internationally recognised specification, national purity requirements may be considered.

Australia opposes removal of criteria 2.1 (d) as proposed by DSM Nutritional Products and supports consideration of stability by regulators.

2. Tables A, B & C
Australia notes that there are a number of nutrient compounds in Tables A, B & C that remain in square brackets. It is unclear what process needs to be undertaken to resolve the status of these nutrient compounds and by whom. Therefore Australia requests that guidance be provided on a uniform process of assessment against the established criteria to resolve the status of these nutrients.

3. List of nutrient compounds that lack official purity requirements
Similarly to point 2 above, further guidance is required to clarify the future process to resolve the status of these nutrient compounds.

4. Table D – Advisory list of Food Additives for Special Nutrient Forms
Australia notes that this matter has been referred to CCFAC and therefore will defer comment until CCNFSDU has received advice from CCFAC on how nutrient carriers are to be addressed.

MEXICO

No.	Compound	Comment
	1.12 Calcium pyrophosphate	Remove brackets
	1.13 Calcium sulphate	Remove brackets
	2.15 Ferrous citrate	Remove brackets
	2.16 Ferrous succinate	Remove brackets
	2.17 Ferrous bisglycinate	Remove brackets
	4.11 Sodium chloride	Remove brackets
	4.12 Sodium sulphate	Remove brackets
	4.13 Sodium tartrate	Remove brackets
	8.6 Zinc carbonate	Remove brackets
	10.1 Sodium selenate	Remove brackets
	10.2 Sodium selenite	Remove brackets
	13.3 Calcium fluoride	Remove brackets
	2.2 Provitamin A other than beta-carotene	Remove brackets
	4.5 D-alpha-Tocopheryl acid succinate	Remove brackets
	2.2 L-Carnitine tartrate	Remove brackets

NEW ZEALAND

Document title
The Committee has agreed to changing the title from "Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Special Dietary Uses Intended for Use by Infants and Young Children" to

"Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Use by Infants and Young Children".

Is this advisory list deemed to be exhaustive? If so we suggest that the title needs to be reviewed. While accepting that the list now covers more than mineral salts and vitamins compounds there are many other nutrient compounds used in the foods for special dietary uses intended for use by infants and young children that are not included in the list eg DHA, ARA.

Order of nutrient compounds
The order in which nutrient compounds are listed in section A, B and C appear to be in no particular order. For ease of cross referencing in the respective standards we suggest that the order should mirrored with the respective standards.

pp18-19
Nucleotides are listed as lacking official purity requirements. Australia New Zealand Food Standard Code Standard 1.3.4 Identity and Purity contain specifications for the following nucloetides that should be acceptable for including in the advisory list:
Inosine - 5' monophosphate disodium salt
Uridine - 5' monophosphate disodium salt
Adenosine - 5' monophosphate (AMP)
Cytidine - 5' monophosphate (CMP)
Guanosine - 5' monophosphate disodium salt

Title for Section D: Advisory list of food additives for special vitamin forms
It has been proposed to replace "vitamin" by "nutrient" to read **D: Advisory list of food additives for special nutrient forms**. This would be in line with the change to the document title. A further change needs to be made as the proposed section title does not line up with the list in this section. The list in section D includes ingredients as well as food additives and we suggest that this should be reflected in the section title.
The INS no. column needs to be reviewed as not all INS numbers are currently listed.
This list is very limited and ad hoc in nature. We suggest that the list be reviewed using risk based principles for inclusion in the list.
If "fish gelatine and peanut oil" are to remain in the list we recommend that a foot note be added for a statement concerning the labelling for potential allergenicity from carry-over is required.

UNITED STATES OF AMERICA

I. General Comments
We appreciate the Delegation of Germany's thoughtful consideration of comments submitted on this topic at the last Committee meeting.

Advisory Lists A, B, and C
At the last session, the Committee supported the addition of the column for Foods for Special Medical Purposes (FSMP) in the Advisory Lists; however, it is unclear what products will be included in this category. We request clarification of whether nutrient compounds, which may be used for nutritional purposes in formula for special medical purposes intended for infants, are included in the Advisory List under the column for IF or FSMP. Given the special nature of formula for special medical purposes intended for infants, we suggest they be included under the column for FSMP even though the term "foods for special medical purposes" remains to be defined. We also recommend that the next revision of the Advisory List identify what products are proposed to be included in the categories for "IF" and "FSMP", and that the four food categories be spelled out
somewhere in the document.
We also support the inclusion of two columns to identify those nutrient compounds that have Codex specifications and those compounds that have other internationally recognized specifications. If no internationally recognized specifications are found, then national requirements may be considered.

We believe that nutrient compounds should meet the criteria for inclusion in Section 2.1 (including 2.1(c)) if they are to be included in the Advisory Lists. Nutrient compounds that do not meet the criteria should be removed.

Advisory List D
When it reintroduced Advisory List D, the Committee specified that the it include only substances that are 1) food additives and 2) used for the purpose of nutrient carriers (ALINORM 05/28/26, para 128.) We support the Committee's recommendation for limiting the scope and further recommend that Advisory List D should not duplicate the listing of food additives that are already permitted for use for other technological functions in the respective standards.
We note that a CCFAC working group has prepared a discussion paper that includes consideration of the definition and approaches for the inclusion of carriers in the GSFA. This includes consideration of the use of food additives as "nutrient carriers," as requested by CCNFSDU (ALINORM 04/27/12, April 2004, para 89). A separate Working Group on the Harmonization of Terms Used by Codex and JECFA will discuss the working document and provide advice to the Committee. The United States has previously supported Option A for defining "carrier" as a functional class for food additives in CCFAC discussion paper (CX/FAC 05/37/13) because it provides for nutrient carriers (ALINORM 04/27/12, April 2004, para 89). We suggest that CCNFSDU encourage CCFAC to adopt a definition that includes provision for nutrient carriers.

In anticipation that CCFAC will soon resolve the issue of carriers, we suggest that this functional class be added and placed in square brackets in the infant formula standard and the processed cereal based food standard, pending the outcome of the CCFAC discussions. This action is consistent with the working principles for consideration of added functional classes by CCNFSDU.
We also suggest that the Committee consider developing a system to ensure that the permitted substances and maximum levels in Advisory List D are consistent with the permitted substances and maximum levels in Section 4 of the infant formula standard and processed cereal based foods standard, which are currently being revised. When other standards are created (e.g., FSMP) or updated (e.g., FUF or CBF), the substances and maximum levels would need to be reconciled by a similar process.

II. Specific Comments

2.1 Nutrient compounds that are to be added for nutritional purposes to foods for infants and young children may be included in the Lists only if:
(c) the purity requirements of the nutrient compounds **conform with the applicable Specifications of Identity and Purity recommended by the Codex Alimentarius Commission, or in the absence of such specifications, with** ~~are established in an~~ **another** internationally recognized specification. ~~or,~~ If there is no internationally recognized specification, national requirements may be considered.
Comment: We continue to support the above proposed edits regarding purity requirements of nutrient compounds (as identified in CX/NFSDU 05/27/8), consistent with the inclusion of Codex purity specifications for nutrient compounds in the Advisory Lists.

2.2 Nutrient compounds may be added to the Lists based on the criteria above. Nutrient compounds shall be deleted from the Lists if they are found no longer to meet the above criteria. **If a country proposes to add or delete a nutrient compound to a list, the country should provide information that addresses how the nutrient compound satisfies/does not satisfy the criteria in Section 2.1.**
Comment: We support the proposal for the order of the sentences in 2.2 as shown above. We also suggest addition of a sentence as also shown above.
Rationale: It should be explicit that it is the responsibility of an individual/country to provide information when addition or deletion of a nutrient compound is proposed.

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

Comment: If footnote 3 is added, it should include free, hydrated and anhydrous forms of amino acids, and the hydrochloride, sodium, and potassium salts of amino acids.
Rationale: We are aware of internationally recognized purity requirements for free, hydrated, and anhydrous forms of amino acids, and their hydrochloride, sodium, and potassium salts. We are not aware of internationally recognized purity requirements for the calcium and magnesium salts of amino acids and suggest that purity requirements be identified if they are to be included in Advisory List C.
Comment: We recommend that the proposed use of L-glutamic acid and L-glutamine in infant formula and follow-on formula be removed from Advisory List C.

Rationale: This action is justified by the general provision that indicates that only essential amino acids may be added to these products to improve the quality of the protein.

D: ADVISORY LIST OF FOOD ADDITIVES ~~FOR SPECIAL NUTRIENT FORMS~~ FOR USE AS NUTRIENT CARRIERS

Comment: We recommend that the title be edited as shown above.

Rationale: This title incorporates the two specifications of the Committee for the scope of Advisory List D (ALINORM 05/28/26, para 128).

~~For reasons of stability and safe handling, some vitamins~~ and nutrients ~~have to be converted into suitable preparations, e.g., stabilized 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~~.

Carriers are required for some nutrients to provide for their safe incorporation into foods for special dietary uses intended for use by infants and young children. Food additives already included in the specific Codex standard and food additives identified as nutrient carriers in this Advisory List may be used for this purpose. Food additives already included in the specific Codex standards for other functional purposes are not duplicated in this Advisory List. Certain ingredients may also function as nutrient carriers, provided they are safe and suitable for their intended use according to the provisions in the respective standards (i.e., IF, FUF, PCBF, CBF) for 1) quality and purity of all ingredients, and 2) optional ingredients. Ingredients are covered under the provision for safe and suitable use in the respective standards and, therefore, are not listed in Advisory List D.

Comment: We propose revision of the introductory statement as shown above.

Rationale: This proposed introductory statement identifies the reason for use of nutrient carriers and is consistent with the specifications of the Committee that the list include only substances that are food additives and used for the purpose of nutrient carriers (ALINORM 05/28/26, para 128). It also incorporates the recommendation of the United States that Advisory List D should not duplicate the listing of food additives that are already permitted for use for other technological functions in the respective standards.

Comments on Advisory List D Table

Comment: To be consistent with the stated scope and purpose of the table, we suggest the following edits to Advisory List D:

List mannitol (INS no. 421) and trisodium citrate (INS no. 331 iii) because they are food additives and are known to be used as nutrient carriers.

Remove citric acid (INS no. 330) because it is already listed as a food additive in the infant formula and processed cereal based food standards.

Remove maltodextrins, fish gelatine, bovine gelatine, glycyl tristearate, peanut oil, and saccharose. They are ingredients, not food additives, and the provisions for 1) quality and purity of all ingredients and 2) optional ingredients in the respective standards (i.e., IF, FUF, PCBF, CBF) would provide for use of ingredients that are safe and suitable for their intended use.

Remove the food additives gum arabic, silicon dioxide, ethylcellulose, BHA/BHT, modified starches, starch sodium octenyl succinate, and sodium L-ascorbate because they are not known to be used as nutrient carriers. Sodium L-ascorbate is already listed as a nutrient source in Advisory List B. Certain modified starches are food additives that are already listed for use as thickening agents in the infant formula standard (INS no. 1412, 1412, 1414, 1440) and in the processed cereal-based food standard (INS no. 1404, 1410, 1412, 1413, 1414, 1420, 1422, 1450, 1451).

Comment: We are uncertain how to interpret the information on the food additives and maximum levels included in Advisory List D and request clarification for the following questions:

Is use of each of the listed food additives--and the single maximum value listed for each--intended to apply to all of the food standards covered by the Advisory Lists?

How were the maximum values determined?

Comment: The food additive sections of the proposed draft revised standards for infant formula and processed cereal based foods include maximum levels for food additives per "100 ml of the ready-to-drink product" and per "100 g of product," respectively. Advisory List D lists maximum levels for food additives used as nutrient carriers as "maximum level in ready-to-use food [mg/kg]". To avoid

confusion, we recommend 1) that the maximum levels for food additives used as nutrient carriers be listed separately for each product category, perhaps using a format similar to Advisory Lists A, B, and C, and 2) that the maximum levels be listed in the same units as food additives listed for other functional purposes in Section 4 of the specific Codex standard.

ISDI – International Special Dietary Foods Industries

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	-	-	-	-	ŧ√ŧ	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**			√			

		(21CFR184.1301)						
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 (21CFR184.1307c)**	[√]	[√]	[√]	[√]	[√]	**Martindale - The Extra Pharmacopoeia**, 29th 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
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.
1.2 L-Arginine hydrochoride		FCC, USP, Ph Eur, BP, DAB	_____	√	

1.23 L- Glutamic acid		JECFA (1987), FCC, USP, Ph Eur	_____				√	Glutamine is no longer considered as an (semi) essential amino acids and therefore can be deleted except for FSMP.
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, 29th 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, 29th edition, 1989
LIST B:								
[DL-alpha-Tocopheryl acid succinate]	**FCC**	?	-	-	-	-	[√]	Martindale, 29th 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, 29th 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, 29th edition, 1989
[L-Leucine hydrochloride]	**FCC**	?					[√]	allowed in USA (21CFR172.320) Martindale, 29th edition, 1989 USP
[L-Lysine acetate]	**FCC**	?					[√]	Martindale, 29th edition, 1989 USP
[L-Lysine L-Aspartate]	?	?			-		[√]	Both lysine aspartate and lysine 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-Lysine L-Glutamate dihydrate]	?	?			-		[√]	
[L-Ornithine]	?	?			-		[√]	Martindale, 29th edition, 1989
[L-Carnitine hydrochloride]	**FCC**	?	[√]	[√]	ISDI: [√]	ISDI: [√]	[√]	Martindale, 29th edition, 1989
[Choline]	**FCC**	?	[√]	[√]	[√]	[√]	[√]	US GRAS (21CFR182.8252) Martindale, 29th 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, 29th edition, 1989
[Adenosine 5- monophosphate sodium salt]	?	?	[√]	ISDI: [√]	-	-	[√]	
[Guanosine 5- monophosphate sodium salt]	**FCC**	?	[√]	ISDI: [√]	-	-	[√]	
[Inosine 5-monophosphate sodium salt]	**FCC**	?	[√]	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 1990by 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: