

*U.S. PRELIMINARY DRAFT Positions for the 26th CCNFSDU Session: For Discussion
Purposes and Solicitation of Comment at the 9/9/04 U.S. Stakeholders Public Meeting*

**CODEX COMMITTEE ON
NUTRITION AND FOODS FOR
SPECIAL DIETARY USES
26th SESSION**

**U.S. DRAFT POSITIONS
As of
September 9, 2004
(PART 2 of 2)**

U.S. PRELIMINARY DRAFT Positions for the 26th CCNFSDU Session: For Discussion Purposes and Solicitation of Comment at the 9/9/04 U.S. Stakeholders Public Meeting

Notice to U.S. Interested Parties in the Activities of the Codex Committee on Nutrition and Foods for Special Dietary Uses

The next session of this Codex committee will be held in Bonn, Germany from November 1-5, 2004. In addition, an *Ad Hoc* Working Group on the Revision of the Composition Requirements of the Draft Revised Standard for Infant Formula will meet on Saturday, October 30, 2004. Dr. Barbara Schneeman will head the U.S. delegation.

This document identifies U.S. preliminary draft positions as of September 9, 2004 on agenda items for the 26th session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)¹:

A public meeting will be held on September 9, 2004 from 1:00 p.m. to 4:00 p.m. in College Park, Maryland in order to provide information and receive public comments on the agenda items that will be discussed at the next CCNFSDU session and on U.S. draft positions (Please refer to the 8/13/04 Federal Register Notice, Vol. 69, No. 156, pp. 50155-57). We also invite you to submit written comments **by September 30, 2004**. Please direct these to: nancy.crane@cfsan.fda.gov. We request comments by this date to facilitate their consideration in preparing final draft U.S. positions for the Bonn meeting. However, we recognize that not all Codex reference documents may be posted on the Codex web site (<http://www.codexalimentarius.net>) by this date.

¹ Note: A separate document (U.S. Draft Positions as of September 1, Part 1 of 2) identifies preliminary draft positions on three other agenda items. These agenda items are:

- #4 Draft Guidelines for Vitamin and Mineral Food Supplements at Step 7;
- #5(a) Draft Revised Standard for Infant Formula at Step 7; and
- #6 Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children at Step 7

**MATTERS REFERRED
BY THE CODEX ALIMENTARIUS COMMISSION
AND/OR OTHER CODEX COMMITTEES**

AGENDA ITEM No. 2

BACKGROUND

Reference:

- CX/NFSDU 04/2 *not yet available*

The Committee is invited to consider matters referred to it by the Codex Alimentarius Commission and/or by other Committees. The above reference document will be based on information prepared by the Codex Secretariat.

DRAFT POSITION

At this time, the United States has not formulated a draft position on matters that are being referred to the Committee, and awaits the release of the above Codex reference document for consideration.

**GUIDELINES FOR THE USE OF NUTRITION CLAIMS:
DRAFT TABLE OF CONDITIONS FOR NUTRIENT CONTENTS
(PART B CONTAINING PROVISIONS ON DIETARY FIBRE
AT STEP 7)**

AGENDA ITEM No. 3

BACKGROUND

Reference:

- Report of the 25th CCNFSDU Session (ALINORM 04/27/26, paras 18-26; Appendix II)
- Comments at Step 6 CX/NFSDU 04/3 *not yet available*
- Proposals for a More Inclusive Definition and Related Methods CX/NFSDU 04/3-Add.1

At the last meeting, the Committee agreed to circulate the Draft Provisions in the Table, as amended for comments at Step 6 for further consideration at the next session.

The Committee could not come to a conclusion on the definition of dietary fibre and agreed that further consideration should be given to this issue. It was agreed that an electronic working group coordinated by the Delegation of France and Sweden would review the proposed definition to make it more inclusive and consider the related methods.

Please refer to the above documents for additional background.

DRAFT POSITION

The United States offers the following comments and recommendations with regard to: 1) the Guidelines for the Use of Nutrition Claims: Draft Table of Conditions for Nutrient Contents (Part B) Dietary Fibre (ALINORM 04/27/26, Appendix II), and 2) the “Proposals for a Definition and Methods of Analysis for Dietary Fibre Content” (CX/NFSDU 04/3-Add.1).

1. Table of Conditions for Dietary Fibre Content Claims

We support the removal of the square brackets surrounding “Dietary Fibre”.

For clarification, we recommend that a level be specified on a per serving basis for both the “Source” and “High” claim. That is:

Not Less than
Source: 3 g per 100 g or 1.5 g per 100 kcal or **3 g** per serving
High : 6 g per 100 g or 3 g per 100 kcal or **6 g** per serving

U.S. PRELIMINARY DRAFT Positions for the 26th CCNFSDU Session: For Discussion Purposes and Solicitation of Comment at the 9/9/04 U.S. Stakeholders Public Meeting

In addition, the United States emphasizes the importance of retaining the option to express dietary fibre claims, as well as other nutrient content claims, on a per serving basis. To not provide the option of expressing dietary fibre claims on a per serving basis would be inconsistent with the provision of this option in current Codex texts (e.g., serving size is included as an option for declaring nutrient content in the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985 (rev.1-1993) and as an option for expressing nutrient content claims about protein and vitamins and minerals (CAC/GL 23-1997, amended 2001). We are unaware of a rational basis for treating dietary fibre differently.

The U.S. has found expressing nutrient content and claims on a per serving basis to be the best option to help U.S. consumers construct healthful diets. Standardized serving sizes reflect amounts that consumers commonly consume. In contrast, the declaration of nutrient content based on a single standard weight such as 100 grams (or volume such as 100 ml) will often not reflect the nutrient levels in amounts commonly consumed. For example, for many grain based snack products such as crackers, cookies, and chips and for ready-to-eat cereals, 100 grams is about three times the average amount eaten by consumers in the United States. Certain of these products would provide 10-15% of the recommended daily intake for dietary fibre per 100 g. However, when commonly consumed in gram amounts of 30 g, they might provide 5% or less of the recommended daily intake, and thus might not contain sufficient amounts to justify a nutrient content claim.

We further note that the weight of products can vary considerably within certain food categories. For example, a cup of some ready-to-eat cereals weighs less than 20 grams while others weigh more than twice that amount. In addition, U.S. consumers most often make comparisons within a food category when purchasing products--which is aided by standardized serving sizes.

2. Definition of Dietary Fibre and Methods of Analysis

The proposed definition includes both a chemical definition as well as a physiologic definition. It would be more appropriate for the physiologic aspects of the definition to be referred to as background information regarding the potential role of fibre in the diet and not be included in the definition used in the Codex guidelines. If these functions of fibre are promoted for a food product, the manufacturer is responsible for having scientific substantiation of such a health claim, as with any nutrient or food component for which a claim is made. The analytical methods as described in the paper on dietary fibre do not address this aspect of the definition, nor is the United States aware of any protocols, which have been validated through the AOAC process, as bioassays for these functions.

In the chemical definition of dietary fibre, the United States recommends that the cut-off for the degree of polymerization should be not lower than 10.

The United States recommends that the table be titled, Methods of Analysis for Dietary Fibre and Other Carbohydrates. In this table a distinction should be made between those

U.S. PRELIMINARY DRAFT Positions for the 26th CCFSDU Session: For Discussion Purposes and Solicitation of Comment at the 9/9/04 U.S. Stakeholders Public Meeting

methods that have proceeded through final action by AOAC (991.43, 985.29, 994.13, 997.08) and those that are still at the first action (995.16, 2002.02, 999.03, 2001.02, 2001.03, 2000.11). The Official Methods are valid for those matrices in which the collaborative studies supporting them were performed. In the case of several of the methods listed, the matrices studied are limited in number and are not representative of the broader range of food products to which the method may eventually be applied. In these cases, additional validation studies are required to determine whether the method performs adequately with newer or more complex food matrices than those originally studied.

The Committee may also wish to consider listing the methods in numerical order, since the number provides the year in which the method was accepted as a “First Action” method. For example, 985.29 received “First Action” status in 1985; 2002.02 received “First Action” status in 2002.

NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES

AGENDA ITEM No. 4

BACKGROUND

Reference:

- Report of the 25th CCNFSDU Session (ALINORM 04/27/26, Para 36-61, Appendix IV)
- CL 2004/13-NFSDU
- Report on the Proposals for Additional or Revised Nutrient Reference Values for Labelling Purposes *not yet available*

While considering Section 5.5 of the Draft Guidelines for Vitamin and Mineral Food Supplements at the 25th CCNFSDU session, the Chairman recalled there was a need to update the Nutrient Reference Values (NRVs) for Labelling Purposes that had been established following the Helsinki Consultation in 1988. Some delegations pointed out that the current list of NRVs was incomplete and required additions and updates. The Committee agreed that a Circular Letter would be sent to ask for proposals for additional or revised NRVs for labelling purposes, that might be established for the general population or for specific population groups. These proposals would be reviewed by an electronic working group coordinated by the Delegation of South Africa in order to develop a document with proposals for revised NRVs for consideration at the next session.

Please refer to the above documents for additional background.

DRAFT POSITION

The United States preliminary draft position is reflected in the U.S. comments below that were submitted in response to Codex Circular Letter 2004/13-NFSDU. We anticipate that we will have additional comments after the Report on the Proposals for Additional or Revised Nutrient Reference Values for Labelling Purposes becomes available for review.

Need for Updated Nutrient Reference Values

The United States strongly supports the need to update the Nutrient Reference Values (NRVs) for Food Labeling Purposes that were established following a joint FAO/WHO expert consultation held in Helsinki in 1988 (Recommended Nutrient Reference Values for Food Labelling Purposes, Report of a Joint FAO/WHO Consultation on Recommended Allowances of Nutrients for Food Labelling Purposes, Helsinki, Finland, September 1988). We agree that these values should be revised and expanded as needed to consider the substantial body of new scientific evidence over the last two decades on human requirements for the wide range of nutrients. For example, newer references on recommended nutrient intakes are available from the Institute of Medicine, through a joint project between Canada and the United States, as well as from the European Union and from the 1998 joint FAO/WHO expert consultation in Bangkok.

U.S. PRELIMINARY DRAFT Positions for the 26th CCFNSDU Session: For Discussion Purposes and Solicitation of Comment at the 9/9/04 U.S. Stakeholders Public Meeting

Need for Guiding Principles The United States also strongly supports the development of guiding principles for deriving labeling reference values from reference values for recommended nutrient intakes. For example, the Institute of Medicine, in another joint project between Canadian and U.S. regulatory agencies, recently proposed guiding principles for nutrition labeling reference values (Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification. Committee on Use of Dietary Reference Intakes in Nutrition Labeling, Food and Nutrition Board, Institute of Medicine, The National Academies Press, 2003). This report provides one example of the type of scientific expertise relevant to food labeling that has been sought by regulatory bodies.

Role of Scientific Experts in Providing Advice to Codex

In carrying out its responsibilities to update the NRVs, the United States recommends that Codex seek advice from scientific experts before coming to final conclusions about labeling reference values. We note that Codex sought scientific advice in 1988 when a joint FAO/WHO expert consultation was convened in Helsinki to discuss recommended nutrient reference values for food labeling purposes. It is our understanding that the CCFNSDU reviewed the report of this expert consultation at the 16th CCFNSDU session before publication (CX/NFS DU 88, CRD No 1), and then made decisions about whether or not to endorse these recommendations.

In a similar fashion, the current needed effort could take the form of a request to WHO and FAO for a scientific workshop or consultancy which could have as its goals to provide Codex with: 1) recommendations on guiding principles to derive labeling reference values from reference values for recommended nutrient intakes, and 2) specific recommendations for revising and expanding the NRVs based on consideration of these guiding principles, and newer references on recommended nutrient intakes such those cited above. The CCFNSDU could then consider these recommendations in proposing updated NRVs.

The United States appreciates the opportunity to offer these comments in response to the Codex Circular Letter 2004/13-NFS DU. We anticipate that we will have additional comments at a later date.

**DRAFT REVISED STANDARD FOR INFANT FORMULA
[AND FORMULAS FOR SPECIAL MEDICAL PURPOSES FOR INFANTS]
SECTION B: FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED
FOR INFANTS AT STEP 4**

AGENDA ITEM No. 5B

BACKGROUND

Reference:

- Report of the 25th CCNFSDU Session (ALINORM 04/27/26, paras 62-102)
- CL 2004/20-NFSDU (Section B draft prepared by Germany)
- Comments at Step 3 CX/NFSDU 04/6 *not yet available*

At the last meeting, the Committee asked the Delegation of Germany to prepare Section B of the Draft Revised Standard for Infant Formula containing provisions for formula for special medical purposes for circulation for comments at Step 3.

Please refer to the above documents for additional background.

DRAFT POSITION

The United States draft position is reflected in the U.S. comments below that were submitted in response to Codex Circular Letter 2004/20-NFSDU.

The United States of America is pleased to offer the following comments in response to Codex Circular Letter 2004/20-NFSDU on the subject of Section B of the Proposed Draft Revised Standard for Infant Formula [and Formulas for Special Medical Purposes Intended for Infants] at Step 3. We appreciate the excellent work of the delegation of Germany in preparing Section B for discussion.

I. General Comments

The United States supports the concept of Section B for formulas for special medical purposes intended for infants and proposes the removal of square brackets in the title.

Our comments on Section B address provisions from Section A that do not have text in square brackets. For provisions in Section A that still have text in square brackets, we recommend deferring any discussions on those provisions in Section B until the brackets are removed from Section A.

As provisions are moved from Section A to Section B, we recommend that they be placed in square brackets in Section B while they are being evaluated for inclusion in Section B.

We anticipate that further comments may be forthcoming as discussions progress.

II. Comments on Specific Sections

U.S. PRELIMINARY DRAFT Positions for the 26th CCNFSDU Session: For Discussion Purposes and Solicitation of Comment at the 9/9/04 U.S. Stakeholders Public Meeting

The United States offers the following comments and recommendations for revisions.

1. SCOPE

B 1.3 is proposed to be the same as section A 1.3:

We defer comments on section B 1.3 until the text in Section A 1.3. has been resolved.

2. DESCRIPTION

2.1 Product Definition

Comment: We find that general definitions cannot be applied to the very diverse types of formulas that comprise foods for special medical purposes for infants. We propose that formulas for special medical purposes intended for infants be grouped by category and discussed. As a starting point for these discussions, we suggest the following categories for consideration:

1. Formulas modified in some essential characteristics but which can be used as the sole source of nutrition (e.g. formulas for preterm infants, extensively hydrolyzed or amino acid formulas for certain disorders).
2. Formulas for inborn errors of metabolism that cannot be used as sole source nutrition. (e.g. product that must omit an essential amino acid such as phenylalanine for use with infants with phenylketonuria (PKU)).

Rationale: If it is the intention to include only products that can be used as sole sources of nutrition, then the proposed definition will cover preterm, protein hydrolysates (extensively hydrolyzed) and amino acid formulas and will exclude formulas for inborn errors of metabolism by definition.

Formulas used for preterm infants have specific nutrients that are present in larger amounts than in routine formulas and they are complete formulas. Extensively hydrolyzed protein or amino acid formulas are also complete formulas. However, formulas used for inborn errors of metabolism have to be “nutritionally incomplete” to meet the needs of the specific disorder (e.g. someone with phenylketonuria has to have a formula without phenylalanine combined with a small amount of routine formula or breast milk to meet growth requirements).

2.1.1 Formula for special medical purposes intended for infants means a breast-milk substitute that complies with section 2, Description of the Codex Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CODEX) STAN 180-1991) and is specially manufactured to satisfy, ~~by itself,~~ the special nutritional requirements of **the infant patients for whom they are intended.** ~~during the first months of life up to introduction of appropriate complementary feeding~~

Comment: We propose the above edits to this sentence to emphasize the uniqueness of these products and the populations for whom they are intended and the addition of the two categories as proposed in 2.1 or as may be modified by discussions.

Rationale: As written, this definition does not fully reflect the conditions of use of formulas for special medical purposes for infants who may have an inborn error of

U.S. PRELIMINARY DRAFT Positions for the 26th CCNFSDU Session: For Discussion Purposes and Solicitation of Comment at the 9/9/04 U.S. Stakeholders Public Meeting

metabolism. Under these circumstances the formulas cannot be sole sources of nutrition and may also be used throughout life.

2.1.2

see Section A 2.1.3

Comment: We request clarification as to whether the intent is to refer to Section 2.1.2 or 2.1.3.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential Composition

Comment: We propose that the content of the table of essential composition in Section A be established before evaluating what type(s) of table(s) might be appropriate for section B.

Rationale: There are unique aspects to formulas for special medical purposes for infants included in section B that require careful consideration.

3.1.1 Formula for Special Medical Purposes Intended for Infants is a product based on ingredients of animal and/or plant origin **and/or** synthetic compounds suitable for infant feeding. [All ingredients and food additives used shall be gluten-free.]

Comment: We propose that the sentence be edited as stated above for clarity.

Rationale: The use of the word “or” would exclude certain formulas that might have synthetic compounds added as ingredients.

3.1.3 The energy content and nutrient composition of Formula for Special Medical Purposes Intended for Infants shall be based on the requirements for infant formula as given in Sections A 3.1.2 and A 3.1.3, except for the compositional provisions which must be modified to meet the special nutrition requirements deriving from disease(s), disorder(s), or medical conditions(s), for whose dietary management the product is specially formulated, labelled and presented.

Comment: Resolution and clarity on the table of essential composition in Section A should be established before referencing it in section B. References to Section A must be done individually for each type of foods for special medical purposes for infants.

Rationale: There are many formulas for special medical purposes for infants. These products differ substantially from routine infant formulas and from each other. Therefore, referring to Section A must be done very carefully.

3.2 Optional Ingredients

3.2.1 In addition to the compositional requirements listed in 2.1.3, other ingredients may be added in order to provide substances ordinarily found in human milk and to ensure that the formulation is suitable ~~as the sole source of nutrition~~ for the infant and for the dietary management of his/her disease, disorder

U.S. PRELIMINARY DRAFT Positions for the 26th CCNFSDU Session: For Discussion Purposes and Solicitation of Comment at the 9/9/04 U.S. Stakeholders Public Meeting

or medical condition.

Comment: We recommend deletion of “as the sole source of nutrition” as indicated in the strikeout above.

Rationale: The use of the phrase “sole source of nutrition” or “by itself,” by definition cannot be used for formulas for infants with metabolic disorders such as phenylketonuria (PKU), Maple Syrup Urine Disease (MSUD) as previously noted. These special formulas are designed to exclude the offending nutrient(s) and are used in combination with routine infant formula or human milk.

3.2.3 Section A 3.2.3: Only L(+) producing lactic acid cultures may be used **in formulas for special medical purposes for infants if shown to be safe and appropriate for use in these vulnerable populations.**

Comment: We propose the above edit.

Rationale: At present, we do not have adequate information to determine the appropriateness or safety of these ingredients or other novel ingredients for all infants who must be fed formulas for special medical purposes.

3.5 Purity Requirements

Section B states: see Section A 3.5

Comment: The United States has proposed changes in the text of Section A 3.5. We recommend that discussion of Section B 3.5 be deferred until the text in Section A is resolved.

3.6 Specific Prohibition

Section B States: see Section A 3.6

Comment: Section A 3.6 contains text in square brackets. We recommend that discussion of section B 3.6 be deferred until the text for Section A is resolved.

9. LABELLING

9.1 The Name of the Food

9.1.2 Information on the nature of ~~the animal or plant~~ proteins **and extent of hydrolysis, if appropriate.** ~~or protein hydrolysates~~

Comment: We propose that the above edits be considered.

Rationale:

- (a) The term “nature” includes the sources.
- (b) The extent of hydrolysis is relevant for appropriate use of products in certain disorders.

U.S. PRELIMINARY DRAFT Positions for the 26th CCNFSDU Session: For Discussion Purposes and Solicitation of Comment at the 9/9/04 U.S. Stakeholders Public Meeting

9.1.3 Formula for Special Medical Purposes Intended for Infants in which the essential characteristics involves a specific modification of the content or nature of the proteins, fats or carbohydrates shall bear a description of this modification and information on the **protein**, amino acid, fatty acid or carbohydrate profile, when necessary.

Comment: We propose the above edit.

Rationale: This edit provides greater clarity.

9.3 Declaration of Nutritive Value

Formula for Special Medical Purposes Intended for Infants shall be labeled with complete nutrition labeling as follows:

9.3.2 Information on energy value shall be expressed in kJ and Kcal per 100 g or per 100 mL as sold as well as prepared for consumption ~~per specified quantity of food as suggested for consumption.~~

Comment: We propose the above deletion.

Rationale: The phrase “per specified quantity of food as suggested for consumption.” suggests a portion size for a food and not infant formulas for special medical purposes. The amounts of formula are not fixed to a specific serving size.

9.3.3 Information on the amounts of protein, carbohydrate and fat in the ~~food~~ **formulas for special medical purposes for infants** shall be expressed per 100g or per 100 mL as sold, **or per 100 kcals (and/or kJ) as consumed.** ~~as well as per specified quantity of the food suggested for consumption.~~ Information on the amounts of essential and non-essential amino acids and/or essential fatty acids may be expressed similarly in metric units as appropriate.

Comment: We propose the above additions and deletions.

Rationale:

- a) The statement should reflect that the name of the product is formula for special medical purposes for infants.
- b) The addition of “or per 100 kcals (and/or kJ) as consumed” is consistent with the text in Section A.
- c) The phrase “per specified quantity of food as suggested for consumption.” suggests a portion size for a food and not infant formulas for special medical purposes. The amounts of formula are not fixed to a specific serving size.

9.3.4 Information on the amounts of vitamins and essential minerals shall be expressed in metric units per 100 g or per 100 mL as sold **or per 100 kcals (and/or kJ) as consumed.** ~~as well as per specified quantity of the food as suggested for consumption.~~

Comment: We propose the above addition and deletion.

Rationale:

U.S. PRELIMINARY DRAFT Positions for the 26th CCFNSDU Session: For Discussion Purposes and Solicitation of Comment at the 9/9/04 U.S. Stakeholders Public Meeting

a) The addition of “or per 100 kcals (and/or kJ) as consumed” is consistent with the text in Section A.

b) The phrase “as well as per specified quantity of the food as suggested for consumption” suggests a portion size for a food rather than infant formulas for special medical purposes. The amounts of formula are not fixed to a specific serving.

9.3.6 Information on osmolality or osmolarity and/or ~~acid-base balance~~ **renal solute load of the product** shall be given when appropriate.

Comment: We propose the above deletions and additions.

Rationale: Maintenance of acid-base balance in the infant is an important physiological state. Label/labeling descriptors for maintaining acid-base balance are: osmolality, osmolarity and renal solute load.

9.5 INFORMATION FOR USE

Section B States: See Section A 9.5

~~9.5: Section A Directions as to the preparation and use of the food, and its storage and keeping after the container has been opened shall appear on the label or on the accompanying leaflet. When in liquid form, infant formula may should be used either directly, or prepared with safe water before feeding according to directions for use. In powdered form infant formula also requires safe, and previously boiled water for preparation.~~

Comment: We propose that section 9.5 be deleted from section B.

Rationale: While appropriate for routine infant formulas, these instructions are too general for formulas for special medical purposes for infants. Information in the additional labeling requirements section 9.6 is more specific and relevant to these special products.

9.6 Additional Labeling Requirements

9.6.4 A prominent statement **identifying whether** ~~indicating that~~ the product is intended as the sole source of nutrition shall appear on the label.

Comment: We propose the above addition and deletion.

Rationale:

(a) Added language clarifies that not all formulas for special medical purposes for infants may be used as a sole source of nutrition:

(b) Sole source of nutrition is not appropriate for all of these types of products.

9.6.9 Feeding instructions, including the method of administration ~~and serving size~~, if applicable.

U.S. PRELIMINARY DRAFT Positions for the 26th CCNFSDU Session: For Discussion Purposes and Solicitation of Comment at the 9/9/04 U.S. Stakeholders Public Meeting

Comment: We propose the above deletion.

Rationale: The phrase “and serving size” suggests a portion size for a food and is not appropriate for infant formulas for special medical purposes. The amounts of formula consumed are not fixed to a specific serving.

9.6.12 The product shall be labeled in such a way as to preclude any confusion with other foods ~~for special dietary uses for infants~~, especially Infant Formula and Follow-up Formulas]

Comment: We propose the deletion above and question the single square bracket.

Rationale: Infant formulas and follow-up formulas are not foods for special medical purposes for infants. This edit clarifies the statement.

In closing, the United States appreciates the opportunity to offer these comments for consideration.

**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)
AT STEP 4**

AGENDA ITEM No. 7

BACKGROUND

Reference:

- Report of the 25th CCNFSDU Session (ALINORM 04/27/26, paras 131-137)
- CL 2004/21-NFSDU (Revised list prepared by Germany)
- Comments at Step 3 CX/NFSDU 04/8 *not yet available*

At the last meeting, the Committee asked the Delegation of Germany to revise the list based on written comments and comments during the meeting. The revised list was circulated for further comment at Step 3.

Please refer to above documents for additional background.

DRAFT POSITION

The United States draft position is reflected in the U.S. comments below that were submitted in response to Codex Circular Letter 2004/21-NFSDU.

The United States is pleased to offer the following comments in response to Codex Circular Letter 2004/21-NFSDU. We appreciate the Delegation of Germany's thoughtful consideration of comments submitted on this topic at the last Committee meeting.

I. General Comments

Proposals to add nutrient compounds to this advisory list

The United States recommends that only nutrient compounds with recognized international or national specifications be included in this list, and all other compounds be removed.

Rationale: The United States strongly supports the Committee's decision to include criteria for amending the advisory list of nutrient compounds. We also support the application of these criteria to the Committee's current deliberations on revisions to this list. That is, if a country proposes to add a nutrient compound to this list the country should also provide information to address how the nutrient compound satisfies all of the criteria in Section 2.1.

For example, we note that the criteria in 2.1(c) specifies that the purity requirements of the nutrient compounds listed be established in an internationally recognized specification or if there is no internationally recognized specification, national purity requirements may be considered. However, as noted in the Circular Letter, no purity criteria at all could be found for a number of the listed substances.

Identity and Purity Specifications for Nutrient Compounds

U.S. PRELIMINARY DRAFT Positions for the 26th CCNFSDU Session: For Discussion Purposes and Solicitation of Comment at the 9/9/04 U.S. Stakeholders Public Meeting

The United States recommends that the CCNFSDU ask the Codex Alimentarius Commission to request that the Joint FAO/WHO Food Standards Programme develop a means to establish identity and purity specifications for nutrient compounds. JECFA could be used as a model.

Rationale: With respect to food additives, it is our understanding that JECFA recommends identity and purity criteria, which are then forwarded to the Codex Committee on Food Additives and Contaminants for endorsement, and then to the Codex Alimentarius Commission for adoption as Codex specifications.

The United States is concerned, however, that the Codex Alimentarius Commission has not systematically established identity and purity specifications for nutrient compounds. As a consequence, it is difficult for the CCNFSDU to make recommendations about the listing of nutrient compounds for which there are no Codex specifications. The use of non-Codex specifications for nutrient compounds will only lead to inconsistencies which do not further the Codex's purpose of protecting consumer health and promoting fair trade practices.

II. Comments on Specific Sections

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

The United States suggests slightly rewording the criteria in Section 2.1 (c) in order to specifically identify Codex specifications in addition to other internationally recognized specifications and national references as follows:

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.

Tables A, B, and C (Purity Requirements):

The United States proposes that the CCNFSDU identify those nutrient compounds that conform with the applicable specifications of identity and purity recommended by Codex rather than listing those evaluated by JECFA. The United States further proposes that the Committee consider whether it would be helpful to give more prominence to nutrient compounds that have Codex specifications compared to those that have other references for purity specifications. For example, the table could include two columns under Purity Requirements: 1) a column labeled "Codex Specifications" that would include a check mark for all nutrient compounds that have Codex specifications, and 2) a second column labeled "Other Specifications" that would include other internationally recognized specifications, and if none, national requirements may be considered.

U.S. PRELIMINARY DRAFT Positions for the 26th CCNFSDU Session: For Discussion Purposes and Solicitation of Comment at the 9/9/04 U.S. Stakeholders Public Meeting

Rationale: The recommendation to identify nutrient compounds that conform with Codex specifications is consistent with the proposed revision of the criteria in 2.1 (c). Moreover, while the purity specifications recommended by JECFA may often be the same as those adopted by the Codex Alimentarius Commission, this is not always the case.

Table A (“...Mineral Salts and Trace Elements...”)

Footnote:

In the latest revision of the advisory list, there is the following footnote for calcium lactate, sodium lactate, and potassium lactate:

“Nutrient compounds that should not be used in infant foods, as proposed by the United States during the 24th Session of the CCNFSDU.”

The United States recommends that this footnote be removed, and that the advisory list only identify the L- forms of these compounds, that is:

- 1.6 Calcium L-Lactate
- 4.6 Sodium L-Lactate
- 5.7 Potassium L-Lactate

Comment: We would like to clarify that at the 24th CCNFSDU Session, the United States did not propose that these nutrient compounds be removed from the advisory list. Rather, the United States pointed out that JECFA has assigned an ADI for these compounds, but includes in their comments that "Neither D(-)-lactic acid nor (DL)- lactic acid should be used in infant foods". Thus, the United States recommended that the forms of the above compounds that may be used in infant foods be clarified in this advisory list, either in the listing of the nutrient source or in a footnote.

Former Table D: United States Justification for the Recommendation to Delete Table D: “Advisory List of Food Additives for Special Nutrient Forms” (in CX/NFSDU 03/8, September 2003)

In the introduction to CL 2004/21-NFSDU, Germany noted that it had removed the “Advisory List of Food Additives for Special Nutrient Forms” based on the proposal made at the 25th CCNFSDU session, but indicated that this topic may require further discussion.

In the event that this topic is reopened for discussion, the United States would like to reemphasize its rationale for proposing that Table D be removed, and that instead, these substances be listed in the food additive sections of the applicable standards, either under existing or new functional classes.

Rationale: The scope of this advisory list should be limited to nutrient compounds for use as nutrient sources. The ingredients listed in Table D appear to serve other purposes (e.g., as carriers of vitamins).

We recognize that the existing advisory list includes a section on “special vitamin forms” that include compounds that are used as carriers of vitamins. This advisory list was developed in the late 1970’s which was before CCFAC and CCFL started work on the

U.S. PRELIMINARY DRAFT Positions for the 26th CCNFSDU Session: For Discussion Purposes and Solicitation of Comment at the 9/9/04 U.S. Stakeholders Public Meeting

Codex International Numbering System for Food Additives (CAC/GL 36). Some Codex members may have supported retaining and expanding this section under the recently proposed title, “Advisory List of Food Additives for Special Nutrient Forms” because the Codex Alimentarius Commission has not established an INS food additive functional class for them (e.g., ingredients used as vitamin carriers).

However, rather than retain and expand a list of substances that are not used as nutrient sources in this advisory list, the United States continues to recommend that CCNFSDU request that CCFAC add an additive functional class for nutrient carriers (or carriers) and possibly other functional classes to the INS as justified to be able to incorporate these substances into the food additive provisions of the respective standards. We note that JECFA has a food additive class for carriers. We further note that the CCFAC is considering a definition for the term “carrier” in view of the development of a suitable approach for consideration of carriers in the General Standard for Food Additives. This committee agreed that a working group would prepare a discussion paper that would address the definition and approaches for the inclusion of carriers in the GSFA, including the use of food additives as “nutrient carriers” as requested by the 25th CCNFSDU session. (ALINORM 04/27/12, April 2004, para 89)

We continue to believe that food additives for use in foods for infants and young children and their maximum use levels are most appropriately listed in the respective food standards rather than in this advisory list. We believe that this will help avoid the potential for inconsistencies (as well as omission and duplication) with this list and the food additive section of these food standards—such as the listing of the same compound in the advisory list and respective standard, but with different maximum levels. Also more specificity may be provided in the food additive provisions in the respective standards. For example, the current version of Table D does not distinguish between permissible food additives and maximum levels according to the type of food and population group (e.g., infant formula, processed cereal based food, etc.). Furthermore, the basis of determining the maximum levels for Table D is unclear.

**PROPOSED DRAFT RECOMMENDATIONS
ON THE SCIENTIFIC BASIS OF HEALTH CLAIMS
(AT STEP 4)**

AGENDA ITEM No. 8

BACKGROUND

Reference:

- Report of the 25th CCNFSDU Session (ALINORM 04/27/26, paras 138-144)
- CX/NFSDU 04/9 (Draft recommendations prepared by France)
- Comments at Step 3 CX/NFSDU 04/9-Add.1 *not yet available*

At the last meeting, the Committee asked the Delegation of France together with all interested parties to revise the document based on written comments and comments during the meeting. The revised document was circulated for further comment at Step 3.

Please refer to the above documents for additional background.

DRAFT POSITION

The preliminary comments below are limited to proposing that the nature and purpose of this Codex text be clarified, and to offering a few suggestions regarding the organization and text in the Preamble. The United States will have comments at a later date regarding the wording of other statements in the preamble and on the organization and content of the major sections of this draft guidance.

I. Nature of Codex Text and Title

The United States proposes that the Committee clarify the nature of this Codex text and pursue its development as Codex guidelines. Moreover, we believe that “guidelines” conveys more accurately the current content in this draft text than “recommendations”.

The United States further notes that the preamble now states that “The following recommendations are intended for governments in order to facilitate their own *evaluation* of health claims ...”. Consequently, we propose that the Committee consider referring to the scientific evaluation of health claims in the title to clarify the purpose of this guidance.

Accordingly, the United States proposes the following edits to the title of this document:

“Proposed Draft ~~Recommendations~~ **Guidelines** on the Scientific Basis-
Evaluation of Health Claims”

U.S. PRELIMINARY DRAFT Positions for the 26th CCNFSDU Session: For Discussion Purposes and Solicitation of Comment at the 9/9/04 U.S. Stakeholders Public Meeting

II. Preamble

The United States proposes the following preliminary edits for consideration:

<p>PREAMBLE</p> <p>“The Codex General Guidelines On Claims (CAC/GL 1-1979 (Rev. 1-1991) states, notably, that:</p> <ul style="list-style-type: none"> • No food should be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect ² • Health claims should be forbidden if they cannot be substantiated ³” <p>“In addition, health claims should be consistent with national nutrition policy and support that policy.”</p> <p>“The following recommendations are intended for governments, in order to facilitate their own evaluation of health claims, used by industry.”</p> <p>“They are only concerned with the nature and the quality of the scientific evidence alleged to support these claims.”</p> <p>“They are not intended for the evaluation of the safety and the quality of the products, for which other provisions are relevant, although it is recalled that definite requirements on these matter have to be met.”</p> <p>“Definition: Hereinafter, the word “product” covers a food, a food group, a constituent of a food (nutrients, other constituents), on which the health claim is based.”</p>	<p>We propose replacing “forbidden” with “prohibited” Rationale: This change uses the same wording in Sec. 3 of the General Guidelines on Claims (i.e., “Prohibited Claims”)</p> <p>We propose deleting this statement: Rationale: This statement is outside the scope of the subject of these guidelines (i.e., the scientific evaluation of health claims) and is already included in the Guidelines for Use of Nutrition and Health Claims which is the correct context for such a statement.</p> <p>We suggest simplifying and clarifying the language as follows: “The following guidelines are intended to provide guidance to governments on the scientific evaluation of health claims.”</p> <p>We recommend that this draft statement for consideration be placed under a new section heading, “SCOPE”.</p> <p>We recommend that this draft statement for consideration be placed under a new section heading, “SCOPE”.</p> <p>We recommend that this draft definition for consideration be placed under a new section heading, “DEFINITIONS”.</p>
--	---

² See CAC/GL 1-1979 (Rev. 1-1991)---Section 1-“SCOPE AND GENERAL PRINCIPLES” Sec. 1.2

³ See CAC/GL 1-1979 (Rev. 1-1991)—Section 3-“PROHIBITED CLAIMS” Sec. 3.3

**DISCUSSION PAPER ON THE APPLICATION OF RISK ANALYSIS
TO THE WORK OF THE CCNFSDU**

AGENDA ITEM No. 9

BACKGROUND

Reference:

- Report of the 25th CCNFSDU Session (ALINORM 04/27/26, paras 145-149)
- CX/NFSDU 04/10 (Discussion paper prepared by Australia) *not yet available*

At the last meeting, the Committee agreed that the Delegation of Australia would lead an electronic working group, with the understanding that an outline of specific guidelines prepared on the basis of Working Principles for Risk Analysis adopted by the Commission would aim to be prepared for consideration at the next session of the Committee.

Please refer to the above documents for additional background.

DRAFT POSITION

U.S. comments submitted in response to a preliminary draft of the discussion paper are summarized below. We anticipate that we will have additional comments after the final discussion paper becomes available.

The United States is pleased to provide the following comments on the *Draft Principles for Risk Analysis for Application to CCNFSDU*, as part of the CCNFSDU electronic working group responsible for developing this document.

COMMENTS

The United States commends Australia for both taking the initiative to encourage CCNFSDU to develop a risk analysis document for the work of CCNFSDU and for an excellent job in developing a thoughtful discussion paper and a good initial draft Working Principles text.

The United States is fully supportive of the development by CCNFSDU of a set of working principles for risk analysis for use by the Committee. A CCNFSDU risk analysis document will be an important guidance text for the future work of the Committee. Such a document is also consistent with the mandate of the Codex Alimentarius Commission for relevant Codex committees to develop specific guidelines on risk analysis pertinent for their own work.

We note that the paper accompanying the Principles document raises several key issues and asks several questions. Principal among these are issues relating to the definitions of risk, hazard and the concept of food safety. These are clearly fundamental issues that, we believe, are worthy of discussion. They will, however, require very careful consideration. For example, we believe that care is needed in considering a redefinition of risk as currently defined by Codex to include nutritional risk.

***U.S. PRELIMINARY DRAFT Positions for the 26th CCNFSDU Session: For Discussion
Purposes and Solicitation of Comment at the 9/9/04 U.S. Stakeholders Public Meeting***

For this concept to move forward, the CCNFSDU will need a full discussion on the issues and questions raised.

DISCUSSION PAPER ON THE DEFINITION OF TRANS-FATTY ACIDS

AGENDA ITEM No. 10

BACKGROUND

Reference:

- Report of the 25th CCNFSDU Session (ALINORM 04/27/26, para 150)
- CX/NFSDU 04/11 (Discussion paper prepared by Malaysia and Denmark)

At the last meeting, the Committee noted that discussions on the definition of *trans* fatty acids required more time and preparation, and accepted the offer of the Delegation of Malaysia in cooperation with Denmark and other interested parties working electronically to prepare a discussion paper for consideration at the next session of the Committee.

Please refer to the above documents for additional background.

DRAFT POSITION

Proposed Definition of *Trans* Fatty Acids

The United States supports the definition proposed for *trans* fatty acids on p. 2 of the discussion paper. The Committee may want to consider whether to simplify the language of the definition that will be placed in the Codex Guidelines on Nutrition Labelling. For example, the language might be simplified as follows:

Trans fatty acids are defined as all unsaturated fatty acids having non-conjugated double bonds in the *trans* configuration and produced through hydrogenation of oils and fats (both vegetable and animal/marine origin) in the presence of a suitable chemical catalyst. The definition however *excludes* those conjugated *trans* fatty acids present naturally in animal fats and their products which include conjugated linoleic acid (CLA).

Edits to the first two sentences on p. 2 are shown below for reference:

~~*Trans* fatty acids are defined as all the geometrical isomers of monounsaturated and polyunsaturated fatty acids having non-conjugated [interrupted by at least one methylene group (CH₂-CH₂-)] carbon-carbon double bonds in the *trans* configuration. This includes the *trans* monoenes (mainly stereoisomers of elaidic acid) and the *trans* isomers of polyunsaturated fatty acids (e.g., *trans* dienes, *trans* trienes etc.) with non-conjugated carbon-carbon double bonds, and produced through hydrogenation of oils and fats (both vegetable and animal/marine origin) in the presence of a suitable chemical catalyst.~~

Appendix- Background Information on *Trans* Fatty Acids

The United States notes that the discussion paper includes an appendix entitled, “Background Information on *Trans* Fatty Acids”, and refers to this appendix on p.2 of the discussion paper under “Proposed Definition of *Trans* Fatty Acids”. The introduction to

U.S. PRELIMINARY DRAFT Positions for the 26th CCNFSDU Session: For Discussion Purposes and Solicitation of Comment at the 9/9/04 U.S. Stakeholders Public Meeting

this appendix states that it is intended to summarize information on the nature and occurrence of *trans* fatty acids as well as their potential impact on human health. It further states that this is not meant to be a comprehensive review of the subject but merely serves to provide some background information to assist in understanding of the proposed definition on *trans* fatty acids.

The United States notes that the Codex Committee on Food Labelling asked the Committee on Nutrition and Foods for Special Dietary Uses(CCNFSDU) to provide a definition of *trans* fatty acids for the purposes of the Guidelines (on Nutrition Labelling) (ALINORM 03/22A, para 35). The United States believes that a discussion of the health effects of *trans* fatty acids is not necessary for a definition to be used by the Codex Committee on Food Labelling. Consequently, we recommend that the CCNFSDU only focus on the definition of *trans* fatty acids, and that reference to this Appendix not be included in the definition statement or be incorporated into the Codex Guidelines on Nutrition Labelling or related Codex texts.