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

U.S. DRAFT POSITIONS

As of

September 1, 2004

(PART 1 of 2)

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 meeting 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, 2004 on the following three agenda items for the 26th session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)[1]:

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

The U.S. government plans to submit comments on the above Codex texts in response to a Codex Circular Letter that requested comments by September 15 (CL 2004/36-GEN). This circular letter and other circular letters can be accessed at the web address below:

http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/oa/codex/nfsdu.htm

As previously noted in Dr. Schneeman's July 22, 2004 letter to interested parties, if you would like to provide comments on any of the above texts to be considered in preparing U.S. comments in response to this Circular Letter, please send them to the following e-mail address by **September 10, 2004.** (nancy.crane@cfsan.fda.gov.) Otherwise, we invite you to submit comments by the end of September in order that the U.S. delegate may still consider them in preparing for the upcoming CCNFSDU meeting.

In addition, 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 these and other 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).

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[1]A separate document (U.S. Draft Positions as of September 9, Part 2 of 2) will identify U.S. preliminary draft positions on the remaining agenda items for the 26th CCNFSDU Session, and will be made available on or before the September 9, 2004 CCNFSDU public meeting..

DRAFT GUIDELINES FOR VITAMIN AND MINERAL SUPPLEMENTS (AT STEP 7)

AGENDA ITEM No. 4

BACKGROUND

Reference:

- Report of the 25th CCNFSDU Session (ALINORM 04/27/26, Para 36-61, Appendix IV
- Comments at Step 6 (CX/NFSDU 04/4) *not yet available*

At the last session, the Committee, recognizing that considerable progress had been made on the text, agreed to advance the proposed draft guidelines for adoption at Step 5 by the Codex Alimentarius Commission.

This document has been before the CCNFSDU for many years. A main point of discussion over the last few sessions has been the text that pertains to setting maximum levels of vitamins and minerals in vitamin and mineral supplements. The United States and other delegations have advocated taking a science-based risk assessment approach to setting maximum levels for a number of years, and this approach was adopted at this session. The United States also advocated for the removal of proposed text indicating that all labels shall bear a statement that the supplement should be taken on advice of a nutritionist, dietician or medical doctor. The Committee agreed to delete this text. Other sections where there have been disagreements, including the Preamble and Scope, were agreed upon.

At the 32nd CCFL session, the CCFL asked the CCNFSDU to consider further the wording of two labeling sections (i.e., section 5.4 which states that the amounts of vitamins and minerals declared should be those per portion of the product as recommended for daily consumption on the labeling, and if different, the amount per single use; and section 5.5 which states that information on vitamins and minerals should also be expressed as a percentage of the nutrient reference values… in the Codex Guidelines on Nutrition Labelling.) The CCFL endorsed all other labeling sections as proposed.

DRAFT POSITION

I. General Comments

Our comments mainly address the text that is still in brackets, which we understand will be the focus of discussion at the next Committee meeting.

II. Comments on Specific Sections

2. DEFINITIONS

2.1 Vitamin and mineral food supplements for the purpose of these guidelines derive their nutritional relevance primarily from the minerals and/or vitamins they contain. Vitamin and mineral supplements are sources in concentrated forms of those nutrients alone or in combinations, marketed in forms such as capsules, tablets, powders, solutions etc., not in a conventional food form and whose purpose is to supplement the intake of vitamins and/or minerals from the normal diet.

~~[They are designed to be taken as measured small unit quantities].~~

Rationale for proposing to delete the sentence in brackets: We believe it is unnecessary because Section 2.1 already indicates that these products are in concentrated forms and are not in conventional food form, and provides examples of the type of products (e.g., capsules, tablets, etc.). In addition, the sentence may not contribute to any additional clarity for the definition because the word "small" is an imprecise term.

3.1.2 The sources of vitamins and minerals may be from either ~~[~~natural or synthetic sources~~]~~ and should be based on considerations such as safety and bioavailability. In addition, purity criteria should take into account FAO/WHO standards, or, if FAO/WHO standards are not available, international Pharmacopoeias or recognized international standards. In the absence of criteria from these sources, ~~and~~ national legislation may be used.

Comment: The United States recommends that the brackets be removed from "natural or synthetic sources", and that this phrase be retained in the standard. For editorial reasons, we propose to delete "and" from the last sentence.

3.2 Contents of Vitamins and Minerals

3.2.2 Maximum amounts of vitamins and minerals in vitamin and mineral supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking into account:

(a) upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups;
(b) the daily intake of vitamins and minerals from other dietary sources.

~~[When the maximum levels are set, due account should be taken to the reference intake values of vitamins and minerals for the population.]~~

Rationale for proposal to delete the sentence in brackets: The United States is unclear as to the meaning or purpose of this statement. It would appear to already be an integral part of the scientific processes involved in both options stated above. In the absence of a clear need for this sentence, we recommend deleting it.

5. LABELLING

5.1 Vitamin and minerals ~~supplements are~~ **should be** labeled according to the Codex Standard for the Labelling of Prepackaged Foods (Codex-Stan 1-1985, Rev. 1- 1991) as well as according to the General Guidelines on Claims (CAC/GL 1-1979).

Rationale for proposed edits: The above edits reflect the recommendations made at the 32nd session of the Codex Committee on Food Labeling for consistency with similar labelling sections in Codex texts (ALINORM 04/27/22, para 26).

5.2 The name of the product shall be "food supplement" with an indication of the category(ies) of nutrients or of the individual vitamin(s) and/or mineral(s) contained in the product as the case may be.

Comment: For editorial reasons, we propose adding "5.2" to identify this section.

5.4 The amounts of the vitamin and minerals declared should be those per portion of the product recommended for daily consumption on the labelling**,** ~~[~~and if different, the amount per single use~~].~~

Comment: The United States recommends that the brackets in this sentence be removed.

DRAFT REVISED STANDARD FOR INFANT FORMULA (AT STEP 7)

AGENDA ITEM No. 5a

BACKGROUND

Reference:

- Report of the 25th CCNFSDU Session (ALINORM 04/27/26, Para 62-102, Appendix V
- CRD 1
- Comments at Step 6 (CX/NFSDU 04/5) *not yet available*

At the 25th CCNFSDU session, the Committee noted that significant progress was made in the revision of the proposed draft standard and agreed to advance Section A containing provisions for infant formula for adoption at Step 5 by the Codex Alimentarius Commisison.

The Committee has discussed the revision of this standard for a number of years. The original standard was adopted in 1981. Subsequent research has provided additional data on optimum nutrition for infants. The Committee had not been able to agree on whether there should be a single standard covering provisions for all infants, or separate standards for formula for healthy infants and for formula for special medical purposes for infants. After lengthy debate, the Committee decided as a compromise to elaborate one standard having a preamble and two different sections: Section A which would cover formula for healthy infants and another (Section B) for formula for special medical purposes for infants. It was agreed that the decision how to incorporate the standard into national law (e.g., whether to have one standard with sections or two separate standards) would be left to national authorities.

At the last session, the Committee decided to work on the revision of Section A formula first as it was further advanced. With regard to establishing minimum and maximum values for the essential composition of infant formula, the U.S. had previously chaired an electronic working group that proposed minimum and maximum values and general principles for establishing these values. Prior to the 25th CCNFSDU session, the Delegation of Germany chaired an electronic working group and a meeting before the plenary session to continue this work. The Committee agreed to attach the general principles as an Annex to the revised standard in order to ensure transparency and document the basis for Committee decisions. The Committee also agreed to generally accept the proposals of the working group for minimum and maximum values, although the proposal included many nutrient values in square brackets where there was still no agreement. The Committee agreed that another working group would be convened before the next session to review further comments and proposals for compositional requirements.

With regard to the food additive provisions of Section A of this draft standard, the proposals from the working group chaired by Switzerland were incorporated**,** and the Committee agreed to retain the whole section in square brackets pending clarification by the Committee on Food Additives and Contaminants on certain issues, and further discussion at the next session. With regard to the labeling provisions, the CCFL endorsed some provisions, and referred others back to the CCNFSDU for further consideration. Two labeling provisions that would prohibit health claims were retained in square brackets pending further discussion in the CCNFSDU and the CCFL, and review after the final adoption of the Draft Guidelines for Use of Health and Nutrition Claims.

The Committee asked the Delegation of Germany to prepare Section B for formula for special medical purposes for circulation for comments at Step 3. (Note: The U.S. draft position below does not address Section B).

DRAFT POSITION

Below are proposed edits on specific sections of this draft standard and the rationale. The comments on various sections of this draft standard are directed primarily to information enclosed in square brackets.

TITLE
We propose removing the square brackets around "and Formulas for Special Medical Purposes Intended for Infants" in the title of this standard.

PREAMBLE:

This standard is divided into two sections. Section A refers to Infant Formula **that meets the normal nutritional requirements of infants**, and Section B deals with Formulas for special medical purposes intended for Infants.~~]~~

> Rationale for adding bolded text: We believe the addition of this phrase would help clarify the differences in the types of products included in Section A and Section B.

Section A: Infant Formula

1. SCOPE

1.3 The application of this section of the Standard should take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA54.2 (2001)**.** ~~and [WHA55.25 (2002)].~~

> Comment: We recommend that WHA 55.25 be deleted from item 1.3.
>
> Rationale: Inclusion of WHA 55.25 would require that Codex consider recommendations

in future resolutions of the World Health Assembly in improving the quality standards of processed foods for infants and young children and promoting their proper use. We do not recommend that Codex commit to a requirement to accept all future WHA resolutions prior to review or evaluation by Codex.

2. DESCRIPTION

2.1 Product Definition

2.1.2 [The safety and nutritional adequacy of infant formula shall be scientifically demonstrated**.** ~~in meeting the nutritional requirements of the infants for whom they are intended.~~ **by clinical studies in infants and other studies as appropriate**].

Comment: We propose replacing the above phrase.

Rationale: Infant formulas must be both safe and nutritionally adequate. While meeting nutrient requirements of the infant is an important part of showing nutritional adequacy and safety of infant formula, these alone may not always provide sufficient information.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

[3.1 Essential Composition

3.1.2 Infant formula prepared ready for consumption in accordance with instructions of the manufacturer shall contain per 100 ml not less than ~~60 kcal (250 kJ~~) **63 kcal (262 kJ)** and not more than [70 ~~or 75~~] kcal ([295 ~~or 315~~] kJ) of energy.

Comment: We propose consideration of a higher minimum energy value for infant formulas. We support adoption of 70 kcal/100 mL (295 kJ/100 mL) as the maximum energy level.

Rationale:

(a) There is a lack of evidence and experience with infant formulas with energy density below 63 kcal/100 mL. Although 60 kcal/100mL may be adequate for breast fed infants, differences in bioavailablity of energy and nutrients in infant formula suggest that a minimum at this low level may not be justified without further research on the effects of decreased caloric density on macronutrient requirements and infant growth and body composition.

(b) We are not aware of evidence that shows energy levels greater than 70 kcal/100 mL are needed to meet the energy and normal nutrient requirements of infants.

3.1.3 Infant formula prepared ready for consumption shall contain per 100 kcal ~~[100 kJ~~] **(100 kJ)** the following nutrients within the following minimum and maximum levels.

The general principles for establishing these levels are identified in Annex II of this standard.

Editorial Comment: The presence of square brackets around 100 kJ is confusing, as this is not a discussion point. The confusion can be alleviated by putting parentheses around 100 kJ as shown.

a. Protein

(i) Protein content = nitrogen content x [6.25 or 6.38]. **The factor 6.38 should be used for intact milk proteins and 6.25 should be used as the factor for soy and other proteins, including partially hydrolyzed proteins.**

Comment: We recommend use of 6.38 as the factor for intact cows milk protein and use of 6.25 as the factor for soy and other proteins, including partially hydrolyzed proteins. If only one value is used, it should be 6.25 for all protein sources used in infant formula.

Rationale: The value 6.38 is well established as a specific factor appropriate for conversion of nitrogen to protein for cows milk. The value of 6.25 is appropriate as a general conversion factor for other protein sources.

(ii) For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex 1); nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together [unless the methionine to cystine ratio exceeds 2.0]

Comment 1: We request reference(s) and clarification for values in the Annex 1 table.

Rationale: The draft standard does not identify the source of data or the method of calculation for this table, so it is not possible to evaluate the quality of the information. It appears that these may be values used for the Table in the 1979 standard. Newer data should be considered if available. Whatever source data are used in this table, all calculations must be transparent, comprehensible, reproducible and referenced.

Comment 2: We recommend the removal of the square brackets around: [unless the methionine to cystine ratio exceeds 2.0]

Rationale: Appropriate ratios are important to amino acid balance. It would be equally appropriate to include the same information about adding the concentrations of phenylalanine and tyrosine and their ratios.

GENERAL TABLE COMMENTS (Section 3.1.3)

Comment: We propose that the table of essential composition in Section A list only essential nutrients (See below). We further propose that another table be added to Section 3.2 that includes some of the constituents that were listed in the table as proposed in ALINORM 04/27/26 (See proposed table under Section 3.2-Optional Ingredients.)

Immediately below we show all of our proposed edits as strike-outs or additions in bold type to the table in ALINORM 04/27/26, which we label Table A. This table may be difficult to follow. Therefore, we provide a list (Table B) that summarizes the changes we propose for the table (ALINORM 04/27/26). For the readers' convenience, we also include a proposed table of essential composition that includes only the essential nutrients (Table C).

Rationale: The expanded scope of the table in Section 3.1.3 is confusing as proposed in ALINORM 04/27/26. Previous versions of the table have included only essential nutrients. We believe that the focus of the table in this standard should be on levels of essential nutrients. The essential nutrients can be provided by various appropriate choices of ingredients that have been shown to be suitable for infant feeding, as provided for in 3.1.1.

Comment: We propose deleting the items in the table of essential composition as proposed in ALINORM 04/27/26 that are not essential nutrients.

Rationale: We are concerned that a table that includes more than one category of constituents (e.g., nutrients and ingredients) is likely to be misinterpreted A table focused on essential nutrients may avoid confusion and potential misinterpretation. In addition, we believe that 3.1.1 which stipulates that ingredients used in infant formula must have been proven to be suitable for infant feeding captures the expectation for safety of ingredients. We are concerned that a table that includes various categories beyond the essential nutrients could appear to be all-inclusive when, in fact, it cannot be so.

Comment with regard to maximum levels in the Section 3.1 table:
We support the inclusion of maximum values for nutrients with a documented risk of adverse health effects that are determined using a science-based risk assessment approach. For those nutrients without evidence of adverse health effects, we propose that no number be placed in the table, and a designation of "To Be Determined (TBD)" be considered in these cases.

Rationale: We continue to believe that numbers for minimum and maximum values should be based on science. We note that the language in item 4 of the General Principles for Establishing Minimum and Maximum Values for the Essential Composition of Infant Formula (Annex II) is in square brackets, and is still open to discussion. This is the language that provides a key principle for setting maximum values.

TABLE A. TABLE OF ESSENTIAL COMPOSITION SHOWING CHANGES PROPOSED BY THE UNITED STATES

Ingredient	Unit	Minimum	Maximum
a) Protein [1]	[g]	**1.8** [2]	**3**
~~Cow's milk protein~~	~~[g]~~	~~1.8~~ [2]	~~3~~
~~Soy protein \ Protein hydrolysates~~	~~[g]~~	~~[1.8 or 2.25]~~	~~3~~
~~L-carnitine~~	~~[mg]~~	~~[≥ 1.2]~~	~~N.S.~~
~~Addition of taurine~~	~~[mg]~~	~~[0]~~	~~[12]~~
~~Nucleotides, if added~~ [4]	~~[mg]~~	~~[0]~~	~~[5]~~
b) Fat and fatty acids			
Total fat	[g]	4.4	[6.0 or 6.5]
~~[Phospholipids]~~	~~-~~	~~N.S.~~	~~[≤ 1 g.L]~~
~~Inositol]~~	~~[mg]~~	~~[4]~~	~~[40]~~
-	-	-	-
~~[Lauric and myristic acids]~~	-	-	~~[Together ≤ 20% of total fatty acids]~~
Linoleic acid	[g]	[0.3 or 0.5]	1.2
[Formulae without added LCPUFA]			
α-linolenic acid	[mg]	[≥50 or 100]	N.S.
Linoleic/α-linolenic ratio		5	15
~~***[Formulae with added LCPUFA]***~~	~~-~~	~~-~~	~~-~~
~~α-linolenic acid~~ [5]	~~[mg]~~	~~[≥50]~~	~~-~~
~~Linoleic/α-linolenic ratio~~ [5]	~~-~~	~~[5-20]~~	~~-~~
~~[n-6 LCPUFA]~~	~~-~~	~~[≤ 2% of total fatty acids]~~	
~~[Arachidonic acid]~~	~~-~~	~~[≤ 1% of total fatty acids]~~	
~~[n-3 LCPUFA]~~	~~-~~	~~[≤ 1% of total fatty acids]~~	
~~[Ratio EPA/DHA (wt/wt)~~	~~-~~	~~[< 1]~~	
~~[Cottonseed/sesame oils~~	~~-~~	~~No use of these type of oils]~~	~~-~~
~~[Conjugated linoleic acid (CLA)~~	~~-~~	~~No intential addition]~~	~~-~~
~~[*trans* fatty acids~~	~~-~~	~~≤ 3 or 4% of total fatty acids]~~	~~-~~
~~[Erucic acid~~	~~-~~	~~-~~	~~≤ 1% of total fatty acids~~
c) Carbohydrates			
Total carbohydrates	[g]	9	14
~~[Lactose in cows' milk protein- and protein hydrolystates formula~~	~~[g]~~	~~≥ 4.5]~~	
~~[Lactose in soy protein formula~~	~~-~~	~~No requirement]~~	

~~[Saccharose~~	-	~~None in cows' milk protein and soy protein formulae ≤ 20% of total carbohydrates in protein hydrolysates formulae]~~	
~~[Fructose~~	-	~~None]~~	
~~[Glucose~~	-	~~No intentional addition of formulae based on intact proteins, ≤ 2 g in formula based on protein hydrolysates]~~	
~~[Maltose, maltodextrins,~~	-	~~Unrestricted]~~	
~~[Starches~~	-	~~≤ 30% of total carbohydrates (≤ 2 g/100 mL) as precooked or gelatinised naturally gluten-free starches. No starches modifed by enzymatic cross-linking or stabilisation]~~	
d) Vitamins			
Vitamin A [6]	[µg RE]	60	180
Vitamin D [7]	[µg]	1	2.5
Vitamin E [8]	[mg αTE]	≥ 0.5 mg αTE/g PUFA ~~[(corrected for double bond, see footnote [9])~~], but in no case less than 0.5 mg /100 kcal	[5]
Vitamin K	[µg]	4	[20]
Thiamin	[µg]	[40 or 60]	[300]
Riboflavin]	[µg	~~[60~~ or 80]	[400]
Niacin	[µg]	[300 or 800]	[1200]
Vitamin B_6	[µg]	35	[165]
Vitamin B_{12}	[µg]	0.1	[0.5]
Pantothenic acid	[µg]	[300 or 400]	[2000]
Folic acid	[µg]	~~[4 or~~ 10]	[30]
Vitamin C [10]	[mg]	[8 or 10]	[30]**.**
Biotin	[µg]	1.5	[7.5]
e) Minerals and Trace Elements			
Iron	[mg]	**[.45]**	**[1.9]**
~~Cow's milk protein and protein **partial** hydrolysate formulae~~	-	~~[0.3 or 0.5]~~	~~[1.3 or 1.5]~~
~~Soy protein formulae~~	-	~~[0.45 or 1.0]~~	~~[1.9 or 2.0]~~

Calcium		50	[140]
Calcium/Phosphorus-Ratio	[mg]	1	[2.0 or 2.2]
Phosphorus		~~Cows' milk protein- and protein hydrolysate formulae: 25~~	90
	[mg]	~~Soy protein formulae: [30]~~	[100]
		[Bioavailable phosphorus, ~~if measured~~:20-70]	
Magnesium		5	15
Sodium	[mg]	20	60
Chloride	[mg]	50	[125 or 160]
Potassium	[mg]	60	[145 or 160]
~~Chromium~~	~~[mg]~~	~~No recommended minimum and maximum levels~~	
Manganese	[µg]	[1 or 5]	[100]
~~Molybdenum~~	[µg]	~~No recommended minimum and maximum levels~~	
Fluoride	[µg]	N.S.	[100]
Iodine	[µg]	[5 or 10]	[50]
Selenium	[µg]	[N.S. or 3]	[9]
Copper [11]	[µg]	[20 or 35]	[80 or 100]
Zinc [mg]	[µg]	**[0.5 or 0.75]**	**[1.5 or 2.4]**
~~Cow's milk protein and protein hydrolysate formulae~~	-	~~0.5~~	~~[1.5]~~
~~Soy protein formulae~~	-	~~0.75~~	~~2.4~~
f) Choline	[mg]	7	[30 or 50]
[Inositol]	[mg]	[4]	[40]

Footnotes for essential composition table:

1. Calculation of protein content: N x [6.25 or 6.38]; **depending on the ingredient source]**[non-protein nitrogen (formulae made from intact protein) <15% of total nitrogen]. **For the following ingredient sources, minimum levels proposed (g/100 kcal) are: cows milk protein, 1.8; soy protein [1.8 or 2.25]; partially hydrolyzed protein* [1.8 or 2.25]; respectively (*extensively hydrolyzed protein formulas are properly categorized as foods for special medical purposes for infants.)**

2. Infant formulae ~~containg 1.8 g/100 kcal~~ **approaching the minimum level of protein** should be clinically evaluated.

3 N.S. = not specified

4 Maximum content per nucleotide as specified in the text. (see end of table).

5 If DHA content >0.2% of total fatty acids.

6 expressed as retinol equivalent (RE). 1 µg RE = 3.33 IU Vitamin A

7 Calciferol. 1 µg calciferol = 40 IU Vitamin D

8 Alpha-Tocopherol-Equivalent (TE)

a) Protein

TABLE B. Summary of suggested edits to ALINORM 04/27/26 Table of Essential Composition

Delete the following from this table and place in footnote to table of essential composition

Cow's milk protein
Soy protein \ Protein hydrolysates

Delete the following from this table and place in new proposed table of optional constituents:

L-carnitine
taurine
Nucleotides
- Cytidine 5'-monophophate (CMP)
- Uridine 5'monophophate (UMP)
- Adenosine 5'-monophophate (AMP)
- Guanosine 5' monophophate (GMP)
- Inosine 5'-monophophate (IMP)

Phospholipids
Formulae with added LCPUFA:
- α-linolenic acid
- Linoleic/α-linolenic ratio
- n-6 LCPUFA]
- Arachidonic acid]
- n-3 LCPUFA]

Delete the following constituents from table of essential composition

Lactose in cows' milk protein- and protein hydrolystates formula
Lactose in soy protein formula
Saccharose
Maltose, maltodextrins,
Fructose
Glucose
Starches

Ratio EPA/DHA (wt/wt)
Cottonseed/sesame oils
Conjugated linoleic acid (CLA)
trans fatty acids

Proposed to move from minimum to maximum column and other proposed changes as shown in proposed table:

n-6 LCPUFA
Arachidonic acid
n-3 LCPUFA

Change location in the table of essential composition
Inositol

TABLE C. PROPOSED TABLE OF ESSENTIAL COMPOSITION THAT INCORPORATES PROPOSED EDITS FROM THE UNITED STATES

Nutrient	Unit	Minimum	Maximum
a) Protein [1]	[g]	**1.8[2]**	**3**
b) Fat and fatty acids			
Total fat	[g]	4.4	[6.0 or 6.5]
Linoleic acid	[g]	[0.3 or 0.5]	1.2
α-linolenic acid	[mg]	[≥50 or 100]	N.S.
Linoleic/α-linolenic ratio		5	15
c) Carbohydrates			
Total carbohydrates	[g]	9	14
d) Vitamins			
Vitamin A [3]	[µg RE]	60	180
Vitamin D [4]	[µg]	1	2.5
Vitamin E [5]	[mg αTE]	≥ 0.5 mg αTE/g PUFA [(~~corrected for double bond, see footnote~~ [9])], but in no case less than 0.5/100 kcal	[5]
Vitamin K	[µg]	4	[20]
Thiamin	[µg]	[40 ~~or~~ 60]	[300]
Riboflavin]	[µg	~~[60 or~~ 80~~]~~	[400]
Niacin	[µg]	[300 or 800]	[1200]
Vitamin B_6	[µg]	35	[165]
Vitamin B_{12}	[µg]	0.1	[0.5]
Pantothenic acid	[µg]	~~[~~300 or 400]	[2000]
Folic acid	[µg]	~~[4 or~~ 10~~]~~	[30]
Vitamin C [6]	[mg]	[8 or 10]	[30]
Biotin	[µg]	1.5	[7.5]
e) Minerals and Trace Elements			
Iron	[mg]	**[.45]**	**[1.9]**
Calcium	[mg]	50	[140]
Calcium/Phosphorus-Ratio		1	[2.0 or 2.2]
Phosphorus	[mg]	[Bioavailable phosphorus~~, if measured:~~ 20	Bioavailable phosphorus~~, if measured~~: 70
Magnesium	[mg]	5	15
Sodium	[mg]	20	60

Chloride	[mg]	50	[125 or 160]
Potassium	[mg]	60	[145 or 160]
Manganese	[µg]	[1 or 5]	[100]
Fluoride	[µg]	N.S.	[100]
Iodine	[µg]	[5 or 10]	[50]
Selenium	[µg]	[N.S. or 3]	[9]
Copper [7]	[µg]	[20 or 35]	[80 or 100]
Zinc	[mg]	**0.5**	**[1.5]**
f) Choline	[mg]	7	[30 or 50]
[Inositol]	[mg]	~~[4]~~	~~[40]~~

Table footnotes:

1. Calculation of protein content: N x [6.25 or 6.38, **depending on the ingredient source**]; [non-protein nitrogen (formulae made from intact protein) <15% of total nitrogen]. **For the following ingredient sources, minimum level proposed (g/100 kcal) are: Cows milk protein, 1.8; Soy protein [1.8 or 2.25]; Partially hydrolyzed protein* [1.8 or 2.25]; respectively (*extensively hydrolyzed protein formulas are properly categorized as foods for special medical purposes for infants.)**
2. Infant formulae ~~containing 1.8 g/100 kcal~~ **approaching the minimum level of protein** should be clinically evaluated.
3. expressed as retinol equivalent (RE). 1 µg RE = 3.33 IU Vitamin A
4. Calciferol. 1 µg calciferol = 40 IU Vitamin D
5. Alpha-Tocopherol-Equivalent (TE)
6. expressed as ascorbic acid
7. ~~[~~Adjustments may be needed in these levels for infant formula made in regions with a high content of copper in the water supply~~]~~

Justification for Proposed Edits

Comment: We recommend a single entry for total protein in the Essential Composition table, as shown by suggested edits in this table below. Footnotes 1 and 2 should be retained with suggested edits as shown in the table. We suggest removal of the square brackets in footnote 1.

Rationale:
(a) As noted in the general comment, this table of essential composition should include only nutrient levels. Ingredient sources should be listed in a separate section for optional ingredients (3.2). If minimum levels are listed for specific ingredients, it would be appropriate to make adjustments for protein quality in any minimum values specified in the optional ingredients section.

(b) Footnote 1: As discussed above in section 3.1.3 (i), use of a different factor for proteins other than cow milk is appropriate based on differences in protein quality. The phrase "depending on ingredient source" should be added to footnote 1 for clarity. The following sentence should be added: "For the following ingredient sources, minimum level proposed (g/100 kcal) are: Cows milk protein, 1.8; Soy

protein [1.8 or 2.25]; Partially hydrolyzed protein* [1.8 or 2.25]; respectively (*extensively hydrolyzed protein formulas are properly categorized as foods for special medical purposes for infants). We propose this addition to include explanatory language for the table.

(c) Footnote 2: The numerical value for the minimum protein content should be deleted in footnote 2. It is no longer appropriate to state a specific value because the value may vary depending on the protein source.

b. Fat and Fatty Acids

Comment: This section contains multiple categories of substances, i.e., essential, optional, and undesirable compounds. Again, we propose including only essential nutrients (total fat and 18-C essential fatty acids and their ratio) in the table. The fat ingredients and fatty acids (e.g., long-chain polyunsaturated fatty acids) that were categorized as optional should be considered under optional components in Section 3.2. We propose deletion from the table of all substances that were identified as undesirable for use in infant formula.

Rationale: This change carries through the earlier discussion about the content of the table of essential composition. We believe that the language in Section 3.1.1 (ingredients which have been proven to be suitable for infant feeding) guards against the use of undesirable and inappropriate ingredients in a comprehensive manner.

c. Carbohydrates

Comment: This section also contains multiple categories of substances. We propose that only total carbohydrate be listed in this table.

Rationale: Individual carbohydrate sources should be deleted from the table as Section 3.1.1 requires use of ingredients that are proven to be suitable for infant feeding. This change carries through the earlier discussion about the content of the table of essential composition.

d. Vitamins

Vitamin E

Comment: We support the minimum value of ≥0.5 mg α- TE/ g PUFA , but in no case less than 0.5 mg/100 kcal. We also suggest deletion of the proposed provision currently included in square brackets.

Rationale:
a) Current science supports the use of this minimum level for vitamin E.

b) Applying correction factors for each individual PUFA will require very exacting analysis for fatty acids and does not appear to offer an advantage over the suggested minimum level of ≥0.5 mg α- TE/ g PUFA , but in no case less than 0.5 mg/100 kcal.

Riboflavin

Comment: We propose selection of 80 ug/100 kcal as the minimum level for riboflavin.

Rationale: Current scientific evidence supports this value as a minimum level for riboflavin.

Folic Acid

Comment: We propose selection of 10 ug/100 kcal as the minimum level for folic acid.

Rationale: The value of 4 ug/100 kcal was based on older analytical methods that did not measure the actual folate content and underestimated the amount that was actually present in human milk. The proposed value of 10 ug/100kcal reflects newer data on folate levels in human milk.

e. Minerals and Trace Elements

Phosphorus

Comment: Three values are currently proposed for minimum and maximum phosphorus levels based on the protein source for the infant formula. We are concerned that recommendation of different levels is inconsistent with the approach used by CODEX for other nutrients. We suggest that the Committee evaluate the use of one minimum and one maximum value for phosphorus. Taking bioavailability into consideration we propose that the minimum value for phosphorus be set as proposed in the table above.

Rationale: Bioavailability of phosphorus from ingredients in infant formula should take into account an additional consideration. Part of the phosphorus content of soy proteins is in the form of phytate and is unavailable as a dietary source of phosphorus. The minimum and maximum phosphorus levels in the above table are applicable to all formulas because of the consideration of bioavailability. Minimum values should be adequate for all formulas and bioavailability of a nutrient in a given formulation must always be considered.

Iron and Zinc

Comment: Two values are currently proposed for minimum and maximum iron and zinc levels based on the protein source for the infant formula. We are concerned that

recommendation of different levels is inconsistent with the approach used by CODEX for other nutrients. We suggest that the Committee evaluate the use of one minimum and one maximum value for each of these minerals. Taking bioavailability into consideration we propose that the minimum values for iron and zinc be set as proposed in the table above.

Rationale: There are divergent recommendations from Expert Scientific Groups regarding the need for different minimum and maximum values for these minerals based on the protein source for the infant formula. Minimum values should be adequate for all formulas and bioavailability of a nutrient in a given formulation must always be considered.

Copper

Comment: We propose removing the square brackets from footnote 7 in ALINORM 04/27/26.

Rationale: Water supplies in different regions of the world vary widely in their copper concentrations. In areas that have high levels of copper, an excess of copper in infant formulas may result unless provision is made for necessary adjustments.

Chromium and Molybdenum

Comment: We propose deleing these minerals from the table.

Rationale: There are no data to provide setting a minimum or maximum levels for these mineral.

3.2 Optional Ingredients:

3.2.1 In addition to the compositional requirements listed under 3.1, 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.

Comment: We propose the addition of an optional constituents table, if appropriate.

3.2.3 Only L(+) producing lactic acid cultures may be used**.**

3.2.4 Proposed New Table: Optional Constituents

Constituent	Units	Minimum	Maximum
Nitrogen containing substances (non-protein):			
L-carnitine	[mg]	[≥ 1.2]	N.S[3]
taurine	[mg]	[0]	[12]
Total Nucleotides	mg]	[0]	[5]
Cytidine 5”-monophasphate (CMP)	[mg	N.S.[1]	2.50
Uridine 5’-monophasphate (UMP)	[mg]	N.S.	1.75
Adeonsine 5’ monophasphate (AMP)	[mg]	N.S.	1.50
Guanosine 5’-monophasphate (GMP)	[mg]	N.S.	0.50
Inosine 5’-monophasphate (IMP)	[mg]	N.S.	1.00
Fats and Fatty Acids			
[Phospholipids]		N.S	[≤ 1 g/L]
[Formulae with added LCPUFA]			
[α-linolenic acid[2]	[mg]	5	[≥ 50 mg]
[Linoleic/α-linolenic ratio[2]		[5-20]	
[n-6 LCPUFA]			[≤ ~~2~~% of total fatty acids]
[Arachidonic acid]			[≤ ~~1~~% of total fatty acids] **[0.75% of total fatty acids]**
[n-3 LCPUFA]			[≤ ~~1~~% of total fatty acids] **[0.5% of total fatty acids as DHA]**

Footnotes for optional ingredient table

[1] N.S. = not specified

[2] If DHA content >0.2% of total fatty acids

Comment: We request resolution of the values for total nucleotides and individual component nucleotides.

Rationale: The total value for the individual nucleotides is greater than the proposed value for total nucleotides.

Comment: We propose further consideration be given to the portion of the table specifying fatty acid content for formulas with LCPUFAs and propose for consideration the levels shown in bold. Additionally, the entries for total n-6 LCPUFAs and arachidonic acid seem contradictory. The only n-6 LCPUFA that we are aware of is arachidonic acid and we are not aware of other n-6 LCPUFAs that would make a separate line for total n-6 LCPUFA level necessary.

Rationale: This is a very complex area of infant nutrition and infant formula safety. Levels of individual LCPUFAs and relationships among the various LCPUFAs are extremely important.

The levels shown in bold are consistent with levels for which there has been evaluation of evidence for safe use.

Comment: We propose that the table make it clear that sources of both DHA and ARA should be added rather than addition of only an n-6 or n-3 LCPUFA source as could currently be interpreted. We further suggest that the committee not include EPA as a LCPUFA for intentional addition to infant formulas.

Rationale: Some studies have reported that infants who consumed infant formula supplemented with fish oil as a source of DHA exhibited reduced growth and a decline in measures of ARA status. The reduced growth seen in these studies could be related to (1) the presence of EPA (2) the lack of a source of ARA in the formula supplemented with fish oil, or (3) a combination of the presence of EPA and the lack of ARA.

Editorial Comment: Percent levels of total fatty acids have been moved to the maximum column.

Rationale: As optional constituents, a minimum is not logical.

3.3 Vitamin Compounds and Mineral Salts

Vitamins and minerals added in accordance with Section ~~3.1.2 (a,b,c,d)~~ **3.1.3 (d and e)** and 3.2.1 should be selected from the Advisory Lists of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979).

Comment: We propose the above deletion.

Rationale: This is the correct section of the standard, as currently edited.

3.5 Purity Requirements

~~All ingredients shall be clean, of good quality, safe and suitable for ingestion by infants. They shall conform with their normal quality requirements, such as colour, flavour and odour.~~

We recommend the following new text for 3.5:

Ingredients, including food additives and nutrient compounds, added to foods should be of appropriate food grade quality and should conform with the applicable Specifications of Identity and Purity recommended by the Codex Alimentarius Commission, or in the absence of such specifications, with appropriate specifications developed by recognized national or international bodies. For safety purposes, food grade quality is achieved by compliance with the specifications and by production, storage and transport in accordance with Good Manufacturing Practice.

Rationale: The above language addresses more specifically the topic of this section (i.e., purity requirements), and the need to protect the health of infants. The United States recommends that similar language be used in the section on quality factors (3.9.1) in the Draft Revised Standard for Processed Cereal-Based Foods for Infants and Young Children.

3.6 Specific Prohibition

The product and its components shall not ~~[contain commercially hydrogenated oils and fats and shall not]~~ have been treated by ionizing radiation

Comment: We propose the above deletion.

Rationale: Section 3.1.1 requires use of ingredients that are proven to be suitable for infant feeding.

4. FOOD ADDITIVES

The United States offers the following general and specific comments on the food additive provisions of this draft standard.

A. Comments About the Process for Revising Section 4

In the interest of making progress on this important issue, the U.S. proposes that the CCNFSDU continue to consider working principles in its discussion of the proposed revisions to the food additive sections of this standard (as well as the Proposed Draft Revised Standard for Cereal-Based Foods for Infants and Young Children).

Our impression from a review of the comments previously submitted and the CCNFSDU's previous discussions, suggest that there are two categories of proposals to revise the food additive sections in this standard. The first category can be characterized as proposals to revise the food additive functional classes considered appropriate in the standard. For example, there are several proposals to revise the standards to allow for the use of additional food additive functional classes (e.g., packing gases). The second category of proposed revisions can be characterized as revisions to the list of food additives and their maximum use level.

The U.S. proposes the following two-step process to guide the Committee's discussion.

1. The CCNFSDU should first resolve questions regarding the technological need for food additive functional classes in these standards. We recommend that this discussion should be based on the following principles:
    a. The technological need for the food additive functional classes in the existing standard is justified.[2] Members of the CCNFSDU that question the need for a food additive functional class in the existing standard are responsible for providing a justification to the CCNFSDU explaining why a particular food additive functional class is no longer justified.
    b. The technological need for additional food additive functional classes should be provided to the CCNFSDU with a justification.

[2] The four food additive functional classes in the existing standard for infant formula (Codex Stan 72-1981) are: thickening agents, emulsifiers, pH-adjusting agents, and antioxidants.

2. Once the need for particular functional classes of additives has been resolved, then the CCNFSDU should try to resolve questions relating to specific food additives (i.e., revisions to the list of food additives and their maximum use level), we recommend that the CCNFSDU's discussion be guided by the following principles:
    a. Only additives assigned a full ADI by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) are eligible for inclusion in the standard.
    b. The food additives listed in the existing standards are justified. Members of the CCNFSDU that question a specific food additive or its level of use in the existing standard are responsible for providing a justification to the CCNFSDU explaining why a particular food additive or its use level in the existing standard is no longer justified.
    c. Once the technological need for a food additive functional class is established, then information supporting additional food additives (to that functional class) and their maximum use levels necessary to achieve a particular technological functional effect should be provided to the CCNFSDU for further discussion.

Consistent with the Codex General Principles for the Use of Food Additives (XOT-1) and the Preamble to the Codex General Standard for Food Additives (CX-STAN 192), justifications for a food additive functional class, or supporting information about any additional food additive and its use level should address the following questions:

1. Will the functional class or additive preserve the nutritional quality of the food;
2. Will the functional class or additive provide necessary ingredients or constituents for the food;
3. Will the functional class or additive enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not so change the nature, substance or quality of the food as to deceive the consumer; or
4. Will the functional class or additive provide aid in the manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these activities?

We believe this approach will expedite the work of the CCNFSDU and ensure that the CCNFSDU's deliberations are transparent and are consistent with the working principles of Codex.

At its 36th session, the CCFAC noted that as part of its charge, a Working Group on the International Numbering System would prepare a discussion paper to address the request

of the 25th Session of the CCNFSDU with regard to the establishment of functional classes that were currently not covered, especially enzymes and propellant gases[3].

B. Proposal to list "Packaging Gas (Propellants)" as an additive functional class and to list several food additives under this functional class

The United States offers the following comments on specific food additive provisions in the draft standard.

The United States continues to seek clarification on the provisions for "packaging gas (propellants)" in this standard. The INS includes a functional class title for propellants but does not contain a functional class title or sub-class technical function for packaging gas (CAC/GL 36-2001).

The INS defines a propellant as a gas, other than air, which expels a food from a container. The technological need for the use of a propellant in infant formula is not clear to us.

Section 3 of the INS associates the technical function "propellant" with nitrous oxide (INS 942), while the listed technical function "packing gas" is associated with carbon dioxide (INS 290), argon (INS 938), helium (INS 939), nitrogen (INS 941), and oxygen (INS 948). In addition, the 34th Codex Committee on Food Additives and Contaminants (CCFAC) forwarded, at step 5/8, a recommendation to amend the INS to include INS 949 for hydrogen with the technological function of "packing gas" (ALINORM 03/12, para. 97 and Appendix VII).

The absence of packing gas as a food additive functional class raises the question of whether the use of substances as packing gases is a <u>food additive</u> use or a <u>processing aid</u> use.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has assigned an "Acceptable" ADI for nitrous oxide (INS 942) as a propellant. The 55th JECFA meeting (2000) considered the request by CCFAC to evaluate the additional use of nitrous oxide as a packaging gas, but JECFA could not carry out this request because no information on intake of nitrous oxide for such use was available.

Moreover, we can find no evidence that JECFA has evaluated the safety of argon (INS 938), helium (939), and oxygen (INS 948), and hydrogen (proposed INS 949) as food additives.

Given the uncertainty regarding the technological function of this class of additives within the context of the Codex INS, the uncertainty over the technological need for the use of packaging gas (propellants) in infant formula and the absence of any guidance from JECFA on the safety of use of these substances as packaging gases we recommend the following step-wise approach:

[3] ALINORM 04/27/12, para.108.

1. CCNFSDU should request CCFAC to consider placing these gases on their JECFA priority list for evaluation of their safe use as packing gases in infant formula (and in processed cereal-based foods for infants and young children).
2. CCNFSDU should defer any decisions on the use of these gases in infant formula and retain the proposal in square brackets until JECFA has completed its evaluation. When CCNFSDU takes up its discussion, CCNFSDU should first consider the technological need for packaging gas and/or propellants in infant formula. If CCNFSDU decides that this technical function is needed in infant formula, then CCNFSDU should determine whether the proposed levels of use are appropriate.

C. Proposal to Add a New Functional Class for Nutrient Carriers

The United States notes that CCNSFDU requested the CCFAC to add an additive functional class for nutrient carriers (or carriers) to the INS. 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, and 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[4].

Accordingly, the United States recommends that the CCNFSDU add this functional class to the Section 4 table in this draft standard and propose nutrient carrier substances to be listed under this functional class.

D. Comments on Section 4 Introductory Text and Specific Food Additive Provisions

<u>Section 4 introductory text</u>
The United States recommends that the following new text be added immediately following the heading of "4. Food Additives":

> "Food additives shall be used in amounts that, in combination with nutrient sources, will not cumulatively exceed maximum levels for nutrients specified in Section 3.1.3 (Essential Composition and Quality Factors) of the Infant Formula Standard. For example, sodium, potassium, calcium, phosphorus, and magnesium are nutrients that have proposed maximum levels in this standard, and food additives containing these or other substances for which maximum nutrient levels are specified should be added in amounts that will not exceed the maximum level."

> Comment: We recognize that for specific food additive provisions, the table includes comments that certain nutrients should stay within the limits for these nutrients identified in Section 3.1.3. However, we believe there is value in including a general provision that clarifies that maximum levels

[4] ALINORM 04/27/12, para. 89.

should not be exceeded for any nutrient as the result of adding food additives.

Specific Food Additive Provisions
The United States offers the following comments on specific food additive provisions.

4.1 Thickening Agents

Xanthan gum (INS No. 145). The United States recommends that xanthan gum be included on the list of acceptable thickeners with a maximum use level consistent with Good Manufacturing Practice.

> Comment: Xanthan Gum (INS No. 415) has been evaluated by JECFA and assigned an ADI of "Not Specified". The Codex INS for food additives lists xanthan gum as a thickener.

4.2. Emulsifiers

Diacetyltartaric Acid and Fatty Acid Esters of Glycerol or DATEM (INS No. 472e).
The United States recommends that DATEM be included on the list of acceptable emulsifiers with a maximum use level of 5000 mg/kg. DATEM has been evaluated by JECFA and assigned an ADI of 0-50 mg/kg bw. The Codex INS for food additives recognizes that DATEM is used as an emulsifier.

Sucrose esters of fatty acids (INS No 473). There are unresolved questions with the use of sucrose esters of fatty acids (SFAE) in infant formula, especially with regard to laxation and the effect of SFAE on the immature gastrointestinal tract of infants. If the Committee proposes to include SFAE in the list of food additives for use in infant formulas, then the United States recommends that the CCNFSDU request that the CCFAC have JECFA review the safety of SFAE in infant formula

4.3 pH-Adjusting Agents

The draft standard proposes limitations on the use of various pH adjusting agents (or acidity regulators) on the basis of GMP and within the limits for potassium and sodium specified in section 3.1.2(e). We support this approach but note that section 3.1.2(e) also limits the level of calcium, phosphorus, and magnesium in infant formula. Therefore, we propose that the limitations on the use of these pH adjusting agents (or acidity regulators) be expressed as:

> "Limited by GMP and within the limits for sodium, potassium, calcium, phosphorus, and magnesium in section 3.1.2(e) of this standard."

Potassium Chloride (INS No. 508) and Magnesium Oxide (INS No. 530) The United States recommends that potassium chloride and magnesium oxide be included on the list

of acceptable pH-adjusting agents with a maximum use level consistent with Good Manufacturing Practice**.** We note that both of these food additives are included in the Codex Advisory Lists of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979, amended 1983, 1991) and have purity requirements established by FAO/WHO.

4.5 Packaging Gas (Propellants)

Please refer to the earlier comments by the United States regarding the proposal to list "Packaging Gas (Propellants)" as an additive functional class and comments on the listing of several food additives under this functional class.

E. Comments on Section 4.5 Carry-Over of Food Additives

The United States recommends that the Committee delete Section 4.5 (b) of the draft revised standard. Section 4.5(b) refers to the listing of carriers for nutrients in the Advisory List of Vitamin Compounds for Use in Foods for Infants and Children which the Committee has agreed to remove from the advisory list.

The US recommends that the food additive section of the Infant Formula standard include the food additive functional class: carriers for nutrients, to accommodate the use of nutrient carriers in foods conforming to this standard.

9. LABELLING

In addition to the requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev.1-1991)), **the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985 (Rev. 1-1993), and the Guidelines for Use of Nutrition and Health Claims [ALINORM 04/27/22, Appendix III]** the following specific provisions apply:

> Rationale: All three of the above Codex texts are applicable to the labeling of infant formula. The proposed clarification influences the nature of edits that the United States proposes for certain labeling provisions in Section 9 that are in brackets (e.g., the deletion of certain text if it is already covered in another Codex standard).

9.1 The Name of the Food

~~9.1.5 [No health claims shall be made regarding the dietary properties of the product.]~~

> Rationale for proposal to delete 9.1.5 (and 9.6.6): The United States notes that the Guidelines for Use of Nutrition and Health Claims that were adopted at the 27th

session of the Codex Alimentarius Commission (ALINORM 04/27/41, para 51) contains the following provision:

> 1.4 Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation.
> (ALINORM 04/27/22, CCFL 32nd Session Report, Appendix III).

Thus, an existing Codex standard already covers the prohibition of nutrition and health claims on infant formula unless provided for in the infant formula standard or in national legislation. Moreover, the current wording in 9.1.5 appears inconsistent with the wording in 1.4, because it does not refer to nutrition and health claims provided for in national legislation.

~~9.1.6 [Products containing not less than 0.5 mg. Iron (Fe)/100 kilocalories shall be labeled "Infant Formula with added Iron"].~~

~~(Or~~

~~[Products containing less than 0.5 mg Iron (Fe)/100 kcal shall be labelled with a statement to the effect that when the product is given to infants over the age of four months, their total iron requirements must be met from other additional sources.]~~

> Rationale for deletion of 9.1.6: Section 9.1.6 appears to be unnecessary. The first option is not needed because all products that meet the provisions in 3.1(b) would contain iron at levels $\geq$ 0.5 mg/100 kcal. The second option is not needed because iron is a required nutrient for infant formulas and all formulas must have a minimum level of 0.5 mg Iron/100 kilocalories of formula in order to meet the standard.

9.2 List of Ingredients

9.2.1 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and added minerals, these ingredients shall be arranged as separate groups for vitamins and minerals, respectively, and within these groups the vitamins and minerals need not be listed in descending order of proportion.

> Comment: : The United States notes that the Codex Committee on Food Labelling referred Section 9.2.1 back to the CCNFSDU for further consideration based on comments made by the U.S. Delegation at the 32nd CCFL session. The comments pointed out certain inconsistencies with text in this provision and the General Standard for the Labelling of Prepackaged Foods (ALINORM 04/27/22, para 34). After seeking further clarification on this issue, we understand that a question was raised as to whether there is justification for vitamins and mineral to deviate from

Section 4.2.1.2 of this general standard which requires that ingredients be listed in descending order of weight. We believe there is justification for not requiring vitamins and minerals to be listed in descending order by weight because they are present in very small amounts (e.g., < 2 %). Thus, we do not see a need to revise the current text.

9.3 Declaration of Nutritive Value

The declaration of nutrition information shall contain the following information ~~in the following order:~~

(a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ) and the number of grammes of protein, carbohydrate and fat per 100 grammes of the food as sold as well as per 100 milliliter of the food ready for use, when prepared according to the instructions on the label.

(b) the total quantity of each vitamin, mineral, choline as listed in paragraph 3.1.2 and any other ingredient as listed in paragraph 3.2 of this Standard per 100 grammes of the food as sold as well as per 100 milliliter of the food ready for use, when prepared according to the instructions on the label.

(c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.

Rationale for proposal to delete "in the following order":
The United States notes that the Codex Committee on Food Labelling referred Section 9.3 back to the CCNFSDU for further consideration based on comments made by the U.S. Delegation at the 32nd CCFL session. The comments pointed out certain inconsistencies with text in this provision and the Codex Guidelines on Nutrition Labelling (ALINORM 04/27/22, para 34). After seeking further clarification on this issue, we understand that neither the Codex General Standard for the Labelling of Prepackaged Foods nor the Codex Guidelines on Nutrition Labelling have provisions that require nutrients to be declared in a specific order. Consequently, we propose that 9.3 not require the nutrition information to be in a specific order to be consistent with the above Codex texts unless there is strong justification otherwise.

9.5 Information for Use

9.5.1 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 formulas should be used according to directions for use. Ready-to-feed** infant formula ~~may~~ **should** be used ~~either~~ **as packaged.** ~~or prepared with safe water before feeding according to directions for use. In powder form~~

~~infant formula also requires safe, and previously boiled water for preparation.~~
Concentrated liquid and powdered forms should be prepared with safe and previously boiled water before feeding.

Comment: We recommend the above edits.

Rationale: This information should be on the label, which is affixed to the can or container. An accompanying leaflet can easily come separated from the product. The subsequent edits are proposed to clarify the text.

9.6 Additional Labelling Requirements

9.6.1 Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points:

a) the words "important notice" or their equivalent;

b) The statement "Breastfeeding is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breastmilk.

Comment: We support the second option for 9.6.1(b). Reference to "diarrhea and other illnesses" on an infant formula product, as proposed in the first option, could be misunderstood by consumers.

c) a statement that the product should only be used on advice of a independent health worker as to the need for its use and the proper method of use;

d) instructions for appropriate preparation;

e) a warning against the health hazards of inappropriate preparation; and a warning that formula remaining after each feeding should be discarded.

f) a warning that all liquid and reconstituted formulas should be stored with refrigeration and used within 24 hours.

Comment: We propose that new section f) be added to address the above warning statements on infant formula products.

~~9.6.6 [No [nutrition and] health claims shall be made regarding the dietary properties of this product.]~~

Rationale for proposal to delete 9.6.6 (and 9.1.5):

As noted in earlier U.S. comments on 9.1.5, an existing Codex standard (i.e., Section 1.4 in the Guidelines for Use of Nutrition and Health Claims) already

covers the prohibition of nutrition and health claims on infant formula unless provided for in the infant formula standard or in national legislation. Moreover, the current wording in 9.6.6 (and 9.1.5) appears inconsistent with the wording in 1.4, because it does not refer to nutrition and health claims provided for in national legislation.

DRAFT REVISED STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN (AT STEP 7)

AGENDA ITEM No. 6

BACKGROUND

Reference:

- Report of the 25th CCNFSDU Session (ALINORM 04/27/26, Para 103-130, Appendix VI
- CRD 1
- Comments at Step 6 (CX/NFSDU 04/7) *not yet available*

At the 25th CCNFSDU session, the Committee noted that significant progress was made on the revision of the text, and agreed to advance the proposed draft standard for adoption at Step 5 by the CAC.

The Committee has discussed the revision of this standard for a number of years. Many of the debates focused on the text in the Scope section which addressed the age of introduction of weaning foods. At the last session, the Committee considered the text section by section, and made a number of amendments.

With regard to the food additive provisions of this draft standard, the proposals from the working group chaired by Switzerland were incorporated and certain issues such as the listing of flavourings were identified for referral to the Codex Committee on Food Additives and Contaminants. With regard to the labeling provisions, the CCFL endorsed some provisions, and referred others back to the CCNFSDU for further consideration. A labeling provision that would prohibit health claims was retained in square brackets pending further discussion in the CCNFSDU and CCFL, and review after the final adoption of the Draft Guidelines for Use of Health and Nutrition Claims.

DRAFT POSITION

Below are proposed edits on specific sections of this draft standard and the rationale.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.9 Quality Factors

~~3.9.1 All ingredients, including optional ingredients, shall be clean, safe, suitable and of good quality.~~

The United States recommends the following new text for 3.9.1:

"Ingredients, including food additives and nutrient compounds, added to foods should be of appropriate food grade quality and should conform with the applicable Specifications of Identity and Purity recommended by the Codex Alimentarius Commission, or in the absence of such specifications, with appropriate specifications developed by recognized national or international bodies. For safety purposes, food grade quality is achieved by compliance with the specifications and by production, storage and transport in accordance with Good Manufacturing Practice."

Rationale: The above language addresses more specifically the topic of this section and the need to protect the health of infants. The United States recommends that similar language be used in the section on purity requirements (3.5) in the Draft Revised Standard for Infant Formula.

4. FOOD ADDITIVES

The United States offers the following general and specific comments on the food additive provisions of this draft standard.

A. Comments About the Process for Revising Section 4

In the interest of making progress on this important issue, the U.S. proposes that the CCNFSDU continue to consider working principles in its discussion of the proposed revisions to the food additive sections of this standard (as well as the Draft Revised Standard for Infant Formula).

Our impression from a review of the comments previously submitted and the CCNFSDU's previous discussions, suggest that there are two categories of proposals to revise the food additive sections in this standard. The first category can be characterized as proposals to revise the food additive functional classes considered appropriate in the standard. For example, there are several proposals to revise the standards to allow for the use of additional food additive functional classes (e.g., packing gases). The second category of proposed revisions can be characterized as revisions to the list of food additives and their maximum use level.

The U.S. proposes the following two-step process to guide the Committee's discussion.

1. The CCNFSDU should first resolve questions regarding the technological need for food additive functional classes in these standards. We recommend that this discussion should be based on the following principles:
    a. The technological need for the food additive functional classes in the existing standard is justified.[5] Members of the CCNFSDU that question the need for a food additive functional class in the existing standard are responsible for providing a justification to the

[5] The food additive functional classes in the existing standard for processed cereal-based foods for infants and children (Codex Stan 74-1981) are: emulsifiers, pH adjusting agents, antioxidants, flavours, enzymes, and leavening agents.

CCNFSDU explaining why a particular food additive functional class is no longer justified.

b. The technological need for additional food additive functional classes should be provided to the CCNFSDU with a justification.

2. Once the need for particular functional classes of additives has been resolved, then the CCNFSDU should try to resolve questions relating to specific food additives (i.e., revisions to the list of food additives and their maximum use level), we recommend that the CCNFSDU's discussion be guided by the following principles:
    a. Only additives assigned a full ADI by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) are eligible for inclusion in the standard.
    b. The food additives listed in the existing standards are justified. Members of the CCNFSDU that question a specific food additive or its level of use in the existing standard are responsible for providing a justification to the CCNFSDU explaining why a particular food additive or its use level in the existing standard is no longer justified.
    c. Once the technological need for a food additive functional class is established, then information supporting additional food additives (to that functional class) and their maximum use levels necessary to achieve a particular technological functional effect should be provided to the CCNFSDU for further discussion.

Consistent with the Codex General Principles for the Use of Food Additives (XOT-1) and the Preamble to the Codex General Standard for Food Additives (CX-STAN 192), justifications for a food additive functional class, or supporting information about any additional food additive and its use level should address the following questions:

1. Will the functional class or additive preserve the nutritional quality of the food;
2. Will the functional class or additive provide necessary ingredients or constituents for the food;
3. Will the functional class or additive enhance the keeping quality or stability of a food or to improve its organoleptic properties, provided that this does not so change the nature, substance or quality of the food as to deceive the consumer; or
4. Will the functional class or additive provide aid in the manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these activities?

We believe this approach will expedite the work of the CCNFSDU and ensure that the CCNFSDU's deliberations are transparent and are consistent with the working principles of Codex.

At its 36th session, the CCFAC noted that as part of its charge, a Working Group on the International Numbering System would prepare a discussion paper to address the request of the 25th Session of the CCNFSDU with regard to the establishment of functional classes that were currently not covered, especially enzymes and propellant gases[6].

B. Proposal to list "Packaging Gas (Propellants)" as an additive functional class and to list several food additives under this functional class

The United States offers the following comments on specific food additive provisions in the draft standard.

The United States continues to seek clarification on the provisions for "packaging gas (propellants)" in this standard. The INS includes a functional class title for propellants but does not contain a functional class title or sub-class technical function for packaging gas (CAC/GL 36-2001).

The INS defines a propellant as a gas, other than air, which expels a food from a container. The technological need for the use of a propellant in the foods covered by this standard is not clear to us.

Section 3 of the INS associates the technical function "propellant" with nitrous oxide (INS 942), while the listed technical function "packing gas" is associated with carbon dioxide (INS 290), argon (INS 938), helium (INS 939), nitrogen (INS 941), and oxygen (INS 948). In addition, the 34th Codex Committee on Food Additives and Contaminants (CCFAC) forwarded, at step 5/8, a recommendation to amend the INS to include INS 949 for hydrogen with the technological function of "packing gas" (ALINORM 03/12, para. 97 and Appendix VII).

The absence of packing gas as a food additive functional class in the INS class system raises the question of whether the use of substances as packing gases is a <u>food additive</u> use or a <u>processing aid</u> use.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has assigned an "Acceptable" ADI for nitrous oxide (INS 942) as a propellant. The 55th JECFA meeting (2000) considered the request by CCFAC to evaluate the additional use of nitrous oxide as a packaging gas, but JECFA could not carry out this request because no information on intake of nitrous oxide for such use was available.

Moreover, we can find no evidence that JECFA has evaluated the safety of argon (INS 938), helium (939), and oxygen (INS 948), and hydrogen (proposed INS 949) as food additives.

Given the uncertainty regarding the technological function of this class of additives within the context of the Codex INS, the uncertainty over the technological need for the use of packaging gas (propellants) in the foods covered by this standard and the absence

[6] ALINORM 04/27/12, para.108.

of any guidance from JECFA on the safety of use of these substances as packaging gases we recommend the following step-wise approach:

1. CCNFSDU should request CCFAC to consider placing these gases on their JECFA priority list for evaluation of their safe use as packing gases in processed cereal-based foods for infants and young children (and in infant formula).

2. CCNFSDU should defer any decisions on the use of these gases in processed cereal-based foods for infants and young children and retain the proposal in square brackets until JECFA has completed its evaluation. When CCNFSDU takes up its discussion, CCNFSDU should first consider the technological need for.packaging gas and/or propellants in this standard. If CCNFSDU decides that this technical function is needed in foods covered by this standard, then CCNFSDU should determine whether the proposed levels of use are appropriate.

C. Proposal to Add a New Functional Class for Nutrient Carriers

The United States notes that CCNSFDU requested CCFAC to add an additive functional class for nutrient carriers (or carriers) to the INS. 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, and 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[7].

Accordingly, the United States recommends that the CCNFSDU add this functional class to the Section 4 table in this draft standard and propose nutrient carrier substances to be listed under this functional class.

D. Comments on Specific Food Additive Provisions in Section 4

4.4 Flavours

If individual flavours are appropriate to use in processed cereal-based foods, we would recommend replacing the flavour section with the following:

> "Natural flavours and natural flavouring substances, nature-identical flavouring substances, and artificial flavouring substances may be added to foods conforming to this standard."

Rationale: The above categories of flavours are those defined by Codex.

4.9 Packaging Gas (Propellants)

[7] ALINORM 04/27/12, para. 89.

Please refer to the earlier comments by the United States regarding the proposal to list "Packaging Gas (Propellants)" as an additive functional class and comments on the listing of several food additives under this functional class.

8. LABELLING

8.1.1 The requirements of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev. 1-1991), Codex Alimentarius Volume 1), **the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985 (Rev. 1-1993), and the Guidelines for Use of Nutrition and Health Claims [ALINORM 04/27/22, Appendix III]** apply to this standard. With specific reference to section 7 of the Codex General Standard for the Labelling of Prepackaged Foods, national jurisdictions may further restrict the use of pictorial devices.

> Rationale: All three of the above Codex texts are applicable to the labeling of products covered by this standard. The proposed clarification influences the nature of edits that the United States proposes for certain labeling provisions in Section 8 that are in brackets (e.g., the deletion of certain text if it is already covered in another Codex standard).

~~[No nutrition and health claims shall be made regarding the dietary properties of the products covered by the provisions of this standard.]~~

> Rationale for proposal to delete above text: The United States notes that the Guidelines for Use of Nutrition and Health Claims that were adopted at the 27th session of the Codex Alimentarius Commission (ALINORM 04/27/41, para 51) contains the following provision:
>
> > 1.4 Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation.
> > (ALINORM 04/27/22, CCFL 32nd Session Report, Appendix III).
>
> Thus, an existing Codex standard already covers the prohibition of nutrition and health claims on processed cereal-based foods for infants and young children unless provided for in this cereal-based foods standard or in national legislation. Moreover, the proposed text above appears inconsistent with the wording in 1.4, because it does not refer to nutrition and health claims provided for in national legislation.

8.3 List of Ingredients

8.3.1 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these shall be arranged as separate groups for vitamins and minerals, respectively, and within these groups the vitamins and minerals need not be listed in descending order of proportion.

Comment: : The United States notes that the Codex Committee on Food Labeling referred Section 8.3.1 back to the CCNFSDU for further consideration based on comments made by the U.S. Delegation at the 32nd CCFL session. The comments pointed out certain consistencies with text in this provision and the General Standard for the Labelling of Prepackaged Foods (ALINORM 04/27/22, para 34). After seeking further clarification on this issue, we understand that a question was raised as to whether there is justification for vitamins and mineral to deviate from Section 4.2.1.2 of this general standard which requires that ingredients be listed in descending order of weight. We believe there is justification for not requiring vitamins and minerals to be listed in descending order by weight because they are present in very small amounts (e.g., < 2 %). Thus, we do not see a need to revise the current text.

8.4 Declaration of Nutritive Value

8.4.1 The declaration of nutrition information shall contain the following information ~~in the following order~~:

Rationale for proposal to delete "in the following order":
The United States notes that the Codex Committee on Food Labeling referred Section 8.4.1 back to the CCNFSDU for further consideration based on comments made by the U.S. Delegation at the 32nd CCFL session. The comments pointed out certain consistencies with text in this provision and the Codex Guidelines on Nutrition Labeling (ALINORM 04/27/22, para 34). After seeking further clarification on this issue, we understand that neither the Codex General Standard for the Labelling of Prepackaged Foods nor the Codex Guidelines on Nutrition Labeling have provisions that require nutrients to be declared in a specific order. Consequently, we propose that 8.4.1 not require the nutrition information to be in a specific order to be consistent with the above Codex texts unless there is strong justification otherwise.