CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 4.6

CX/CAC 23/46/8 Add. 1
October 2023
Original Language Only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Forty-sixth Session

COMMENTS ON DRAFT STANDARDS AND RELATED TEXTS SUBMITTED BY THE 43RD CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES[1]

BACKGROUND

1. This document compiles the comments on the draft standards submitted at Step 5, Step 5/8 and Step 8 of the Procedure. The comments are as shown in Appendices I, II and III.

2. OCS is an online tool that enables Codex Contact Points to submit comments on draft texts in a standardised way, thus providing more transparency and better management of comments on different Codex texts as requested through Circular Letters. Since its launching at CAC39 (2016), the OCS has been used for different Codex Committees.

EXPLANATORY NOTES ON APPENDICES I, II AND III

3. The comments received are presented in a table format, with two columns as follows:

    - **First column –** Presents the comments with the rationale.
    - **Second column –** Presents the provider of the comments (name of member or observer)

[1] This document compiles comments submitted through OCS, or via email by the time this document was issued, in reply to CL 2023/67/OCS-CAC, CL 2023/68/OCS-CAC and CL 2023/74/OCS-CAC

Appendix I

COMMENTS IN REPLY TO CL 2023/67/OCS-CAC - REQUEST FOR COMMENTS AT STEP 5 ON THE GENERAL PRINCIPLES FOR ESTABLISHING NRVS-R FOR PERSONS AGED 6 TO 36 MONTHS

Comments of Argentina, Australia, Brazil, Cambodia, Colombia, Cook Island, Costa Rica, Egypt, El Salvador, Kenya, New Zealand, Paraguay, Peru, Saudi Arabia, Sierra Leone, USA, American Herbal Products Association, Helen Keller International and International Special Dietary Food Industries.

COMMENT	MEMBER / OBSERVER
Argentina considera que los Principios generales para el establecimiento de VRN-N para las personas de entre 6 y 36 meses de edad están listos para su adopción por parte de la CAC. Argentina desea realizar las siguientes sugerencias editoriales a la versión en español de la Norma para preparados complementarios (CXS 156-1987) (rebautizada como Norma para preparados complementarios para lactantes de más edad y producto para niños pequeños)	**Argentina**
It is the view of Australia that the General Principles for the establishment of NRVs-R for persons aged 6–36 months are ready for adoption (at Step 5); • Australia notes that there are only a few aspects where the Committee did not reach agreement and text has been retained in square brackets. • Australia supports the continuation of work to revise the draft Stepwise Process taking into account the revisions to the draft General Principles, and application of this process to a list of 23 identified nutrients for the 6-12months, 12-36 months and 6-36 months age groupings.	**Australia**
Brazil appreciates the excellent work made by Ireland, Costa Rica and United States of America and the efforts made by CCNFSDU to forward the principles for the PROPOSED DRAFT GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES FOR PERSONS AGED 6 TO 36 MONTHS to CAC46 for adoption at Step 5. Brazil has no objection to the text agreed by CCNFSDU at its last session (Appendix III of the REP23/NFSDU) and will follow the discussion to improve the revised text and conclude the pending issues.	**Brazil**
Cambodia agrees with the draft texts on general principles for establishing Nutrient Reference Values for Persons aged 6 to 30 months and support for adoption at Step 5.	**Cambodia**
Los principios generales sobre el establecimiento de VDRs-N para lactantes de más edad y producto para niños pequeños no tienen observaciones y están listos para adopción.	**Colombia**
No comment	**Cook Island**
Costa Rica apoya su adopción en Trámite 5.	**Costa Rica**
Egypt appreciates the work done in the document & agrees that the General Principles are ready for adoption at Step 5.	**Egypt**
El Salvador agradece a la Secretaría del Codex por la distribución de la presente solicitud de observaciones y en esta oportunidad se indica que: Tomando en consideración: i. El consenso alcanzado del CCFNSDU43 ii. Qué existe evidencia que son sujetos de comercio internacional diversos alimentos que abarcaban toda la franja de edad de entre 6 y 36 meses, por lo tanto, es necesario examinar posibles enfoques para establecer VRN-N para el grupo de edad de 6 a 36 meses. iii. Que El Salvador está de acuerdo con los VRN-N propuestos por el GTe, para los siguientes micronutrientes, que se indican a continuación: Vitamina B12 (µg): 0.5 para lactantes de más edad y 0.9 para niños pequeños; Vitamina B6 (mg): 0,3 para lactantes de más edad y 0,5 para niños pequeños;	**El Salvador**

Riboflavina (mg): 0,4 para lactantes de más edad; Tiamina (mg): 0,3 para lactantes de más edad y Niacina (mg NE): 4 para lactantes de más edad y 6 para niños pequeños iv. Qué en El Salvador se aplican distintos VRN para Riboflavina, Tiamina y Vitamina C para lactantes de más edad y niños pequeños. v. Contar con VRN establecidos a nivel internacional contribuye a la protección de la salud y al desarrollo de las personas de 6 a 36 meses de edad, prioridad de país en consonancia con el marco jurídico nacional. Se apoya que los Principios generales para el establecimiento de valores de referencia de nutrientes – necesidades (VRN-N) para las personas de entre 6 y 36 meses de edad, se aprueben en el trámite 5 como un Proyecto de Norma para que continúe su elaboración a la luz de la evidencia técnica y científica disponible por los países miembros de la Comisión del Codex Alimentarius.	
Kenya supports the adoption at step 5 of the proposed draft General Principles for establishing Nutrient Reference Values (NRVs-R) for persons aged 6 to 36 months by CAC46, as Kenya actively participated in its development.	**Kenya**
New Zealand supports the recommendation of CCNFSDU43 to progress the General Principles for establishing Nutrient Reference Values (NRVs-R) for persons aged 6 to 36 months to Step 5. The General Principles had been discussed through a physical working group and within the Committee and provide a necessary basis to progress the work on deriving the NRVs for this age group. New Zealand supports progressing the work to Step 5 so that Committee can progress with working through the stepwise process of deriving NRVs-R for persons aged 6 to 36 months. Thank you for the opportunity to provide feedback on the CL.	**New Zealand**
Paraguay esta de acuerdo a la adopción en el trámite 5 del documento ANTEPROYECTO DE PRINCIPIOS GENERALES PARA EL ESTABLECIMIENTO DE VALORES DE REFERENCIA DE NUTRIENTES PARA PERSONAS DE ENTRE 6 Y 36 MESES DE EDAD.	**Paraguay**
La Comisión NO tiene observaciones al documento en consulta.	**Peru**
The Kingdom of Saudi Arabia supports the adoption of the general principles for establishing nutrient reference values for persons aged 6 to 36 months at step 5.	**Saudi Arabia**
Sierra Leone is convinced that the general principles are ready for adoption.	**Sierra Leone**
The United States supports the adoption of the General Principles for establishing NRVs-R for interim adoption at Step 5. The United States suggests that prior to completing the work and progressing the General Principles to Step 8, CCNFSDU give further consideration to including principles for establishing NRVs-Non-Communicable Disease (NCD). For some nutrients NRVs-NCD may be more appropriate, such as sodium, saturated fats and added or total sugars for example.	**USA**
AHPA has no comments or revisions on this matter.	**American Herbal Products Association**
Helen Keller International agrees that this text has been discussed and agreed upon and is ready for adoption.	**Helen Keller International**
ISDI welcomes the draft general principles on establishing NRV-R for older infants and young children at step 5. ISDI thanks Ireland, Chair, and Costa Rica and United States of America, co-chairs, to lead this work. We welcome the progress made and agree with the principles so far and support continuation of the work in order to establish values on the relevant nutrients.	**International Special Dietary Food Industries**

Appendix II

COMMENTS IN REPLY TO CL 2023/68/OCS-CAC - REQUEST FOR COMMENTS AT STEP 5/8 AND STEP 8 ON THE REVISED STANDARD FOR FOLLOW-UP FORMULA (CXS 156 – 1987) (RENAMED: THE STANDARD FOR FOLLOW-UP FORMULA FOR OLDER INFANTS AND PRODUCT FOR YOUNG CHILDREN)

Comments of Argentina, Australia, Brazil, Cambodia, Chile, Colombia, Cook Islands, Costa Rica, Egypt, Kenya, New Zealand, Paraguay, Peru, Sierra Leone, United Republic of Tanzania, USA, American Herbal Products Association, ENCA, Helen Keller International, International Baby Food Action Network, International Special Dietary Food Industries and World Public Health Nutrition Association

COMMENT	MEMBER / OBSERVER
Argentina desea sugerir algunas modificaciones editoriales a la versión en español. Dado que las mismas no pueden ser incorporadas en el documento publicado en esta plataforma serán remitidos por email al Secretariado de Codex. Argentina desea realizar las siguientes sugerencias editoriales a la versión en español de la Norma para preparados complementarios (CXS 156-1987) (rebautizada como Norma para preparados complementarios para lactantes de más edad y producto para niños pequeños) *Sección A - Inciso 8.1.1* 8.1.1 El texto de la etiqueta y toda otra información que acompañe el producto deberán estar escritos en el idioma o los idiomas adecuados/correspondientes**.** ***Sección A - Inciso 8.1.3*** *8.1.3 En la etiqueta se indicará claramente el origen de las proteínas que contiene el producto.* *a) Si el origen de las proteínas* es exclusivamente la leche* de [nombre del animal]*, el producto podrá etiquetarse «preparado complementario para lactantes de más edad a base de proteína de leche* de [nombre del animal]*».* *b) Si el origen de las proteínas* es exclusivamente* ***de*** *[nombre del vegetal], el producto podrá etiquetarse «preparado complementario para lactantes de más edad a base de proteína de [nombre del vegetal]».* *c) Si el origen de las proteínas* es tanto la leche* de [nombre del animal] *como de [nombre del vegetal], el producto podrá etiquetarse «preparado complementario para lactantes de más edad a base de proteína de leche* de [nombre del animal] *y proteína de [nombre del vegetal]» o «preparado complementario para lactantes de más edad a base de proteína de [nombre del vegetal] y proteína de leche* de [nombre del animal]*».* ** Se aclara que la adición de distintos aminoácidos, cuando sean necesarios para mejorar la calidad de las proteínas, no impide el uso de las opciones de etiquetado anteriores.* *Sección A - Inciso 8.3 Declaración del valor nutritivo* La declaración de información nutricional de los productos definidos en la Sección 2.1 deberá contener la siguiente información, en el orden en que aquí se indican: ***Sección B - Inciso 8.1.1*** 8.1.1 El texto de la etiqueta y toda otra información que acompañe el producto deberán estar escritos en el idioma o los idiomas adecuados/correspondientes**.** ***Sección B - Inciso 8.1.3*** *8.1.3 En la etiqueta se indicará claramente el origen de las proteínas que contiene el producto.* *a) Si el origen de las proteínas* es exclusivamente la leche de [nombre del animal], el producto podrá etiquetarse «bebida con nutrientes añadidos para niños pequeños a base de proteína de leche de [nombre del animal]» o «producto con nutrientes añadidos para niños pequeños a base de proteína de*	**Argentina**

leche de [nombre del animal]» o «bebida para niños pequeños a base de proteína de leche de [nombre del animal]» o «producto para niños pequeños a base de proteína de leche de [nombre del animal]». *b) Si el origen de las proteínas* es exclusivamente de [nombre del vegetal], el producto podrá etiquetarse «bebida con nutrientes añadidos para niños pequeños a base de proteína de [nombre del vegetal]» o «producto con nutrientes añadidos para niños pequeños a base de proteína de [nombre del vegetal]» o «bebida para niños pequeños a base de proteína de [nombre del vegetal]» o «producto para niños pequeños a base de proteína de [nombre del vegetal]».* *c) Si el origen de las proteínas* es tanto la leche de [nombre del animal] como [nombre del vegetal], el producto podrá etiquetarse «bebida con nutrientes añadidos para niños pequeños a base de proteína de leche de [nombre del animal] y proteína de [nombre del vegetal]» o «producto con nutrientes añadidos para niños pequeños a base de proteína de leche de [nombre del animal] y proteína de [nombre del vegetal]»o «bebida para niños pequeños a base de proteína de leche de [nombre del animal] y proteína de [nombre del vegetal]» o «producto para niños pequeños a base de proteína de leche de [nombre del animal] y proteína de [nombre del vegetal]».* ** Se aclara que la adición de distintos aminoácidos, cuando sean necesarios para mejorar la calidad de las proteínas, no impide el uso de las opciones de etiquetado anteriores.* ***Sección B - Inciso 8.3 Declaración del valor nutritivo*** La declaración de información nutricional de los productos definidos en la Sección 2.1 deberá contener la siguiente información, en el orden en que aquí se indican: ***** En la Sección A - Inciso 8.5.6 Argentina propone incluir una coma después de "sexto mes de vida", por ser la correcta redacción en las enumeraciones en español. ***Sección A - Inciso 8.5.6*** 8.5.6 La etiqueta de los preparados complementarios para lactantes de más edad deberá contener una declaración de que el producto no se introducirá antes del sexto mes de vida, de que el producto no deberá usarse como única fuente de nutrientes y de que los lactantes de más edad deberán recibir alimentos complementarios además del producto.	
It is the view of Australia that the revised Standard is ready for adoption (at Step 5/8 and 8); • Australia notes the reservations lodged by nine countries in relation to the inclusion of paragraphs two and/or three of the final preamble. • Australia supports the completion of the Standard and as a compromise supports one standard with two parts, as well as the inclusion of a preamble (comprising three paragraphs).	**Australia**
Brazil appreciates the excellent work made by New Zealand, France and Indonesia and the efforts made by CCNFSDU to reach a consensus and forward the STANDARD FOR FOLLOW-UP FORMULA FOR OLDER INFANTS AND PRODUCT FOR YOUNG CHILDREN to CAC46 for adoption at Step 5/8 and 8. Brazil has no objection to the proposed draft revised standard agreed by CCNFSDU at its last session (Appendix II of the REP23/NFSDU). Regarding the preamble, Brazil underlines the importance of retaining all three paragraphs as agreed by the Committee considering all relevant issues raised by many countries during the plenary (para. 40 of the REP23/NFSDU) and the extensive debate to reach a consensus on the text.	**Brazil**
Cambodia has no objection to have the draft standard for follow-up formula for older infants and product for young children to be adopted at Step 5/8 and Step 8.	**Cambodia**
Chile apoya la revision de la norma y su adopcion a tramite 5/8	**Chile**

Se solicita precisiones en dos sentidos: 1.Confirmar que la traducción al inglés y al español es fiel al documento original. Específicamente en el en el artículo 3.1.1 del Apéndice 2. 2. Aclarar el alcance del concepto “inocuidad nutricional” e “idoneidad de los preparados” del párrafo en español. 3.No hubo consensó en la necesidad de incluir una nota relacionada con el uso racional de los aditivos.	**Colombia**
No comment	**Cook Islands**
Costa Rica apoya su adopción en los trámites 5/8 y 8.	**Costa Rica**
Egypt appreciates the work done in the document & agrees that the revised Standard is ready for adoption at Step 5/8 and 8.	**Egypt**
Kenya supports the adoption of: a) proposed draft revised standard with the title as shown in Appendix II; the Structure and the Preamble together with the remaining sections of Part A and B, agreed to at CCNFSDU42, to CAC46 at Step 5/8. b) submitted parts of the text of the draft Revised Standard for Follow-up Formula (Standard for Follow-up Formula for Older Infants and Product for Young Children) to CAC46 for at Step 8.	**Kenya**
New Zealand supports the recommendation of CCNFSDU43 to adopt the revised Standard follow-up formula for older infants and product for young children noting the overall conclusion of CCNFSDU43 and the Committee agreement that was reached on the title, the structure and the Preamble and recalling that CCNFSDU42 had already reached agreement on all other issues in the remainder of the text. New Zealand strongly supports adoption and then publication of the revised standard so that member Countries can start using the standard as soon as possible.	**New Zealand**
Paraguay esta de acuerdo con la adopción en los trámites 5/8 y 8 del documento NORMA PARA PREPARADOS COMPLEMENTARIOS PARA LACTANTES DE MÁS EDAD Y PRODUCTO PARA NIÑOS PEQUEÑOS.	**Paraguay**
La Comisión NO tiene observaciones al documento en consulta.	**Peru**
Sierra Leone recommends that since the definition of follow-up formula for older infants is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be safe and suitable for the feeding of older infant, the label of the product should state the animals/group of animals whose milk is being used to produce the product	**Sierra Leone**
Tanzania accepted to be adopted by CAC 46	**United Republic of Tanzania**
The United States supports adoption at Step 5/8 and Step 8 the revised Standard for Follow-up Formula (CXS 156-1987) renamed as the Standard for Follow-up Formula for Older Infants and Product for Young Children; however, the United States maintains its reservations on two points in the final text as forwarded to CAC46 for adoption. The United States confirms its reservation filed at the 44th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU44) concerning Paragraph 2 of the preamble which states: “The application of this Standard should be consistent with national/regional health and nutrition policies and relevant national/regional legislation and take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes, as per the national/regional context.” The Committee was only presented with the option of a preamble comprised of all three paragraphs, which limited deliberations. The fact that Members filed reservations on the preamble suggests that a full consensus was not reached.	**USA**

It is unfortunate that the compromise proposed by the United States of a preamble comprised of Paragraphs 1 and 3 was not provided as an option to the Committee for deliberation. The reference to the Code is also unnecessary and may confuse readers of the standard, since consensus was reached only to define follow-up formula for older infants 6-12 months of age (Part A) as a breast-milk substitute. The United States remains concerned that Paragraph 2 is inconsistent with international trade obligations and the use of intellectual property prevented by the more expanded view of the coverage of the International Code of Marketing of Breast-milk Substitutes. In Section B: Drink for Young Children with Added Nutrients or Product for Young Children with Added Nutrients or Drink for Young Children or Product for Young Children, section 3 Essential Composition and Quality Factors, section 3.1 defines Essential Composition and Quality Factors. Section 3.1.3 c) defines Carbohydrates setting a Maximum of 12.5 g/100Kcal. The United States would like to provide specific comments on footnotes 6, 7, and 8. Footnote 6 states that lactose should be the preferred carbohydrate for products based on milk but does not limit the sweetness of carbohydrate sources in milk-based products. Footnote 6 continues stating that the carbohydrate sources for non-milk protein products are limited to those with no contribution to sweet taste and in no case sweeter than lactose. The United States has concerns that the standard is biased in that it does not limit the sweetness of the carbohydrate sources added to milk-based formula and that additional carbohydrates will be necessary for formulations at the lower end of the protein range to provide sufficient calories. Footnote 8 recognizes that for products with lower amounts of protein from milk (below 3 grams), extra carbohydrates may be added to provide sufficient calories giving national authorities the option of increasing the maximum amount of carbohydrate to 14 g/100 kcal. As milk protein levels become lower, so does lactose from milk. Products formulated as milk substitutes (~8 grams Protein per 100 Kcal) will provide ~12.5 grams lactose per 100 Kcal which is the maximum level for carbohydrates so no additional carbohydrates are needed. As protein levels from milk are reduced so will the lactose provided from the milk solids, at the minimum protein content of 1.8 grams/100 kcal from milk, the milk will only provide ~3 grams lactose. The products will require addition of as much as 9.5 grams other carbohydrate sources and the sweetness of these carbohydrates is not restricted in footnote 6. Footnote 7 limits the addition of mono- and disaccharides, other than lactose to less than 2.5g/100 Kcal. It also notes that sucrose and/or fructose should not be added. Based on relative sweetness tables lactose is only 20.5% as sweet as sucrose. Limiting mono- and disaccharides to no more than 2.5g/100 Kcal is sufficient to limit sweetness to similar levels to milk. The United States continues to have the position that footnote 6 is not needed to limit the sweetness of products to not more than cow's milk, noting human milk contains more lactose than cow's milk. CCNFSDU does not need to expend limited resources to determine methods to determine compliance with footnote 6, as footnote 6 is not needed to achieve the goals of the committee. The United States requests that the CAC to consider adopting the standard at Step 5/8 and Step 8 with the exception of footnote 6.	

AHPA has no comments or revisions on this matter.	**American Herbal Products Association**
ENCA is of the opinion that the Standard is not ready for adoption at Step 5/8 and 8. ENCA's recommended text and comment is in red; Name of the product for young children ENCA proposes to retain the two names: Product for Young Children or Drink for Young Children and to delete the subsidiary names through the text of the standard. Rationale: Allowing secondary, subsidiary names is unnecessary and will confuse legislators, especially when the names include the claim 'with added nutrients'. This is a misleading and highly promotional claim that will imply that the product contains nutrients in addition to the mandatory ingredients. Such a claim should not be allowed in any Codex Standard. PREAMBLE ENCA Proposes the following inclusions to strengthen the preamble. This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants, and Section B deals with Drink for Young Children. DELETE: with Added Nutrients, or Product for Young Children DELETE with Added Nutrient. The application of this Standard [ADD: should be consistent] with national/regional health and nutrition policies and relevant national/regional legislation [ADD: and be in conformity with] the International Code of Marketing of Breast-milk Substitutes as per the national/regional context and World Health Organization (WHO) guidelines and policies [ADD and] World Health Assembly (WHA) resolutions, [ADD that] were considered in the development of this Standard and may provide further guidance to countries. [ADD: These products are not considered nutritionally necessary in the diets of older infants and young children and their marketing should not undermine breastfeeding.] Rationale: The test will ensure consistency with relevant WHA Resolutions and WHA 39.28 that in Para 3.2 "requested the Director General to specifically direct the attention of Member States and other interested parties to the following (b) the practice being introduced in some countries of providing infants with specially formulated milks (so-called "follow-up milks") is not necessary". SECTION B SCOPE – Product for young children To ensure consistency with the Standard for Infant Formula and SMPs ENCA proposes ADDING the following text as a new para 1.4 to both sections A and B. 1.4The application of this section of the Standard shall conform to the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), and subsequent relevant World Health Assembly (WHA) resolutions. 4. Food Additives Section B ENCA proposes the deletion of the following text relating to Flavourings. 4.6 Flavourings 15)	**ENCA**

[DELETE: Natural Fruit Extracts: GMP Vanilla extract: GMP Ethyl vanillin (JECFA no. 893): 5 mg/100 ml Vanillin (JECFA no. 889): 5 mg/ 100 ml The flavourings used in products covered by this Standard should comply with the Guidelines for the Use of Flavourings (CXG 66-2008).] 15) National and/or regional authorities may restrict or prohibit the use of [DELETE: the listed] flavourings Rationale: Flavourings, fruit extracts, vanilla extracts etc. should NOT be permitted for this product, Flavourings will promote the needless use of these products and develop taste preferences at an early age for flavoured, sweetened products – especially if the labels are idealized with images of fresh fruits. Such images will act as a health claim. 8.5 Information for Use (SECTIONS A and B) 8.5.1 Ready to use products in liquid form should be used directly. Concentrated liquid products and powdered products must be prepared with potable water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice. ENCA PROPOSES TO ADD to both A and B the following text which aligns with WHO/FAO recommendations for the reconstitution of powdered infant formula products. [ADD: Preparation instructions for powdered products must state clearly that the product is not sterile and must be reconstituted with safe water at 70 degrees centigrade] ADD the flowing references as a footnote: WHO/FAO (2007) guidelines, “Safe preparation, storage and handling of powdered infant formula.(http://apps.who.int/iris/bitstream/handle/10665/43659/9789241595414_eng.pdf?sequence=1) WHA resolutions WHA 58.32 (2005) and 61.20 (2008) Codex Alimentarius 'Code of hygienic practice for powdered formulae for infants and young children (2008), Additional Labelling Requirements ENCA proposes the following changes in Sections A and B 8.6.2 Labels should not [DELETE: discourage INSERT: UNDERMINE] breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points: 8.6.4 Follow-up formula for older infants shall be distinctly labelled in such a way as to avoid any risk of confusion with Infant formula, Drink for young children [DELETE: with added nutrients] or Product for young children [DELETE with added nutrients or Drink for young children or Product for young children,] and or Formula for Special Medical Purposes intended for infants, in particular as to the text, images and colours used, to enable consumers to make a clear distinction between them. Cross promotion between product categories is not permitted.	

8.6.5 The labelling of follow-up formula for older infants shall not [DELETE refer to. INSERT: RESEMBLE] Infant formula, Drink for young children [DELETE with added nutrients] or Product for young children [DELETE with added nutrients] or Drink for young children or Product for young children, or Formula for special medical purposes intended for infants, including numbers, text, statements, or images of these products. Rationale: Cross-promotion is a misleading and pervasive marketing practice that promotes needless use and undermines healthy feeding practices for infants and young children. Additional Safeguards: ENCA strongly recommends the inclusion of a text prohibiting the use of genetically modified ingredients in these products. ENCA recommends that the Standard is not adopted at step5/8 until CCMAS determines the outstanding issue of the measurement of sweetness of these products.	
Helen Keller International agrees that this text has been discussed and agreed upon and is ready for adoption. Helen Keller International also congratulates CCNFSDU for the work that has been accomplished on this standard over the last decade, and appreciates the contributions and commitment from the EWG and chairs.	**Helen Keller International**
IBFAN comment STANDARD FOR FOLLOW-UP FORMULA FOR OLDER INFANTS AND PRODUCT FOR YOUNG CHILDREN* (For adoption at Step 5/8 and 8) IBFAN is of the opinion that the Standard is not ready for adoption at Step 5/8 and 8. IBFAN's recommended text and comment is in red; Name of the product for young children Allowing 3 different names for the product intended for young children will confuse and mislead consumers and legislators. IBFAN strongly opposes the naming of these products as having "added nutrients". This too will be confusing for consumers. For consumers this could mean nutrients added beyond those mandated by regulations, or additional optional ingredients that are permitted by national regulations. The term "with added nutrients" is a claim that is embedded in the name of the products and should not be permitted in any Codex standards. IBFAN proposes to accept only two names Product for Young Children, Drink for Young Children. PREAMBLE IBFAN Proposes the following inclusions to strengthen the preamble. PREAMBLE This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants, and Section B deals with Drink for Young Children with Added Nutrients, or Product for Young Children with Added Nutrients, or Product/Drink for Young Children. The application of this Standard, production, distribution, marketing, sale and use of follow-up formula for older infants and product/drink for young children should be consistent with national/regional health and nutrition policies and relevant national/regional legislation. These products are not necessary as determined by Member States (World Health Assembly 39.28) and should not undermine breastfeeding. The labelling and marketing of these products must	**International Baby Food Action Network**

be in conformity with the International Code of Marketing of Breast-milk Substitutes. per the national/regional context. Relevant World Health Organization (WHO) guidelines and policies and World Health Assembly (WHA) resolutions were considered in the development of this Standard and may provide further guidance to countries. 1 SCOPE Ensure consistency with the Standard for Infant Formula and SMPs by ADDING the following text as para 1.4 to both sections A and B. 1.4The application of this section of the Standard shall conform to the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), and subsequent relevant World Health Assembly (WHA) resolutions. 4. Food Additives Section B 4.6 Flavourings 15) Natural Fruit Extracts: GMP Vanilla extract: GMP Ethyl vanillin (JECFA no. 893): 5 mg/100 ml Vanillin (JECFA no. 889): 5 mg/ 100 ml The flavourings used in products covered by this Standard should comply with the Guidelines for the Use of Flavourings (CXG 66-2008). 15) National and/or regional authorities may restrict or prohibit the use of the listed flavourings Flavourings, fruit extracts, vanilla extracts etc. should NOT be permitted for this product, Flavourings will promote the needless use of these products and develop taste preferences at an early age for flavoured, sweetened products – especially if the labels are idealized with images of fresh fruits. These will act as a health claim. 8.5 Information for Use 8.5.1 Ready to use products in liquid form should be used directly. Concentrated liquid products and powdered products must be prepared with potable water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice. ADD to both A and B the following text which aligns with WHO/FAO recommendations for the reconstitution of powdered infant formula products. Preparation instructions for powdered products must state clearly that the product is not sterile and must be reconstituted with safe water at 70 degrees centigrade, ADD the flowing references as a footnote: WHO/FAO (2007) guidelines, “Safe preparation, storage and handling of powdered infant formula.(http://apps.who.int/iris/bitstream/handle/10665/43659/9789241595414_eng.pdf?sequence=1) WHA resolutions WHA 58.32 (2005) and 61.20 (2008) Codex Alimentarius 'Code of hygienic practice for powdered formulae for infants and young children (2008), 8.6.4 The product as defined in Section 2.1 shall be distinctly labelled in such a way as to avoid any risk of confusion with infant formula, follow-up formula for older infants, and formula for special medical purposes intended for infants, in particular as to the text, images and colours used, to enable consumers to make a clear distinction between them.	

Add: to both A and B: Cross promotion between product categories is not permitted on the labelling of the product. IBFAN strongly opposes the marketing strategy of cross-promotion. This is a harmful practice that promotes needless use and undermines healthy feeding practices for infants and young children. IBFAN also strongly suggests to add a provision that genetically modified ingredients be prohibited for these products. Additionally the standard should not be adopted at step5/8 until CCMAS determines the outstanding issue of the measurement of sweetness of these products.	
ISDI welcomes the revision of the Standard for Follow-up Formula (CXS-156-87) and supports the adoption at Step 8. The Standard fundamentally changes with 2 sections addressing 2 different age groups and is the result of extensive discussions on the composition and labelling requirements. In this revised Standard, the Section A covers follow-up formulae for older infants (aged 6-12 months) and Section B covers product/drink for young children with added nutrients. The macronutrient and micronutrients balance of these products reflects the dietary requirements of the respective age groups – with maximum levels on carbohydrates and sugars being established. This long-awaited revised standard is a major milestone and reflects the latest scientific evidence in terms of nutrient composition for both older infants and young children and will ensure that the best possible products will be made available for each age group. ISDI wishes to express a particular gratitude to the Chair of the eWG, New-Zealand, for its leadership and perseverance throughout the last decade in steering the discussions. As Observer, ISDI is equally committed to help implement the revised standard into national regulations and support the smooth transition as regulations will be adapted and products formulated to meet these new requirements.	**International Special Dietary Food Industries**
WPHNA is of the opinion that the Standard is not ready for adoption at Step 5/8 and 8. WPHNA's recommended text and comment is in red; Name of the product for young children Allowing 3 different names for the product intended for young children will confuse and mislead consumers and legislators. WPHNA strongly opposes the naming of these products as having "added nutrients". This too will be confusing for consumers. For consumers this could mean nutrients added beyond those mandated by regulations, or additional optional ingredients that are permitted by national regulations. The term "with added nutrients" is a claim that is embedded in the name of the products and should not be permitted in any Codex standards. WPHNA proposes to accept only two names Product for Young Children, Drink for Young Children. PREAMBLE WPHNA Proposes the following inclusions to strengthen the preamble. PREAMBLE This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants, and Section B deals with Drink for Young Children with Added Nutrients, or Product for Young Children with Added Nutrients, or Product/Drink for Young Children. The application of this Standard, production, distribution, marketing, sale and use of follow-up formula for older infants and product/drink for young children	**World Public Health Nutrition Association**

should be consistent with national/regional health and nutrition policies and relevant national/regional legislation. These products are not necessary as determined by Member States (World Health Assembly 39.28) and should not undermine breastfeeding. The labelling and marketing of these products must be in conformity with the International Code of Marketing of Breast-milk Substitutes. per the national/regional context. Relevant World Health Organization (WHO) guidelines and policies and World Health Assembly (WHA) resolutions were considered in the development of this Standard and may provide further guidance to countries. 1 SCOPE Ensure consistency with the Standard for Infant Formula and SMPs by ADDING the following text as para 1.4 to both sections A and B. 1.4The application of this section of the Standard shall conform to the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), and subsequent relevant World Health Assembly (WHA) resolutions. 4. Food Additives Section B 4.6 Flavourings 15) Natural Fruit Extracts: GMP Vanilla extract: GMP Ethyl vanillin (JECFA no. 893): 5 mg/100 ml Vanillin (JECFA no. 889): 5 mg/ 100 ml The flavourings used in products covered by this Standard should comply with the Guidelines for the Use of Flavourings (CXG 66-2008). 15) National and/or regional authorities may restrict or prohibit the use of the listed flavourings Flavourings, fruit extracts, vanilla extracts etc. should NOT be permitted for this product, Flavourings will promote the needless use of these products and develop taste preferences at an early age for flavoured, sweetened products – especially if the labels are idealized with images of fresh fruits. These will act as a health claim. 8.5 Information for Use 8.5.1 Ready to use products in liquid form should be used directly. Concentrated liquid products and powdered products must be prepared with potable water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice. ADD to both A and B the following text which aligns with WHO/FAO recommendations for the reconstitution of powdered infant formula products. Preparation instructions for powdered products must state clearly that the product is not sterile and must be reconstituted with safe water at 70 degrees centigrade, ADD the flowing references as a footnote: WHO/FAO (2007) guidelines, “Safe preparation, storage and handling of powdered infant formula.(http://apps.who.int/iris/bitstream/handle/10665/43659/9789241595414_eng.pdf?sequence=1) WHA resolutions WHA 58.32 (2005) and 61.20 (2008) Codex Alimentarius 'Code of hygienic practice for powdered formulae for infants and young children (2008), 8.6.4 The product as defined in Section 2.1 shall be distinctly labelled in such a way as to avoid any risk of confusion with infant formula, follow-up	

formula for older infants, and formula for special medical purposes intended for infants, in particular as to the text, images and colours used, to enable consumers to make a clear distinction between them. Add: to both A and B: Cross promotion between product categories is not permitted on the labelling of the product. WPHNA strongly opposes the marketing strategy of cross-promotion. This is a harmful practice that promotes needless use and undermines healthy feeding practices for infants and young children. WPHNA also strongly suggests to add a provision that genetically modified ingredients be prohibited for these products. Additionally the standard should not be adopted at step5/8 until CCMAS determines the outstanding issue of the measurement of sweetness of these products.	

Appendix III

COMMENTS IN REPLY TO CL 2023/74/OCS-CAC - REQUEST FOR COMMENTS ON THE AMENDMENTS TO THE STANDARD FOR CANNED BABY FOOD (CXS 73-1981) AND THE ADVISORY LIST OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN (CXG 10-1979)

*Comments of Argentina, Australia, Brazil, Chile, Colombia, Costa Rica, Egypt, Kenya, New Zealand, Paraguay, Peru, Saudi Arabia, Sierra Leone, ENCA, Helen Keller International and International Special Dietary Food Industries***.**

COMMENT	MEMBER / OBSERVER
Argentina está de acuerdo con la enmienda propuesta a la norma CSX 73-1981	**Argentina**
It is the view of Australia that the amendments are ready for adoption; - Australia supports the recommendation to delete paragraph 9.5.2 relating to nitrates in beetroot and spinach from Standard for Canned Baby Foods (CXS 73-1981). - Australia supports the recommendation to extend the permitted use of the folic acid source, Calcium-L-Methyl-Folate, in the Advisory List of nutrient compounds (CXG 10-1979), for use in all six categories of foods for special dietary uses intended for infants and young children. Australia also supports the addition of the reference to USP to the column International and/or national bodies.	**Australia**
Brazil has no objection to the amendments proposed to THE STANDARD FOR CANNED BABY FOODS (CXS 73-1981) and to THE ADVISORY LISTS OF NUTRIENT COMPOUNDS FOR USE IN FOODS FOR SPECIAL DIETARY USES INTENDED FOR INFANTS AND YOUNG CHILDREN (CXG 10-1979) as agreed by CCNFSDU43 (paras. 100 and 101 of the REP23/NFSDU).	**Brazil**
Chile agradece la invitación a entregar la opinion pais. Chile Apoya la la adopción	**Chile**
Las enmiendas requieren los siguientes ajustes para ser adoptadas: Con respecto al punto 9.5.1 sugerimos eliminar la opción de folleto y dejar exclusivamente la información en la etiqueta, como se presenta a continuación: Las instrucciones sobre su preparación y uso, así como sobre su almacenamiento y conservación antes y después de que se haya abierto el envase deberán figurar en la etiqueta, o bien en el folleto que acompaña al producto. Nos permitimos solicitar la supresión del párrafo 9.5.2 de la norma CXS 73-1981.	**Colombia**
Costa Rica supports its adoption.	**Costa Rica**
Egypt appreciates the work done in the document & agrees that the amendments are ready for adoption.	**Egypt**
Kenya supports: a) the recommendation of the PWG on their submission to delete paragraph 9.5.2 from Standard CXS 73- 1981 and the amendment for adoption at CAC46 (Appendix IV). b) The recommendation of the PWG for the adoption of Appendix V at CAC46 to revise the Advisory list of nutrient compounds in CXG 10-1979, part B, row 10.2 Calcium-L-methyl-folate by adding four additional checkmarks in the columns Sec. A of IF, FUF, PCBF, and CBF as well as adding the reference USP to the column International and/or national bodies.	**Kenya**
New Zealand supports the recommendation of CCNFSDU43 to revise the Advisory list of nutrient compounds in CXG 10-1979, part B, row 10.2 Calcium-L-methyl-folate by adding four additional checkmarks in the columns Sec. A of IF, FUF, PCBF and CBF as well as adding the reference USP to the column International and/or national bodies. New Zealand supports the EFSA scientific risk assessment that concluded that there are no safety concerns with the permitted use of calcium-L-methyl-folate in foods for infants and young children. EFSA have assessed calcium-L-methyl-folate at the levels provided through formula, is as bioavailable as folic acid. New Zealand is aware of the risks with	**New Zealand**

global food supply chains and a small number of suppliers of folic acid. If the science is there to support other forms of folic acid New Zealand is of the view that CCNFSDU should be flexible to ensure worldwide access to ingredients for the essential composition of formula products. New Zealand supports the recommendation of CCNFSDU43 to delete paragraph 9.5.2 from Standard CXS 73-1981. This would remove the risk of the provision being in conflict with the WHO breastfeeding recommendations and the dietary guidelines of many countries that are recommending exclusive breastfeeding up until the age of 6 months. Any risk management decisions relating to nitrates should be based on science, as such a global risk assessment should first be undertaken before CCNFSDU can consider any specific requirements relating to the consumption of nitrate containing foods by older infants. Countries that have a concern regarding the consumption of vegetables high in nitrates could ensure that their national dietary guidelines for infants and young children have the appropriate guidance and messaging.	
Paraguay considera que dicha Propuesta de Enmienda esta lista para su adopción.	**Paraguay**
La Comisión NO tiene observaciones al documento en consulta	**Peru**
The Kingdom of Saudi Arabia supports the adoption of the amendments to CXS 73-1981 and CXG 10-1979.	**Saudi Arabia**
Sierra Leone is in favor of the proposed recommendations	**Sierra Leone**
ENCA believes that this standard is out of date, not fit for purpose and should be revoked. Any amendment is likely to give the false impression that the standard is up-to-date.	**ENCA**
Helen Keller International agrees that these amendments for the Standard for Canned Baby Foods (CXS 73-1981) have been discussed and agreed upon and are ready for adoption.	**Helen Keller International**
ISDI welcomes the proposed amendments to both Codex texts with: • Deletion of paragraph 9.5.2 from Standard CXS 73-1981 – as there is no scientific justification for the current text • Revision of the Advisory list of nutrient compounds in CXG 10-1979, part B, row 10.2 Calcium-L-methyl-folate by adding four additional checkmarks in the columns Sec. A of IF, FUF, PCBF and CBF as well as adding the reference USP to the column International and/or national bodies – as this is scientifically justified.	**International Special Dietary Food Industries**