codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 6 **CX/NFSDU 06/28/6-Add. 1**
October 2006

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
28th Session

Chiang Mai, Thailand, 30 October - 3 November 2006

PROPOSED DRAFT REVISION OF THE ADVISORY LIST OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR THE USE BY INFANTS AND YOUNG CHILDREN

- Comments at Step 3 of the Procedure -

Comments from:
BRAZIL
UNITED STATES OF AMERICA
VIETNAM

AIDGUM - International Association for the Development of Natural Gums
ISDI - International Special Dietary Foods Industries

BRAZIL

LIST OF NUTRIENT COMPOUNDS THAT LACK OFFICIAL PURITY REQUIREMENTS

Suggestion: Brazil proposes the withdrawal of this list from the document in case it's not defined the requirements for the level of pureness of the compositions cited on the list.

UNITED STATES OF AMERICA

I. GENERAL COMMENTS

Advisory Lists A, B, and C

Column Headers in Tables A, B, and C

The Delegation of Australia has proposed two alternatives for changes in column headers and subheaders that address our request for identification of products in the individual food standards. Option (b) links use of nutrient sources to the specific food standards. Those standards contain definitions of the products covered, thus making it very explicit what foods the nutrient sources can be used in. For this reason, we support changing the main header to "Use in Codex Food Standards Applicable to Infants and Young Children." If option (b) is selected, it is then appropriate to subdivide the IF column into Part A and Part B columns. This organization makes it clear that the Part B: Formulas for Special Medical Purposes Intended for Infants is a part of the Infant Formula Standard. With the inclusion of Part B formulas as a subdivision in the Infant Formula column, the content of the present FSMP column should be moved to "IF Section B". We agree with the suggestion by Germany that the Committee should consider whether a column for FSMP for young children is needed.

Addition/Deletion of Nutrient Compounds in Tables A, B, and C

Several delegations recommended addition or deletion of nutrient compounds from Tables A, B, and C. Criteria for inclusion and deletion of nutrient compounds have been agreed upon and are listed in Section 2.1 of the Proposed Draft Revision of the Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for the Use by Infants and Young Children (CX/NFSDU 06/28/6). We support the criteria in Section 2.1. Based on the comments submitted, it appears that a process may be helpful to facilitate Committee decisions for the addition or deletion of nutrient compounds. We suggest the following procedure:

1. For nutrient compounds that are listed in the existing Advisory Lists, the use of these nutrient compounds should generally be considered as justified, given that CCNFSDU and CAC previously endorsed their use. Members of the CCNFSDU that raise concerns about the continued listing of a specific nutrient compound are responsible for providing the data and information to the CCNFSDU explaining why the specific nutrient compound is no longer justified based on the criteria in Section 2.1. If a member raises a concern for a listed nutrient compound, the CCNFSDU will consider the information provided and decide whether there is justification to remove the nutrient compound from the list. The nutrient compound shall only be removed from the list if the CCNFSDU finds the evidence supports removal from the list.

2. For nutrient compounds that are not listed in the existing Advisory List, the members who propose the addition are responsible for providing data and information that justify the nutrient compound for use in products covered in the standard (e.g., infant formula or processed cereal based foods) based on criteria in Section 2.1. If a member objects to the proposal, this member is responsible for providing data and information to the CCNFSDU explaining why addition of the specific nutrient compound is not justified. The CCNFSDU shall consider all the data and information provided and decide whether there is reason to list the nutrient compound.

We also note that purity standards for some substances proposed for addition to the Advisory Lists include U.S. GRAS as a purity standard. We wish to clarify that we would not regard specifications in a GRAS notice as a national purity requirement and request that "US GRAS (year)" be deleted in the list of purity requirements.

Inclusion of Nutrient Compounds without International or National Purity Requirements

Several delegations requested that substances be included in the Advisory Lists even though they lack official purity requirements. 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. We are unaware of reasons why exceptions to those criteria should be allowed. We support the proposal of the Delegation of the EC that if nutrient compounds without purity requirements are to be removed, that it is advisable to make this decision when the list is finalized (ALINORM 06/29/26, para 136). We recommend that nutrient compounds without international or national purity requirements be kept in square brackets and believe that countries that want these substances to be listed should work to establish national purity requirements so that the substances will meet all of the criteria for inclusion. If any exceptions are considered, the reasons and process for doing so must be transparent and agreed upon by all countries.

Advisory List D

When the Committee reintroduced Advisory List D at the 26th CCNFSDU Session, the Committee specified that 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.

We note that CCFA has proposed a functional class for "carrier" (ALINORM 06/29/12, Appendix XV: Proposed Draft Revision of the Codex Class Names and the International Numbering System). The definition for carrier, currently in square brackets, includes nutrient carrier.

II. SPECIFIC COMMENTS

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 suggest addition of a sentence as 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 7 p. 20-21 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 removal is warranted by the general provision that indicates that only essential amino acids may be added to these products to improve the quality of the protein.

Comment: We note that "antioxidants" has been introduced as new category of compounds for consideration in Advisory List C. We recommend against addition of a category for antioxidants in the Advisory Lists.

Rationale: The category of "antioxidants" is a functional class of food additives. Other compounds used for antioxidant purposes (e.g., ascorbyl palmitate and tocopherol compounds) are listed as food additives in Section 4 of the draft revised standard and compounds listed under the proposed antioxidant category would be appropriate listed under Section 4, as well.

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, i.e., that Advisory List D include only substances that are 1) food additives and 2) used for the purpose of nutrient carriers (ALINORM 05/28/26, para 128).

Comment: CX/NFSDU 06/28/6--Revised includes three proposals for introductory paragraphs for Table D (i.e., language in previous draft, ISDI/Switzerland proposed language, and EC proposed language). We recommend deletion of the introductory paragraph from the previous draft and the introductory paragraph proposed by ISDI and Switzerland. We recommend retaining the paragraph proposed by the EC with the edits shown below.

Rationale: CCNFSDU agreed that the introductory paragraph should refer only to food additives (ALINORM 06/29/26. para 137 and ALINORM 05/28/26, para 128). These two introductory paragraphs include use of "edible materials" and "substances" as nutrient carriers, which is outside the scope of Advisory List D agreed to by the Committee.

We propose the following edits to the EC proposal for consideration:

For reasons of stability and safe handling, some vitamins and other 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 food additives included in the respective specific Codex standard may be used. In addition, the following food additives may be used as nutrient carriers.
The maximum levels should be based on the amount needed to achieve the technical effect of a nutrient carrier under good manufacturing practice.
Where a food additive used as a nutrient carrier is also permitted in a Codex food standard for infants and young children for a different technological function, the maximum level in the food should be determined by the function with the highest acceptable maximum use level under good manufacturing practice.

Rationale for suggested edits to the above introductory paragraph:

- Because vitamins are nutrients, the word "other" should be inserted in the first sentence to make this clear.

- We propose deleting the examples of "stabilized oily solutions", "gelatine", and "fat embedded preparations" because they do not apply to <u>food additives</u> used as nutrient carriers.

- The phrase "as nutrient carriers" should be added to the third and fourth sentences to emphasize that these food additives are used for the purpose of nutrient carriers.

- We propose that the CCNFSDU identify the criteria for determining maximum levels, and offer the above draft text for consideration.

- We propose the last sentence to clarify how the maximum level in a food should be determined when a food additive used as a nutrient carrier is also permitted for a different technological function (e.g., silicon dioxide may function both as an anticaking agent in processed cereal-based foods for infants and young children and as a nutrient carrier).

Scope of Substances to be Listed in Table D

Comment: We wish to clarify that we propose deletion of the first version of the table, which includes substances that are not food additives.

Rationale: This version of the table lists substances that are outside the scope agreed to by the Committee. That is, the table should be limited to food additives used as nutrient carriers (ALINORM 05/28/26 para 128 and ALINORM 06/29/26 para 137). It is recognized that 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. Consequently, such ingredients are covered under the provisions for safe and suitable use in the respective standards and, therefore, should not be listed in Advisory List D.

Comment: The EC comments to CL 2005/53 indicated that not all of the Codex standards for foods intended for infants and young children list the following additives that may be used as nutrient carriers: gum Arabic (INS 414) , silicon dioxide (INS 551), mannitol (INS 421), starch sodium octenyl succinate (INS 1450), and sodium L-ascorbate (INS 301). They proposed that these five food additives be listed in Table D in the Advisory List. The United States agrees that the Committee should consider listing these and any other food additives that meet appropriate criteria including technological need.

Format for Table D

Comment: We earlier proposed to expand the format of Table D to be consistent with the format of Tables A, B, and C. We note that use of an expanded format would involve collection and presentation of a large amount of specific information. Before continuing to suggest use of this format, we request that the Committee clarify if this specificity is needed or if use in all of the standards for foods for infants and young children could be listed in one column with footnotes to indicate if a nutrient carrier is not suitable for products in a particular food standard (e.g., infant formula).

Working Principles for Food Additive Provisions in Table D

Comment: The United States previously proposed working principles for food additive provisions in Table D. We note that the Commission recently adopted a revision of the preamble to the General Standard for Food Additives (GSFA) at Step 8 and that there is other work by the CCFA that may have bearing on these food additive provisions. In light of recent developments, we are examining the working principles we previously proposed for food additive provisions in Table D with the U.S. Delegate to CCFA and anticipate providing additional comments at the upcoming session.

VIETNAM

The list is at step 3 (see *Report Appendix V*) of the Codex procedure and is acceptable.

The delegation of Germany will continue their excellent work.

AIDGUM - INTERNATIONAL ASSOCIATION FOR THE DEVELOPMENT OF NATURAL GUMS

AIDGUM as official observer found in the background papers for the 28th Session that it was proposed that Gum Arabic/ gum Acacia level should be reduced from 100 to 10 mg/ kg in the Ready to Use Food (page 36 of the CX/NFSDU 06/28/6).

In the first table Gum Arabic/ Gum Acacia is indicated at 100 mg/kg. It should be even 500 mg/kg as for maltodextrins, as both products are used the same way. Therefore it should not be 10 mg/kg.

Because of its low viscosity and high solubility, Gum Arabic /Gum Acacia does not present safety problems that have been associated with high viscosity and low solubility gums.

In fact Gum Arabic/ Gum Acacia has beneficial effects in foods for infants and young children due to its pre biotic properties.

JECFA has assigned Gum Acacia an "ADI not specified" status when used as an additive, meaning that it can be used for additive purposes according to good manufacturing practice (GMP) principles. In some countries, such as the USA, Gum Acacia is classified as a generally recognized as safe (GRAS) food component and in France AFSSA has recognized Gum Acacia (Arabic) as a soluble dietary fibre with pre biotic properties.

ISDI - International Special Dietary Foods Industries

In this document ISDI will not reiterate the entire comments made in its previous document 06/124 but would like to focus on additional comments or on comments that were not taken into account in the Codex document CX/NFSDU 06/28/6-Revised.

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	FUF	PCBF	CBF	FSMP	
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.

B: ADVISORY LIST OF VITAMIN COMPOUNDS 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	FUF	PCBF	CBF	FSMP	
4. Vitamin E								
4.6 DL-alpha-Tocopheryl acid succinate		NF, MP, MI, USDP, Ph Eur, FCC	-	-	-	-	~~[~~√~~]~~	Martindale, 29th edition, 1989
~~[~~4.7 DL-alpha-Tocopheryl polyethylene glycol 1000 succinate~~]~~	?	FCC, USP	-	-	-	-	~~[~~√~~]~~	
10. Sources of Folic Acid								
10.2 Calcium-L-methylfolate		Notified as GRAS (US FDA)	√	-	-	-	√	Approved in the EU and included in Directive 2001/15/EC on substances that may be added for PARNUTS

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

Nutrient Source	Purity Requirements by		Use in Food Categories for Infants and Young Children					ISDI Comments
	CAC[2]	international and/or national bodies	IF	FUF	PCBF	CBF	FSMP	
2. Carnitine								
2.3 L-Carnitine tartrate		FCC, Ph Eur	√	√			√	This component is also allowed for use in the EU for Infant Formulae and Follow-up Formulae.
6. Nucleotides								
6.1 Adenosine 5-monophosphate (AMP)		~~FCC,~~ FSANZ	√	√			√	There is no FCC criteria for this component.
6.5 Uridine 5-monophosphate sodium salt		~~FSANZ, Jap Food Stan~~	√	√			√	Those purity criteria correspond to the disodium forms and not to the sodium

6.6 Guanosine 5-monophosphate sodium salt		~~FCC, JECFA (2000), FSANZ, Jap Food Stan~~	√	√			√	forms.
6.7 Inosine 5-monophosphate sodium salt		~~FCC, JECFA (2000), FSANZ, Jap Food Stan~~	√	√			√	
6.11 Disodium Uridine 5-monophosphate salt		FSANZ, Jap Food Std	√	√	-	-	√	Food Standards Australia New Zealand (Std 1.3.4) Japan's Specifications and Standards for Food Additives, 7th ed (2000)
6.12 Disodium Guanosine 5-monophosphate salt		FCC, JECFA, FSANZ, Jap Food Std	√	√	-	-	√	FCC 5th ed (2005), JECFA, Food Standards Australia New Zealand (Std 1.3.4), Japan's Specifications and Standards for Food Additives, 7th ed (2000)
6.13 Disodium Inosine 5-monophosphate salt		FCC, JECFA, FSANZ, Jap Food Std	√	√	-	-	√	FCC 5th ed (2005), JECFA, Food Standards Australia New Zealand (Std 1.3.4), Japan's Specifications and Standards for Food Additives, 7th ed (2000)
~~[~~9. Other Compounds~~]~~								
~~[~~9.1 ARA ~~(arachidonic acid-rich single cell oil derived from the soil fungus Mortierella alpina)]~~		US GRAS (2001), FSANZ	~~[~~√~~]~~	~~[~~√~~]~~			~~[~~√~~]~~	ISDI does not believe that these ingredients should be specifically specified unless we want to make an extensive list of lipid sources used in infant nutrition products since these ingredients are not pure, but a mixture of oils.
~~[~~9.2 DHA ~~(docosahexaenoic acid-rich single cell oil derived from the microalgal species Crypthecodinium cohnii)]~~		US GRAS (2001), FSANZ	~~[~~√~~]~~	~~[~~√~~]~~			~~[~~√~~]~~	

D: ADVISORY LIST OF FOOD ADDITIVES FOR SPECIAL NUTRIENT FORMS

	INS no.	Additive/Carrier	Maximum Level in	ISDI Comments

			Ready-to-use food [mg/kg]	
(a)	414	EC: Gum Arabic (gum acacia)	~~10~~ 100	ISDI supports the EC proposal and would like to see the maximum level for Arabic Gum increased.
(b)	551	EC: Silicon dioxide	10	ISDI supports the EC proposal for this carrier.
(c)	421	EC: Mannitol	10	ISDI supports the EC proposal for this carrier.
(l)		Fish gelatine		ISDI supports the addition of Fish Gelatine as it is used as a carrier for Vitamin E. Since Fish Gelatine is a food ingredient, ISDI believes that no maximum level in needed.
(m)		Glycyl Tristearate		ISDI supports the addition of Glycyl Tristearate as is it used as a carrier for certain forms of Vitamin E and Ascorbic Acid
~~(u)~~	~~420~~	~~ISDI: Sorbitol (carrier in L-Ascorbic Acid)~~	~~?~~	ISDI would like to withdraw its request for this nutrient.

ANNEX 1: REFERENCES & ABBREVIATIONS

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
FSANZ	Food Standards Australia New Zealand
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