CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Forty-third Session

COMMENTS ON DRAFT STANDARDS AND RELATED TEXTS SUBMITTED TO THE COMMISSION FOR ADOPTION AT STEP 5 [1]

BACKGROUND

This document compiles the comments on the proposed draft standards submitted at Step 5 of the Procedure. The comments have been received through the Codex Online Commenting Systems (OCS), or received via email by the time this document was issued. The comments are as shown in Appendix I.

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), OCS has been used for different Codex Committees.

EXPLANATORY NOTES ON APPENDIX I

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 country or observer)

[1] This document compiles comments received through OCS, or via email by the time this document was issued, in reply to: CL 2019/113-NFSDU, CL 2019/114-NFSDU, CL 2019/112-FH, CL 2020/4-AMR, CL 2019/104-AFRICA, CL 2020/15-NASWP and CL 2020/16-NASWP.

Appendix I

Codex Committee on Nutrition and Foods for Special Dietary Uses
Comité du Codex sur la Nutrition et Les Aliments Diététiques ou de Régime
Comité del Codex sobre Nutrición y Alimentos para Regímenes Especiales

Review of the Standard for Follow-up Formula: Section B: proposed draft scope, description and labelling

In reply to CL 2019/113-NFSDU

Comments from Argentina, Australia, Brazil, Burkina Faso, Cambodia, Canada, Chile, Colombia, Costa Rica, Egypt, Guatemala, Indonesia, Iraq, Malaysia, Mali, Mexico, Nepal, New Zealand, Nigeria, Norway, Panama, Peru, Republic of Korea, Senegal, Switzerland, USA, Viet Nam, ENCA, EU Specialty Food Ingredients, HKI, IDF/FIL, International Baby Food Action Network, International Special Dietary Food Industries and UNICEF

COMMENTS	COUNTRY / OBSERVER NAME
SCOPE Argentina agrees with the scope. DESCRIPTION Argentina agrees with paragraph 2.1.1 and considers that it is important to maintain the phrase in square brackets "[which may contribute to the nutritional needs of young children]" in the DEFINITION OF THE PRODUCT, as this, given its role, may contribute to address nutritional deficiencies of young children in the transition to the family diet. Paragraph 2.1.2 agrees with the proposal and further wishes to express that for consistency, in NAME OF THE PRODUCT, where the CCNFSDU41 proposed: "young children's drink/product with added nutrients", or "young children's drink" that the wording of "product" should also apply to "young children's drink". Resulting in "Beverage/Young Child Product with added nutrients" or "Beverage/Young Child Product". LABELLING Argentina is concerned that the new section 9.6.5 in the ADDITIONAL LABELLING REQUIREMENTS is open to various interpretations without further qualification. This may lead to differences in interpretation and implementation contrary to Codex principles. And considers necesary that further guidance is provided for proper implementation of the Standard in line with the intent clarified the new provision to limit the ability that products are labelled to make reference to other formula products in the range.	**Argentina**
Australia has no comments and supports progressing to adoption at Step 5.	**Australia**
General Comments Brazil appreciates the excellent work done by New Zealand, France and Indonesia and thanks for the opportunity to present the following comments. Specific Comments Brazil agrees with the two options for the name of the product for young children (‘Drink/Product for young children with added nutrients’ and ‘Drink for young children’), with countries able to choose between these options. However, for consistency, Brazil suggests that the word “product” also applies to the name ‘Drink for young children’. Thus, the names would read: ‘Drink/product for young children with added nutrients’ or ‘Drink/product for young children’ throughout the text of the standard where the product name is mentioned.	**Brazil**

With regard section 2.1.1, Brazil considers that the text in square brackets should be deleted since other products or foods traditionally used as part of the diversified diet of young children may also contribute to the nutritional needs of young children. Thus, the phrase in square brackets could give a false concept of superiority of this product in relation to other foods used in the diet of this age group. 2.1.1 Drink/product for young children with added nutrients or Drink/Product for young children means a product manufactured for use as a liquid part of the diversified diet of young children.	
SECTION B : BOISSON/PRODUIT POUR ENFANTS EN BAS ÂGE AVEC ÉLÉMENTS NUTRITIFS AJOUTÉS OU BOISSON POUR ENFANTS EN BAS ÂGE 1 CHAMP D'APPLICATION [1.1, 1.2, 1.3] : Le Burkina Faso approuve les textes proposés et es d'accord pour leur adoption 2 DESCRIPTION 2.1 Définition du produit [2.1.1] : Le Burkina Faso accepte les propositions faites comme un compromis acceptable. Cependant le Burkina Faso se prononce pour la suppression du texte entre crochets [qui contribue aux besoins nutritionnels des enfants en bas âge]1. Les justifications sont que le consensus était général que ces produits n'étaient pas nécessaires et ne jouent pas de grand rôle aussi l'o ne doit pas conserver ce texte entre crochets. [2.1.2] : Le Burkina Faso accepte le texte tel que proposé 2.2 Autres définitions [2.2.1] : Le Burkina Faso accepte le texte tel que proposé 9. ÉTIQUETAGE 9.1 Nom du produit [9.1.1, 9.1.2, 9.1.2, 9.1.3, 9.1.4] : Le Burkina Faso accepte le texte tel que proposé 9.2 Liste des ingrédients [9.2.1, 9.2.2] : Le Burkina Faso accepte le texte tel que proposé 9.3 Déclaration de la valeur nutritive [a, b, c] : Le Burkina Faso accepte le texte tel que proposé 9.4 Datage et instructions d'entreposage [9.4.1, 9.4.2] : Le Burkina Faso accepte le texte tel que proposé 9.5 Mode d'emploi [9.5.1, 9.5.2, 9.5.3, 9.5.4, 9.5.5, 9.5.6] : Le Burkina Faso accepte le texte tel que proposé 9.6 Spécifications d'étiquetage supplémentaires [9.6.1, 9.6.2, 9.6.3, 9.6.4, 9.6.5] : Le Burkina Faso accepte le texte tel que proposé	**Burkina Faso**
1. Scope: Cambodia agrees that this text has been discussed and agreed upon and is ready for adoption. 2. Description: 2.1.1 Cambodia agrees that, despite its voice and that of many LMIC delegates being overruled regarding these products being explicitly defined as breast-milk substitutes, this text has been discussed and agreed upon and the footnote was an accepted compromise. We note that there is still text in square brackets [which may contribute to the nutritional needs of young children] that needs to be discussed and around which Cambodia has strong views. We believe the text in square brackets must be deleted. Justification: There has been global agreement that these products are not necessary. The text in [ ] implies that they have a role to play. This is not the case and so it should not be implied in the definition of these products. 2.1.2 Cambodia agrees that this text has been discussed and agreed upon and is ready for adoption. 2.2.1 Cambodia agrees that this text has been discussed and agreed upon and is ready for adoption. 9. Labelling: 9.1 Cambodia agrees that this text has been discussed and agreed upon and is ready for adoption. 9.2 Cambodia agrees that this text has been discussed and agreed upon and is ready for adoption.	**Cambodia**

9.3 Cambodia agrees that this text has been discussed and agreed upon and is ready for adoption. 9.4 Cambodia agrees that this text has been discussed and agreed upon and is ready for adoption. 9.5 Cambodia agrees that this text has been discussed and agreed upon and is ready for adoption. 9.6 Cambodia agrees that this text, although compromise text from what we were requesting, is ready for adoption	
General comment: Canada thanks New Zealand, France and Indonesia for chairing the eWG and for their extensive work to date on the standard. Canada agrees that the text for the proposed draft scope, description and labelling sections for follow-up formula for older infants is ready for adoption. However, we have the following specific comments. Specific omments: 2.1.1 Drink/product for young children with added nutrients or Drink for young children means a product manufactured for use as a liquid part of the diversified diet of young children [which may contribute to the nutritional needs of young children]1 Canada agrees with the revised definition and supports retaining the text in square brackets to help differentiate these types of products from other beverages consumed by young children. Canada also strongly supports retaining footnote 1 as it is a factual statement that was supported by the large majority of members at the last session.	**Canada**
Chile está de acuerdo con el avance del documento.	**Chile**
El texto está listo para su aprobación, pero se presentan las siguientes observaciones: 2.1.1 Por bebida/producto con nutrientes añadidos para niños pequeños o bebida/ producto para niños pequeños se entiende todo producto fabricado para ser utilizado, cuando se requiera, como parte líquida del régimen alimentario diversificado de los niños pequeño]. 1 En algunos países, estos productos se regulan como sucedáneos de la leche materna. - Justificación Se considera que se debe agregar la palabra producto cada vez que se defina. No solo se hablará de bebida sino bebida/producto. Esto aplica en el numeral 2.1.2 y 9.1.3. Se considera que se debe agregar a la definición la expresión: cuando se requiera. Esto permite aclarar que el producto será parte del régimen alimentario, pero solo en los casos que se necesite ya que no hace parte de los productos recomendados para la población en las guías alimentarias para la población colombiana menor de 2 años. Se opina que el párrafo completo no es claro, genera confusión, da lugar a diferentes interpretaciones y puede ir en contra de los principios del Codex. Se envía nuevamente definición propuesta por Colombia y se recuerda que el objetivo es evitar confusión entre los productos. "Los productos serán etiquetados de manera diferenciada evitando cualquier riesgo de confusión entre preparados para lactantes, preparados complementarios para lactantes de más edad, [nombre del producto] para niños pequeños y preparados para usos medicinales especiales, en particular, por el texto, las imágenes y los colores utilizados, y de manera que los consumidores los distingan claramente; no se permitirán indicaciones en [etiqueta/etiquetado] o actividades que refieran que un producto para un grupo particular de edad es adecuado para otro grupo; así como deberá especificarse en cada grupo de alimentos el rango de edad para el cual el producto está destinado"	**Colombia**
Costa Rica reconoce los progresos realizados en la reunión 41ª del Comité del Codex sobre Nutrición y Alimentos para Regímenes Especiales (CCNFSDU41) para definir la futura Norma y desea agradecer el trabajo realizado por la Presidente y los copresidentes del grupo de trabajo electrónico. Comentarios: 1. Costa Rica apoya los cambios propuestos por CCNFSDU, en su 41ª período de sesiones, en los apartados 9.2.2, 9.4.1 y 9.6.4. 2. Apoya el avance del anteproyecto de secciones de ámbito de aplicación y definición y etiquetado al trámite 5 para su aprobación en el 43.º período de sesiones de la CAC (Apéndice IV). Sin embargo, Costa Rica quisiera ratificar las preocupaciones externadas en la 41ª sesión del CCFSNDU, con el objeto de que sean consideradas en las próximas discusiones:	**Costa Rica**

A. Sección 9.1.2, NOMBRE DEL PRODUCTO: añadir la palabra «producto» también a la frase «bebida para niños pequeños». Así, los nombres quedarían del modo siguiente: ……«bebida/producto con nutrientes añadidos para niños pequeños» o «bebida/producto para niños pequeños». Justificación: el producto puede presentarse en polvo y no solamente como bebida. B. Referente a la redacción propuesta en el apartado 9.6.5., Costa Rica concuerda en que, la intención de dicha propuesta es que en el etiquetado del producto no se incluyan "números, textos, declaraciones o imágenes de estos productos", que describan o hagan referencia a otros productos. Sin embargo, considera que es necesario una aclaración respecto a su correcta aplicación con el fin de evitar interpretaciones erróneas. Justificación: la Norma General para el Etiquetado de Alimentos Envasados (CXS 1-1985), en su sección 4.1.1.4 establece que, "Se podrá emplear un nombre "acuñado", "de fantasía" o "de fábrica", o una "marca registrada", siempre que vaya acompañado de uno de los nombres indicados en las disposiciones 4.1.1.1 a 4.1.1.3. ". En ese sentido, se considera que, el término "imágenes" podría entenderse erróneamente como un "logotipo", "nombre de marca", "marca comercial". Razón por la cual, se considera importante aclarar que, esta disposición debe aplicarse en concordancia con lo establecido en el apartado 5. Requisitos obligatorios adicionales de la Norma General para el Etiquetado de los Alimentos Preenvasados (CXS 1-1985), y especialmente con la excepción incluida en el inciso (d) de este mismo apartado "normas específicas del Codex Alimentarius relativas a los productos que estén en conflicto con los requisitos aquí descritos". Asimismo; los términos "texto" y "declaraciones" necesitan claridad para su correcta interpretación y aplicación. La misma norma CXS 1-1985, en su nota al pie No.1 menciona: "En las Directrices generales sobre declaraciones de propiedades, se dan ejemplos de las formas de describir o presentar a que se refieren estos principios generales", por lo que se considera necesario en esta propuesta ser más específicos o referir en el apartado a los textos aclaratorios de etiquetado del Codex antes mencionados. Finalmente, Costa Rica apoya la inclusión de la frase «que puede contribuir a las necesidades nutricionales de los niños pequeños» incluida en la DEFINICIÓN DEL PRODUCTO, sección 2.1.1, pues describe la función del mismo ya que podría ayudar a compensar deficiencias de nutrientes durante la transición de los niños pequeños hacia una dieta familiar.	
SECTION B: ~~[NAME OF PRODUCT] FOR YOUNG CHILDREN~~ **DRINK FOR YOUNG CHILDREN OR DRINK FOR YOUNG CHILDREN WITH ADDED NUTRIENTS** 1.1 This section of the Standard applies to ~~[name of product] for young children~~ **the product as** defined in Section 2.1, in liquid or powdered form. 1.2 This section of the Standard contains compositional, quality, safety, labelling, analytical and sampling requirements for ~~[name of product] for young children.~~ **the product as defined in Section 2.1.** 1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard shall be presented as ~~[name of product] for young children~~. **Drink for young children Or Drink for young children with added nutrients**. **2.1.1. [Name of product] for young children** means a product ~~specially~~ **~~[formulated and]~~** manufactured for use **~~[as a breast-milk substitute]~~**, as a liquid part of the **~~[progressively]~~** ~~[~~diversified~~]~~ diet of young children **[in order to contribute to the nutritional needs of young children] ~~[when nutrient intakes may not be adequate to meet nutritional requirements~~**~~].~~ **2.1.1 Drink for young children Or Drink for young children with added nutrients means a product manufactured for use as a liquid part of the of young children's diet.1** **2.1.2. ~~[Name of product] for young children~~ Drink for young children Or Drink for young children with added nutrients** is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold.	**Egypt**

9. LABELLING The requirements of the General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985), the Guidelines on Nutrition Labelling (CXG 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) apply to ~~[Name of Product] for young children~~ **the product as defined in Section 2.1** 9.1.2 The name of the product shall be ~~Name of Product] for Young Children~~ "**Drink for young children Or Drink for young children with added nutrients"** as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national or regional usage. **9.1.3** The sources of protein in the product shall be clearly shown on the label. a) If [name of animal] milk is the only source of protein*, the product may be labelled '~~[Name of Product] for Young Children~~ "**Drink for young children Or Drink for young children with added nutrients"** Based on [name of animal] milk protein'". b) If [name of plant] is the only source of protein*, the product may be labelled ~~[Name of Product] for Young Children~~ "**Drink for young children Or Drink for young children with added nutrients"** Based on [name of plant] protein'. c) if [name of animal] milk and [name of plant] are the sources of proteins*, the product may be labelled ~~[Name of Product] for Young Children~~ "**Drink for young children Or Drink for young children with added nutrients"** Based on [name of animal] milk protein and [name of plant] protein' or ~~[Name of Product] for Young Children~~ **"Drink for young children Or Drink for young children with added nutrients"** Based on [name of plant] protein and [name of animal] milk protein. 9.1.4 A product which contains neither milk nor any milk derivative **shall [**~~may~~**]** be labelled "contains no milk or milk products" or an equivalent phrase. 9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate functional classes names for ~~these ingredients and~~ **the food** additives may be included on the label. ~~[~~The food additive~~s~~ INS number may also be optionally declared ~~the INS number~~]. **9.3 Declaration of Nutritive Value** The declaration of nutrition information for ~~[name of product] for young children~~ **Drink for young children Or Drink for young children with added nutrients** shall contain the following information which should be in the following order: c) In addition to a) and b), the declaration of nutrients per [serving size and/or per] 100 kilocalories **(kcal)** (or per 100 kilojoules) **(kJ)** is permitted. 9.5.6 The label of ~~[name of product] for young children children~~ "**Drink for young children Or Drink for young children with added nutrients "**shall include a statement that the product shall not be introduced before 12 months of age and should be part of a [diversified] [balanced] diet.**]** **~~[~~9.6.1** The label of [~~name of product] for young children children~~ "**Drink for young children Or Drink for young children with added nutrients"** shall have no image, text or representation **[,including pictures of feeding bottles,]** ~~that~~ could undermine or discourage breastfeeding or which idealises the use of [name of product] for young children. The terms 'humanized', 'maternalized' or other similar terms must not be used on the label.**~~]~~[9.6.2]** Products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants~~, [name of product] for young children, children~~, **Drink for young children Or Drink for young children with added nutrients** and formula for special medical purposes **~~[~~ and to enable consumers to make a clear distinction between them~~, in particular as to the text, images and colours used~~]**.~~]~~**	
Guatemala expresa su aprobación a la presente norma, sin embargo, considera que en el apartado de etiquetado (Capítulo 9) hay párrafos en donde se puede aún mejorar la redacción, específicamente para evitar repeticiones de normas ya aprobadas como las Directrices para el Uso	**Guatemala**

de Declaraciones Nutricionales y de Propiedades Saludables (CXG 23-1997). Aunque se debe tener en cuenta las declaraciones sobre propiedades nutricionales, saludables y la función de los nutrientes que deberían permitirse siempre que el nutriente esté en una cantidad suficiente para lograr tales efectos y que esté científicamente justificado; ya que no hacerlo se podrían crear condiciones competitivas desiguales y permitir una elección de alimentos no saludables para niños. Por otro lado, se sugiere que al final del párrafo 9. 5. 6 sea agregada el texto "y que no ha sido formulado como un sustituto de la leche materna y no es apropiado como única fuente de nutrición. Guatemala, igualmente, expresa su preocupación por que la nueva sección 9.6.5 de los Requisitos de Etiquetado Adicionales pueda interpretarse de maneras distintas si no se detalla más, lo que podría dar lugar a interpretaciones o aplicaciones contrarias a los principios de Codex. De igual manera se podría dar lugar a una restricción contraria a las obligaciones internacionales que rigen los derechos de propiedad intelectual (por. ejemplo., la palabra «imágenes» puede entenderse como logotipos, marcas comerciales o registradas). Por tanto, Guatemala propone añadir instrucciones para aplicar correctamente la Norma de acuerdo con el propósito definido por el país (con el apoyo de algunas delegaciones) que ha introducido la nueva disposición. El objetivo es limitar la posibilidad de que los productos se etiqueten de modo que hagan referencia a otros preparados en la categoría.	
Indonesia supports the adoption at step 5 of Proposed Draft Revised Standard for Follow-Up Formula: Section B: proposed draft scope, description and labelling.	**Indonesia**
We agree with review of the standard / section B without any comments. Our regards.	**Iraq**
2.1.1 Malaysia proposes to retain the sentence [which may contribute to the nutritional needs of young children] in the PRODUCT DEFINITION, section 2.1.1 as the product can help address nutrition deficiencies for young children during transition to a family-based diet. The rationale for this proposal are as follows: • Young Children (12-36 months) have very specific nutritional requirements during the transition to a family diet with a wider range of foods. • At least half of children worldwide aged 6 months to 5 years suffer from one or more micronutrients deficiency. o "The contribution to the nutritional needs of young children where the consumption of the nutrient is widely inadequate" was one of the principles for selecting the essential composition of the product (REP17/NFSDU). • Drink/product for Young Children may contribute to improved health status of the young children. o They are specifically formulated for young children 12 to 36 months of age providing key nutrients such as Iron, Zinc and Vitamin A to contribute to appropriate nutrient intakes as part of the whole diet. 9.1.2 Malaysia proposes to align the text used in Section 9.1.2 NAME OF THE PRODUCT for consistency by adding the word "product" to "drink for young children". The names would then be read as: "Drink/product for young children with added nutrients" or "Drink/product for young children". The rationale for this proposal are as follows: • According to CODEX GENERAL STANDARD FOR THE LABELLING OF PREPACKAGED FOODS (CODEX STAN 1-1985) the name should be specific and not generic. • "Drink" is not an appropriate denomination for certain countries (meaning it is a liquid to be given to relieve thirst). • It is normally a requirement in Codex texts that the name of the product reflects the true nature of the food. 9.6.5 Malaysia has no objection with the proposed text but request for further guidance be provided for proper implementation of the standard. The rationale for this proposal are as follows: • The term "images" could be wrongly understood as a "logo', "brand name", "trade mark" which are out of the scope based on the interpretation given and this should be clearly acknowledged: o It is permitted as optional labelling elements1 providing they are not in conflict with the General principles established for the labelling of pre-packaged foods. o They are examples of intellectual property and therefore cannot be in the scope. o Brand/stage of the product itself/logo/trademark/brand identification" helps caregivers:	**Malaysia**

□ to identify appropriate nutritional products based on the child's age and needs, □ to identify recognized and trusted products. • "text" and "statements" are very similar terms: o The use of these terms in a Codex Standard without further qualification of the specific" text" or "statements" considered is open to various interpretation leading to differences in implementation.	
1. Le Mali approuve le texte tel qu'il a été discuté et reste favorable à la poursuite des travaux. 2.1.1 Le Mali définie ces produits comme des substituts du lait maternel, ce texte a été discuté et approuvé et la note de bas de page était un compromis accepté. 2.1.2 Le Mali approuve la suppression des crochets autour du texte [qui peut contribuer aux besoins nutritionnels des jeunes enfants]. Justifications : Il a été convenu qu'à l'échelle mondiale que ces produits ne sont pas nécessaires. Le texte entre implique qu'ils ont un rôle à jouer. Ce n'est pas le cas et cela ne devrait donc pas être impliqué dans la définition de ces produits. Une évaluation récente utilisant les données d'Innova Market Insights a examiné la composition actuelle de ces produits en Indonésie. Bien que la reconnaissance de la norme révisée nécessite des changements de composition, les résultats sont toujours importants. Ils montrent que malgré leur enrichissement en une gamme de vitamines et minéraux, la composition de ces produits pour la tranche d'âge 12-36 mois ne répond pas aux besoins nutritionnels de ces jeunes enfants. Plus d'un quart des laits de cette catégorie d'âge n'étaient pas conformes à la recommandation révisée convenue de moins de 2,5 g de sucre gratuit pour 100 kcal et 1 personne sur 10 (11%) n'a pas fourni suffisamment d'informations pour évaluer leur conformité. De plus, presque tous les produits contenaient un ou plusieurs sucres ajoutés (la moyenne étant de 5) et les trois quarts contenaient du saccharose. De plus, par rapport au lait de vache entier, ce qui est recommandé pour ces jeunes enfants, l'utilisation de ces produits a des impacts substantiels sur la consommation quotidienne de sucre et ajoute 10 à 16 g de sucre par jour supplémentaires au jeune enfant. Cela va à l'encontre des recommandations mondiales visant à réduire et à limiter le sucre dans l'alimentation des jeunes enfants et les expose à de futures maladies de surcharge pondérale et non transmissibles. De nombreux changements de composition sont nécessaires avant que ces produits ne répondent même à la norme de composition Codex. Dans l'intérêt de la santé infantile, et considérant qu'elles ne sont pas nécessaires, elles ne peuvent être définies comme contribuant aux besoins nutritionnels des jeunes enfants. En outre, 2019 a vu la publication d'un rapport technique sur la consommation de boissons saines dans la petite enfance qui fournit des recommandations des principales organisations nationales américaines de santé et de nutrition [Academy of Nutrition and Dietetics (AND), l'American Academy of Pediatric Dentistry (AAPD), l'Amérique Academy of Pediatrics (AAP) et l'American Heart Association (AHA)] sur la consommation optimale de boissons pendant la petite enfance et soutiennent une approche fondée sur le cycle de vie pour le développement de modèles alimentaires sains et la prévention des maladies chroniques. Les experts font une recommandation claire. «0-12 mois: éviter la supplémentation avec des formules de« transition »ou de« sevrage »; les besoins en nutriments doivent être satisfaits principalement par le lait maternel et / ou les préparations pour nourrissons. La justification donnée est la suivante: le groupe d'experts a conclu que «bien qu'il n'y ait aucune preuve indiquant que le lait pour tout-petits est nocif, ces produits n'offrent aucune valeur nutritionnelle unique au-delà de ce qui pourrait être obtenu grâce à une alimentation nutritionnellement adéquate; en outre, ils peuvent apporter des sucres ajoutés à l'alimentation. Le lait pour tout-petits est également plus cher qu'un volume équivalent de lait de vache. Les nourrissons et les jeunes enfants devraient d'abord viser à répondre aux besoins en nutriments principalement par le lait maternel et / ou les préparations pour nourrissons, puis de plus en plus par le biais d'aliments et de boissons sains lors de leur transition vers des aliments solides. Si l'apport alimentaire riche en nutriments semble insuffisant, d'autres stratégies visant à accroître l'acceptation des aliments doivent être essayées avant de recourir à des laits pour tout-petits, telles que des expositions répétées à des aliments sains. » 2.1.2 Le Mali convient que ce texte a été discuté, approuvé et prêt pour adoption 2.2.1 Le Mali convient que ce texte a été discuté, approuvé et prêt pour adoption 9.1 Le Mali convient que ce texte a été discuté, approuvé et prêt pour adoption 9.2 Le Mali convient que ce texte a été discuté, approuvé et prêt pour adoption 9.3 Le Mali convient que ce texte a été discuté, approuvé et prêt pour adoption 9.4 Le Mali convient que ce texte a été discuté, approuvé et prêt pour adoption	**Mali**

9.5 Le Mali convient que ce texte a été discuté, approuvé et prêt pour adoption 9.6 Le Mali convient que ce texte a été discuté, approuvé et prêt pour adoption	
2.1.1 Por preparado para niños pequeños, se entiende como un sucedáneo de la leche materna especialmente fabricado para satisfacer parcialmente las necesidades nutricionales de los niños pequeños. Justificación: La definición y el nombre del producto establecida en 2.1.1 no describe las características particulares del producto en comento, en virtud de que "producto fabricado para ser utilizado como parte líquida del régimen alimentario" y "que puede contribuir a las necesidades nutrimentales de los niños pequeños" son características que también aplican a la leche, a las bebidas a base de proteína de soya, a los jugos, a los néctares o cualquier líquido que se oferte a los niños entre 12 a 36 meses de edad. En este sentido, la característica que le da la particularidad a este producto es su uso como "sucedáneo de la leche materna". Con base en la duración de la lactancia materna recomendada por la Organización Mundial de la Salud (hasta los dos años de edad o más), el producto en comento es un sucedáneo de la leche materna, en virtud de sustituir parcial o totalmente a la leche materna a partir del año de edad, no obstante que no tenga la misma composición de la leche materna, conforme se clasifica en las Orientaciones sobre la forma de poner fin a la promoción inadecuada de alimentos para lactantes y niños de corta edad de la Organización Mundial de la Salud, motivo por el cual no puede considerarse como una parte líquida del régimen alimentario diversificado de los niños pequeños. Por tales motivos, se considera inadmisible que la condición de "sucedáneo de la leche materna" quede a criterio de los países, y más aún, que determinados requisitos de etiquetado dependan de dicha condición. Por lo que se sugiere eliminar el pie de página No. 1, eliminar el texto "para ser utilizado como pate líquida del régimen alimentario diversificado de los niños pequeños" y eliminar los corchetes de la última frase con un cambio. De esta forma, se propone la definición siguiente: 2.1.1 Por preparado para niños pequeños, se entiende como un producto sucedáneo de la leche materna especialmente fabricado para satisfacer parcialmente a las necesidades nutricionales de los niños pequeños. 9.1.1 El producto se denominará , preparado para niños pequeños tal como se define en la Sección 2.1, o cualquier otra denominación apropiada que indique la verdadera naturaleza del producto, de conformidad con las costumbres del país o de la región. Justificación En virtud de considerar al producto como un sucedáneo de la leche materna conforme se argumentó anteriormente y del cual se establecieron requisitos de composición nutrimental, se propone denominarlo como "preparado para niños pequeños". Sobre el texto "con nutrientes añadidos" se observa no refleja la verdadera naturaleza del producto en comento, en virtud de que su composición nutrimental se deriva de una formulación estandarizada, por lo que puede inducir a error o a engaño al consumidor. Asimismo, este texto puede afectar negativamente la práctica de la lactancia materna o desalentar dicha práctica, al establecer una comparación con la leche materna o al denotar que el producto en comento es superior a la leche materna. De acuerdo con el ESTÁNDAR GENERAL del CODEX PARA EL ETIQUETADO DE LOS ALIMENTOS PREENVASADOS (CODEX STAN 1-1985) el nombre debe ser específico y no genérico. • "Bebida" no es una denominación apropiada para ciertos países (lo que significa que es un líquido que se debe administrar para aliviar la sed). • Normalmente es un requisito en los textos del Codex que el nombre del producto refleje la verdadera naturaleza de los alimentos (CSX 1-1985 subsección 4.1.1). Por lo que se reitera el cambio del nombre del producto a "preparado para niños pequeños". 9.3 Declaración del valor nutritivo a) La cantidad de energía, expresada en kilocalorías (kcal) y/o kilojulios (kJ), y la cantidad en gramos de proteínas, carbohidratos y grasa por cada 100 g o cada 100 ml de alimento vendido, [así como] [o] por 100 ml del alimento listo para el consumo que se haya preparado de acuerdo con las condiciones indicadas en la etiqueta. b) La cantidad total de cada vitamina y mineral indicados en el apartado 3.1.3 de la Sección B, y de cualquier otro ingrediente indicado en la lista del apartado 3.2 de la Sección B, por 100 g o cada 100 ml de alimento vendido, [así como] [o] por 100 ml del alimento listo para el consumo que se haya preparado según las instrucciones indicadas en la etiqueta.	**Mexico**

c) Además, se permitirá la declaración del contenido de nutrientes por cada 100 kcal (o por cada 100 kJ) Justificación: En virtud de que el uso del producto en comento no debe ser un producto básico dentro de las guías alimentarias de los niños y de las niñas pequeños, en virtud de que sus requerimientos nutrimentales pueden ser cubiertos por la leche materna y por alimentos y suplementos alimenticios de uso regular y dado que su uso debe ser recomendado por el profesional de la salud con base en las necesidades nutrimentales individuales del niño o de la niña pequeños, se recomienda no incluir la declaración nutrimental del contenido de nutrimentos por porción y por lo anterior solicitamos eliminar la última frase del inciso c de este numeral. 9.5 Instrucciones de uso 9.5.1 … 9.5.2 En la etiqueta se darán instrucciones adecuadas para la preparación y el uso apropiados del producto, así como para su conservación y su eliminación después de su preparación, es decir, que deberá desecharse el producto sobrante. 9.5.3 No se deberán incluir esquemas de alimentación que indiquen el número de tomas por edad del lactante. Justificación: Es una práctica común en el etiquetado de los sucedáneos de la leche materna la inclusión de tablas que establecen número de tomas de determinada concentración y volumen por edad del lactante. A partir de considerar que los esquemas de alimentación deben ser establecidos por el profesional de la salud, conforme se dispone en el inciso b) del numeral 9.6.2, se recomienda prohibir el uso de dichas tablas, en virtud de que dicha información puede inducir a la interrupción de la lactancia materna continua posterior al año de edad del niño o de la niña o ser utilizada de forma inadecuada por el cuidador del niño de corta edad, pudiendo ocasionar una alimentación deficiente o excesiva en el niño pequeño. En consecuencia, solicitamos incluir el siguiente texto: No se deberán incluir esquemas de alimentación que indiquen el número de tomas por edad del lactante.	
Nepal supports the definition 2.1.1, but strongly proposes to delete the text []. Nepal strongly believes that these products are unnecessary as Nepal Government's programs promote breastfeeding and discourage these products. The current text in [] gives the impression that these products are necessary. Given the opportunity with the text in the [], manufacturers and distributors of these products are more lively to use it for the marketing purpose, leading mothers to believe that these products offer nutrient benefit to their children, where, in fact, these products provide no unique nutrition value, instead will contribute to added sugar in the diet of the young children. Furthermore, these products are not yet covered in the Nepal's Mothers Milk Substitute Act giving government less opportunity to monitor these products. Therefore, Nepal strongly proposes to delete the text in the []. 2.1.2 Nepal agrees that this text is ready for adoption. 2.2.1 Nepal agrees that this text is ready for adoption. 9.1 Nepal agrees that this text is ready for adoption. 9.2 Nepal agrees that this text is ready for adoption. 9.3 Nepal agrees that this text is ready for adoption. 9.4 Nepal agrees that this text is ready for adoption.	**Nepal**

9.5 Nepal agrees that this text is ready for adoption. 9.6 Nepal agrees that this text is ready for adoption.	
New Zealand appreciates the opportunity to comment on the Circular Letter at Step 5 concerning the proposed draft scope, description and labelling within Section B of the revised Codex Standard for Follow-up Formula. New Zealand strongly supports the adoption of Section B: proposed draft scope, description and labelling for 'Drink/Product for Young Children with Added Nutrients' and 'Drink for Young Children'. We note that the 2020 EWG has been charged with finalising the definition of 'Drink/Product for young children with added nutrients' and 'Drink for young children', by reviewing the outstanding text [which may contribute to the nutritional needs of young children]; and will also consider the linkages and impact between the definition and name for 'Drink/Product for young children with added nutrients' and 'Drink for young children'. New Zealand will provide more detailed comments on the definition and name of product as per the EWG Terms of Reference during the EWG consultation period, in addition to providing comment at Step 6. Any comments made in response to these calls for comment do not change New Zealand's support for the adoption of the text contained within this CL at Step 5.	**New Zealand**
1. The text on SCOPE is ready for adoption. 2. Clause 2.1.1. Nigeria is of the opinion that the text in square brackets [which may contribute to the nutritional needs of young children] should be deleted therefore 2.1.1 is not ready for adoption. Rationale: There is a clear statement from the World Health Organization (WHO) that these products are not necessary. The text in square brackets suggests/implies that the products are somewhat necessary to meet the nutritional needs of young children, which they are not. Furthermore, the text could be construed to be a nutrition claim. 3. Clause 2.1.2. The text as presented is ready for adoption. 4. Clause 2.2.1. The text as presented is ready for adoption. 5. Clause 9.1.1. Nigeria is of the opinion that this text is ready for adoption. 6. Clause 9.1.2. Nigeria is of the opinion that the text is not ready for adoption. Rationale: Nigeria would like to point out that the second option 'Drink for young children' has not taken into account the fact that the product may not yet be a drink as packaged, that it may be a concentrated liquid product or powdered product which needs to be (reconstituted) into a drink so it should be named 'Drink/product for young children'. This is the same rationale for which the first option was named 'Drink/product for young children with added nutrients. To buttress this point, reference is being made to 9.5.1 (under Information for use) where it clearly indicates and specifically mentions 'concentrated liquid products and powdered products' in the following: "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." 7. Clause 9.1.4. Nigeria is of the opinion that this text is ready for adoption. 8. Clause 9.2. Nigeria is of the opinion that this text is ready for adoption. 9. Clause 9.3 Nigeria is of the opinion that this text is ready for adoption. 10. Clause 9.4. Nigeria is of the opinion that this text is ready for adoption. 11. Clause 9.5. Nigeria is of the opinion that this text is ready for adoption. 12. Clause 9.6.5. Nigeria is of the opinion that this text is not ready for adoption. The labelling of the product as defined in Section 2.1 shall not refer to infant formula, follow-up formula for older infants, or formula for special medical purposes intended for infants, including numbers, text, statements, or images of these products. Rationale: The word 'refer' should be replaced with 'resemble' which better conveys the intent of cross-promotion. Proposed text: The labelling of the product as defined in Section 2.1 shall not resemble that of infant formula, follow-up formula for older infants, or formula for special medical purposes intended for infants, including numbers, text, statements, or images of these products.	**Nigeria**

We can support adoption at step 5, with an amendment to the explanation of the concept “cross promotion” in para 9.6.5 to include a clear mentioning of the fact that the product shall “not resemble” infant formula: “9.6.5 The labelling of the product as defined in Section 2.1 shall not refer to or resemble infant formula, follow-up formula for older infants, or formula for special medical purposes intended for infants, including numbers, text, statements, or images of these products.” Rationale: At CCNFSDU 41 we accepted including in paragraph 9.6.5 more explanatory text to replace “cross promotion” with the understanding that the intent would be kept. We are concerned that the current text without the amendment might not be understood as fully covering all aspects of brand stretching (related to packaging, branding and labelling). Therefore, in order to provide clarity, we suggest amending 9.6.5 with the inclusion of "resemble". This will better capture the intent of "cross promotion", and better protect infants and young children from the consequences of inappropriate marketing. This proposal is in line with the description of “Cross promotion” in the WHO Guidance document to WHA 69.9 Cross-promotion (also called brand crossover promotion or brand stretching) is a form of marketing promotion where customers of one product or service are targeted with promotion of a related product. This can include packaging, branding and labelling of a product to closely resemble that of another (brand extension). In this context, it can also refer to use of particular promotional activities for one product and/or promotion of that product in particular settings to promote another product.	**Norway**
Sección B / Título de la Sección SECCIÓN B: BEBIDA/PRODUCTO CON NUTRIENTES AÑADIDOS PARA NIÑOS PEQUEÑOS O BEBIDA PARA NIÑOS PEQUEÑOS Panamá Recomienda la siguiente redacción: SECCIÓN B: PRODUCTO BEBIBLE O EN POLVO CON NUTRIENTES AÑADIDOS PARA NIÑOS PEQUEÑOS O PRODUCTO BEBIBLE O EN POLVO PARA NIÑOS PEQUEÑOS Justificación: La terminología de bebida puede confundirse con el sistema de clasificación de alimentos (CODEX STAN 192-1995) en donde los alimentos clasificados como bebidas corresponde a la clasificación 14.0 “Bebidas, excluidos los productos lácteos”, en cambio los alimentos que se relacionan con los preparados complementarios pertenece a la clasificación 13.0 “Productos alimenticios para usos nutricionales especiales”. Para el párrafo 2.1.1 Por bebida/producto con nutrientes añadidos para niños pequeños o bebida para niños pequeños se entiende todo producto fabricado para ser utilizado como parte líquida del régimen alimentario diversificado de los niños pequeños [que puede contribuir a las necesidades nutricionales de los niños pequeños]. Panamá recomienda la siguiente redacción: Por producto bebible o en polvo con nutrientes añadidos para niños pequeños o producto bebible o en polvo para niños pequeños se entiende como todo producto alimenticio fabricado para ser utilizado como parte líquida del régimen alimentario diversificado de los niños pequeños, [que puede contribuir a cubrir las necesidades nutricionales de los niños pequeños].1 Justificación: Mejorar la redacción de lo que se entiende de la definición del producto: La Norma para Preparados Complementarios (CXS 156-1987) menciona en su definición del numeral 2.1.1. “Por preparados complementarios se entiende que ES TODO ALIMENTO destinado a ser utilizado como parte líquida de una ración de destete para lactantes a partir del sexto mes y para los niños pequeños”; por tal razón para reforzar la definición en esta sección se sugiere mejorar la redacción, ampliándolo como un PORDUCTO ALIMENTARIO. Por otro lado, si un alimento es parte del régimen alimentario diversificado de los niños pequeños, esta diversidad alimentaria es con el fin de CONTRIBUIR A CUBRIR NECESIDADES NUTRICIONALES, lo cual no es lo mismo que se mencione “contribuir a las necesidades nutricionales.	**Panama**

Para el párrafo 9.6.5 El etiquetado de los productos definidos en la Sección 2.1 no deberá hacer referencia a preparados para lactantes, preparados complementarios para lactantes de más edad o preparados para usos medicinales especiales destinados a los lactantes, incluidos los números, los textos, las declaraciones o las imágenes de estos productos. Panamá recomienda la siguiente redacción: El etiquetado de los productos definidos en la Sección 2.1 no deberá hacer referencia a preparados para lactantes, preparados complementarios para lactantes de más edad o preparados para usos medicinales especiales destinados a los lactantes, incluidos los números, los textos, las declaraciones o las imágenes ilustrativas de en los empaques de estos productos, sin contravenir los derechos de propiedad intelectual" Justificación: la sección 9.6.5 podría dar lugar a una prohibición o restricción contraria a las obligaciones internacionales que rigen los derechos de propiedad intelectual (p. ej., la palabra «imágenes» puede entenderse como logotipos, marcas comerciales o registradas). Por tanto, proponemos añadir instrucciones para aplicar correctamente la Norma de acuerdo con el propósito definido por el país (con el apoyo de algunas delegaciones) que ha introducido la nueva disposición. El objetivo es limitar la posibilidad de que los productos se etiqueten de modo que hagan referencia a otros preparados de la gama. Para el párrafo 9.11 El producto se denominará «bebida/producto con nutrientes añadidos para niños pequeños» o «bebida para niños pequeños», tal como se define en la Sección 2.1, o cualquier otra denominación apropiada que indique la verdadera naturaleza del producto, de conformidad con las costumbres del país o de la región. Panamá recomienda la siguiente redacción: El producto se denominará producto bebible o en polvo con nutrientes añadidos para niños pequeños» o producto bebible o en polvo para niños pequeños», tal como se define en la Sección 2.1, o cualquier otra denominación apropiada que indique la verdadera naturaleza del producto, de conformidad con las costumbres del país o de la región. Justificación: Por coherencia, solicitamos que en la sección 9.1.2, NOMBRE DEL PRODUCTO, en las frases propuestas en CCNFSDU41 «bebida/producto con nutrientes añadidos para niños pequeños» o «bebida para niños pequeños», se añada la palabra «producto» también a la frase «bebida para niños pequeños». Así, los nombres quedarían del modo siguiente: «bebida/producto con nutrientes añadidos para niños pequeños» o «bebida/producto para niños pequeños».	
Perú está de acuerdo con todo lo propuesto en las secciones Ámbito de aplicación, Descripción y Etiquetado de la carta circular CL 2019/113/OCS-NFSDU	**Peru**
ROK reviewed 'the Standard for follow up formular : section B' and accepted the document as it presented. Thanks to the delegate of New Zealand for their hard work and dedication.	**Republic of Korea**
SECTION B : BOISSON/PRODUIT POUR ENFANTS EN BAS ÂGE AVEC ÉLÉMENTS NUTRITIFS AJOUTÉS OU BOISSON POUR ENFANTS EN BAS ÂGE 1 CHAMP D'APPLICATION Commentaire : le Sénégal supporte le texte tel qu'il a été discuté et approuvé pour adoption à l'étape 5 2 DESCRIPTION 2.1.1 Commentaire : le Sénégal supporte cette définition pour enfants en bas âge avec la note en bas de page (Dans certains pays, ces produits sont réglementés en tant que substituts du lait maternel) qui a été longuement discutée au cours de la session précédente et approuvée. Cependant nous pensons que ces produits ne sont pas nécessaires et la phrase entre crochet [qui contribue aux besoins nutritionnels des enfants en bas âge]1 doit être supprimée. 2.1.2. Commentaire : Le Sénégal supporte le texte tel que discuté et approuvé pour adoption à l'étape 5 2.2.1 Commentaire : Le Sénégal supporte le texte tel que discuté et approuvé pour adoption à l'étape 5	**Senegal**

9. ÉTIQUETAGE Commentaire : Le Sénégal supporte le texte tel que discuté et approuvé pour adoption à l'étape 5 9.2 Liste des ingrédients Commentaire : Le Sénégal supporte le texte tel que discuté et approuvé pour adoption à l'étape 5 9.3 Commentaire : Le Sénégal supporte le texte tel que discuté et approuvé pour adoption à l'étape 5 9.4 Commentaire : Le Sénégal supporte le texte tel que discuté et approuvé pour adoption à l'étape 5 9.5 Mode d'emploi Commentaire : Le Sénégal supporte le texte tel que discuté et approuvé pour adoption à l'étape 5 9.6 Spécifications d'étiquetage supplémentaires Commentaire : Le Sénégal supporte le texte tel que discuté et approuvé pour adoption à l'étape 5	
Switzerland can support adoption at step 5, with the same amendment as proposed by Norway to the explanation of the concept "cross promotion" in para 9.6.5 to include a clear mentioning of the fact that the product shall "not resemble" infant formula based on the same rationale: "9.6.5 The labelling of the product as defined in Section 2.1 shall not refer to [or resemble] infant formula, follow-up formula for older infants, or formula for special medical purposes intended for infants, including numbers, text, statements, or images of these products".	**Switzerland**
For Section 1 – Scope, the United States supports adoption of the text agreed by the committee during CCNFSDU42. For Section 2.1, the United States supports retaining the text in square brackets as part of the product definition. As a committee, we agreed to a select list of mandatory added nutrients and other optional nutrients that could be added; we then set minimum levels for those nutrients. This action was based on scientific data showing that most young children are not getting sufficient amounts of these nutrients from their diversified diet. As there was a clear scientific and public health basis for the added nutrients, the United States is of the view that the product definition should reflect the committee's decisions and that it should represent the product composition. The United States continues to express our reservation with respect to the footnote. We do not support including footnotes as part of a standard that are stating a fact and not a decision of the committee and do not support the practice of employing footnotes to address issues on which the committee is not able to agree. This statement could be appropriate in the Committee report, as reflecting the discussion during the session, but it is not appropriate in a Codex standard. For Para. 2.2.1, the United States can support adoption of the text. However, we would like clarity as to how more than 12 months is interpreted. We would interpret more than 12 months to mean the start of the 13th month of age. For Section 9.1, in general, the United States can support adoption of the text in Section 9.1 – Paras. 9.1.1 through 9.1.3. However, we have a few suggested edits for consistency as explained below and as noted in track changes. First, both name options should include the options of "Drink" or "Product." Currently, "Drink for Young Children" omits the option of "Product" that the committee decided to include to cover the powdered products sold. For consistency, the second name should read "Drink/Product for Young Children." This change occurs in both Para. 9.1.2 and Para. 9.1.3(a)-(c). Second, we agree that, rather than list the alternative names in each case, the names be replaced with a reference to them; however, we suggest that the reference in the text should be "as named in 9.1.2" rather than the current reference to "section 2.1" since Section 2.1 is the definition section and Para. 9.1.2. is within the name section. For Paras. 9.1.2 and 9.1.3, we offer the following text: 9.1.2 The name of the product shall be ""Drink/Product for Young Children with Added Nutrients" or "Drink/Product for Young Children" as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national or regional usage. 9.1.3 The sources of protein in the product shall be clearly shown on the label. a) If [name of animal] milk is the only source of protein*, the product may be labelled "Drink/Product for Young Children with Added Nutrients Based on [name of animal] milk protein" or "Drink/Product for Young Children Based on [name of animal] milk protein". b) If [name of plant] is the only source of protein*, the product may be labelled "Drink/Product for Young Children with Added Nutrients	**USA**

Based on [name of plant] protein" or "Drink/Product for Young Children Based on [name of plant] protein". c) if [name of animal] milk and [name of plant] are the sources of proteins*, the product may be labelled "Drink/Product for Young Children with Added Nutrients Based on [name of animal] milk protein and [name of plant] protein" or "Drink/Product for Young Children Based on [name of animal] milk protein and [name of plant] protein" or "Drink/Product for Young Children with Added Nutrients Based on [name of plant] protein and [name of animal] milk protein" or "Drink/Product for Young Children Based on [name of plant] protein and [name of animal] milk protein". For Section 9.2, the United States supports adoption of the text. For Section 9.3, the United States supports adoption of the text. For Section 9.5, in general, the United States supports adoption of Section 9.5. However, we request clarification on the text at the end of Para. 9.5.6 where it states: "… not to be used as a sole source of nutrition". Is this phrase intended to be explicitly stated on the label as is? Or would suitable alternative text be permitted to communicate to the care giver that product is intended to be used as part of a diversified diet? For Section 9.6, in general, the United States can support adoption of the text under Section 9.6. However, we offer an edit in Para. 9.6.5 as noted in track changes. The purpose of the edits is to add clarity and to reflect comments during CCNFSDU41 plenary. The US intervention was documented in the CCFNSDU41 Report Para. 78 (REP20/NFSDU). Therefore, we suggest that Para. 9.6.5 be edited as follows: "… including numbers, text, and statements referring to these products or images of these products." For Para. 9.6.5, we offer the following text: 9.6.5 The labelling of the product as defined in Section 2.1 shall not refer to infant formula, follow-up formula for older infants, or formula for special medical purposes intended for infants, including numbers, text, and statements, referring to these products or images of these products.	
In section 9.1.2: Vietnam support the name "Product" rather "Drink", because this name could be confused with other drinks such as coca cola. So Vietnam proposes section 9.1.2 would be wording as follow: Product for Young Children with Added Nutrients or Product for Young Children. With the new section 9.6.5: Vietnam suposes that it would be resulting to differences in interpretations and implementation contrary to Codex principles.Vietnam proposes that the section 9.6.5 would be wording as follow: The products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow up formula for older infant, and formula for special medical purposes intended for infant.	**Viet Nam**
General Comments ENCA considers that the text is NOT ready for adoption at step 5. Here are our reasons explained: • The lack of adequate safeguards to prevent inappropriate marketing of these products will lead to increase their needless use around the world as projected in business forecasts. WHO and other health authorities declare follow-on milks and toddler milks for young children "not necessary". Continued breastfeeding is recommended to two years and beyond for optimal young child health, hence the use of these products, which function as breastmilk substitutes pose a risk to the health of young children during critical stages of growth and development. The current text will lead to children being fed inappropriate expensive products that do not meet their nutritional needs. • The current text fails to forbid the deceptive marketing strategy of cross promotion between product categories for drinks for young children, other formula and follow-up milks and products The text in Section 9.6.4 forbids only references to infant formula. Current marketing practices demonstrate that this is an insufficient safeguard. The text should clearly state that marketing of Drinks for young children should not ' resemble' infant formula, FSMPs and other drinks and foods marketed for infants and young children. • Drinks for young children are not necessary therefore it is critical that the ban on health and nutrition claims is retained. Claims will be	**ENCA**

deceptive and mislead parents and care givers into believing that the use of these products provide benefits that cannot be derived from breastmilk or animal milks other drinks or complementary food or family food. • Follow-on milks and drinks for young children must carry the warnings regarding intrinsic contamination for products in powdered form. • ENCA maintains that all four categories of products that FUNCTION as breastmilk substitutes - infant formulas, formulas for special medical purposes, follow-up formulas and drinks for young children - should be brought under one Codex standard that is divided into 4 parts with one overarching preamble. It would then be clear that all products are covered by the marketing restrictions outlined in the International Code and subsequent relevant WHA Resolutions, ie - none should be promoted in any way. SECTION B: DRINK PRODUCTS FOR YOUNG CHILDREN WITH ADDED NUTRIENTS OR DRINK FOR YOUNG CHILDREN ENCA comment: The term “with added nutrients” is a claim which gives parents and care givers the impression that the product has added nutritional value and may be a necessary nutritional requirement for young child growth. Such a product name is misleading and deceptive and bears an intrinsic nutrient content claim. The use of follow-up products has been declared “not necessary” by the World Health Organization and is not needed as a part of the diversified diet for young children. ENCA recommends that the name of the product should be “drink for young children”. This will eliminate confusion and deception for parents and care givers as to the use and lack of need for these products. SECTION 1.4 should be added: 1.4 The application of this section of the Standard shall conform to the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions, including the WHA resolution 69.9 (2016) and its accompanying WHO Guidance on Ending the Inappropriate Marketing of Foods for Infants and Young Children, the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA54.2 (2001). 2.1.1. The proposed text should be replaced with Para 59 of the Report (that received ‘considerable’ support): "Drink for Young Children means a product manufactured for use as a liquid part of the diversified diet of young children that functions as a substitute for either breastmilk or other milks and is not nutritionally adequate to meet the requirements of young children”. The following footnote or text in the standard should be added: In many countries these products are regulated as breastmilk substitutes 9.5 Information for use Add warnings about intrinsic contamination of powdered products. 9.5.1 Ready to use products in liquid form should be used directly. Concentrated liquid 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. ADD the following: Products in powdered form must contain a statement that the product is not sterile and preparation instructions must include that the product be reconstituted with safe water at 70 degrees centigrade according to the (WHO/FAO (2007) guidelines, “Safe preparation, storage and handling of powdered infant formula and WHA resolutions WHA 58.32 (2005) and 61.20 (2008) as well as the Codex Alimentarius 'Code of hygienic practice for powdered formulae for infants and young children (2008), which provides relevant recommendations for the labeling of powdered infant formula and follow-up formula. Delete: Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice.	
Comment on paragraph 9.1.2 We understand that the proposed wording was agreed at the last CCNFSDU Session. However, we believe that there is a need for some language adjustment and harmonisation/alignment with the raised comments: - “Drink/product for young children with added nutrients”: it seems that the young children are fortified. We believe a more correct	**EU Specialty Food Ingredients**

wording would be “Drink/product with added nutrients for young children” - “or Drink for young children”: for the second option, the term “product” is missing. This term was added to the first proposed name following the comment from one country that, in some cases, the product appears in powder form and therefore cannot be named “drink”. We would recommend to align with the first option and introduced the word “product” All through the text, the wording would then read “Drink/product with added nutrients for young children or Drink/product for young children”	
SECTION B: DRAFT SCOPE Helen Keller International agrees that this text has been discussed and agreed upon and is ready for adoption. SECTION B: DRAFT DESCRIPTION 2.1.1 Helen Keller International agrees that, despite its voice and that of many LMIC delegates being overruled regarding these products being explicitly defined as breast-milk substitutes, this text has been discussed and agreed upon and the footnote was an accepted compromise. We note that there is still text in square brackets [which may contribute to the nutritional needs of young children] that needs to be discussed and around which HKI has strong views. We believe the text in square brackets must be deleted. Justification: 1. There has been global agreement that these products are not necessary. The text in [ ] implies that they have a role to play. This is not the case and so it should not be implied in the definition of these products. 2. Recent assessment using Innova Market Insights data has considered the current composition of these products in Indonesia. While recognising the revised standard will require composition changes, the findings are still important. They show that despite their fortification with a range of vitamins and minerals the composition of these products for the 12-36 month age group does not support the nutritional needs of these young children. Over a quarter of milks for this age category were not compliant with the agreed upon revised recommendation of less than 2.5g of free sugar per 100kcal and 1 in 10 (11%) did not supply sufficient information to assess their compliance. In addition, almost all the products contained one or more added sugar (the average being 5) and three quarters contained sucrose. Further, when compared with full fat (whole) cow’s milk, which is what is recommended for these young children, the use of these products has substantial impacts on daily sugar intake and adds an additional 10-16g of sugar a day to the young child’s diet. This goes against global recommendations to reduce and limit sugar in young children’s diets and places them at risk of future overweight and non-communicable diseases. A great deal of composition changes are required before these products even meet the Codex compositional standard. In the interests of child health, and considering that they are not necessary, they cannot be defined as contributing to the nutritional needs of young children. Furthermore, 2019 saw the release of a technical report on Healthy Beverage Consumption in Early Childhood which provides recommendations from key US national health and nutrition organisations [Academy of Nutrition and Dietetics (AND), the American Academy of Pediatric Dentistry (AAPD), the America Academy of Pediatrics (AAP), and the American Heart Association (AHA)] on optimal beverage consumption during early childhood and supports a life course approach to the development of healthy dietary patterns and prevention of chronic diseases. The experts give a clear recommendation. “0-12 months: Avoid supplementation with “transition” or “weaning” formulas; nutrient needs should be met primarily through human milk and/or infant formula. The rationale given is: The expert panel concluded that “although there is no evidence to indicate that toddler milk is harmful, these products offer no unique nutritional value beyond what could be achieved through a nutritionally adequate diet; furthermore, they may contribute added sugars to the diet. Toddler milk is also more expensive than an equivalent volume of cow’s milk… Infants and young children should first aim to meet nutrient needs primarily through human milk and/or infant formula, and then increasingly through healthy foods and beverages as they transition to solid foods. If nutrient-rich food intake appears to be inadequate, other strategies to increase food acceptance should be tried first, before resorting to toddler milks, such as repeated exposures to healthy foods.” 2.1.2 Helen Keller International agrees that this text has been discussed and agreed upon and is ready for adoption. 2.2.1 Helen Keller International agrees that this text has been discussed and agreed upon and is ready for adoption. SECTION B: DRAFT LABELLING HELEN KELLER INTERNATIONAL COMMENTS: 9.1 Helen Keller International agrees that this text has been discussed and agreed upon and is ready for adoption. 9.2 Helen Keller International agrees that this text has been discussed and agreed upon and is ready for adoption. 9.3 Helen Keller International agrees that this text has been discussed and agreed upon and is ready for adoption. 9.4 Helen Keller International agrees that this text has been discussed and agreed upon and is ready for adoption.	**HKI**

9.5 Helen Keller International agrees that this text has been discussed and agreed upon and is ready for adoption. 9.6 Helen Keller International agrees that this text, although compromise text from what we were requesting, is ready for adoption.	
IDF appreciates the opportunity to comment on the Circular Letter at Step 5 on the Review of the Standard for Follow-up Formula (section B) concerning the proposed draft scope, description and labelling for “drink/product for young children with added nutrients” or “drink for young children”. IDF agrees with the adoption of the text at step 5 as agreed upon during CCNFSDU41.	**IDF/FIL**
IBFAN General Comments: IBFAN considers that the text is NOT ready for adoption for the following reasons: The lack of adequate safeguards to prevent inappropriate marketing of these products will lead to increase their needless use around the world as projected in business forecasts. WHO and other health authorities declare follow-on milks and toddler milks for young children “not necessary”. Continued breastfeeding is recommended to two years and beyond for optimal young child health, hence the use of these products, which function as breastmilk substitutes pose a risk to the health of young children during critical stages of growth and development. The current text will lead to children being fed inappropriate expensive products that do not meet their nutritional needs. The current text fails to forbid the deceptive marketing strategy of cross promotion between product categories for drinks for young children, other formula and follow-up milks and products The text in Section 9.6.4 forbids only references to infant formula. Current marketing practices demonstrate that this is an insufficient safeguard. The text should clearly state that marketing of Drinks for young children should not ‘ resemble’ infant formula, FSMPs and other drinks and foods marketed for infants and young children. Drinks for young children are not necessary therefore it is critical that there is a ban on health and nutrition claims. Claims will be deceptive and mislead parents and care givers into believing that the use of these products provide benefits that cannot be derived from breastmilk or animal milks other drinks or complementary food or family food. Follow-on milks and drinks for young children must carry the warnings regarding intrinsic contamination for products in powdered form. IBFAN maintains its original position that all four categories of products that FUNCTION as breastmilk substitutes - infant formulas, formulas for special medical purposes, follow-up formulas and drinks for young children - should be brought under one Codex standard that is divided into 4 parts with one overarching preamble. It would then be clear that all products are covered by the marketing restrictions outlined in the International Code and subsequent relevant WHA Resolutions, ie - none should be promoted in any way. IBFAN Specific comments: SECTION B: DRINK PRODUCTS FOR YOUNG CHILDREN WITH ADDED NUTRIENTS OR DRINK FOR YOUNG CHILDREN IBFAN comment: The term “with added nutrients” is a claim which gives parents and care givers the impression that the product has added nutritional value and may be a necessary nutritional requirement for young child growth. Such a product name is misleading and deceptive and bears an intrinsic nutrient content claim. The use of follow-up products has been declared “not necessary” by the World Health Organization and is not needed as a part of the diversified diet for young children. IBFAN recommends that the name of the product should be “drink for young children”. This will eliminate confusion and deception for parents and care givers as to the use and lack of need for these products. 1. SCOPE 1.1 This section of the Standard applies to DRINK FOR YOUNG CHILDREN as defined in Section 2.1, in liquid or powdered form. 1.2 This section of the Standard contains compositional, quality, safety, use, labelling and analytical and sampling requirements for DRINK FOR YOUNG CHILDREN. 1.3 Only products that comply with the criteria laid down in the provisions of this section of this Standard shall be presented as DRINK FOR YOUNG CHILDREN. SECTION 1.4 should be added:	**International Baby Food Action Network**

1.4 The application of this section of the Standard shall conform to the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), relevant WHO guidelines and policies as well as relevant World Health Assembly (WHA) resolutions, including the WHA resolution 69.9 (2016) and its accompanying WHO Guidance on Ending the Inappropriate Marketing of Foods for Infants and Young Children, the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA54.2 (2001). 2 DESCRIPTION 2.1 Product Definition 2.1.1. The proposed text should be replaced with Para 59 of the Report (that received 'considerable' support): "Drink for Young Children means a product manufactured for use as a liquid part of the diversified diet of young children that functions as a substitute for either breastmilk or other milks and is not nutritionally adequate to meet the requirements of young children". The following footnote should be added: In many countries these products are regulated as breastmilk substitutes. 2.1.2 DRINK FOR YOUNG CHILDREN is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal recommended conditions of handling, use, storage and distribution in the country where the product is sold. 2.2 Other Definitions 2.2.1 The term young child means a person from the age of 12 months up to the age of three years (36 months. 9. LABELLING The requirements of the General Standard for the Labelling of Pre-packaged Foods (CXS 1-1985), the Guidelines on Nutrition Labelling (CXG 2-1985) and the Guidelines for Use of Nutrition and Health Claims (CXG 23-1997) apply to DRINK FOR YOUNG CHILDREN in Section 2.1. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation. 9.1 The Name of the Product 9.1.1 The text of the label and all other information accompanying the product shall be written in the appropriate language(s). 9.1.2 The name of the product shall be DRINK FOR YOUNG CHILDREN as defined in Section 2.1, or any appropriate designation indicating the true nature of the product, in accordance with national [or regional] usage. 9.1.3 The sources of protein in the product shall be clearly shown on the label. a) If [name of animal] milk is the only source of protein[*], the product may be labelled 'DRINK FOR YOUNG CHILDREN based on [name of animal] milk [protein]'. b) If [name of plant] is the only source of protein[*], the product may be labelled DRINK FOR YOUNG CHILDREN based on [name of plant] [protein]'. c) If [name of animal] milk and [name of plant] are the sources of protein[*], the product may be labelled DRINK FOR YOUNG CHILDREN Based on [name of animal] milk protein and [name of plant] protein' or DRINK FOR YOUNG CHILDREN based on [name of plant] protein and [name of animal] milk protein'. * For clarity, addition of individual amino acids where needed to improve protein quality does not preclude use of the above labelling options. 9.1.4 A product which contains neither milk nor any milk derivative shall be labelled "contains no milk or milk products" or an equivalent phrase. 9.2 List of Ingredients 9.2.1 A complete list of all ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion. 9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate functional classes for food additives should be included on the label. The food additives INS number may also be optionally declared. 9.3 Declaration of Nutritive Value The declaration of nutrition information DRINK FOR YOUNG CHILDREN shall contain the following information, which should be in the following order: a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grams of protein, carbohydrate and fat per 100 g or per 100 ml of the food as sold as well as per 100 ml of the food ready for use, when prepared according to the instructions on the	

label. b) the total quantity of each vitamin, and mineral as listed in paragraph 3.1.3 of Section A and any other ingredient as listed in paragraph 3.2 of Section A per 100 g or per 100 ml of the food as sold as well as per 100 millilitres 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. 9.4 Date Marking and Storage Instructions 9.4.1 The date marking and storage instructions shall be in accordance with section 4.7.1 of the General Standard for the Labelling of Prepackaged Foods. If not otherwise determined in an individual Codex standard, the following date marking shall apply, unless clause 4.7.1 (vii) applies: (i) When a food must be consumed before a certain date to ensure its safety and quality the “Use–by Date” or “Expiration Date” shall be declared. (ii) Where a “Use-by Date” or “Expiration Date” is not required, the “Best-Before Date” or “Best Quality Before Date” shall be declared. IBFAN considers that the use of “Best Before Date” or “Best Quality Before Date” is not appropriate for DRINK FOR YOUNG CHILDREN products. The CXS 1-1985 states that when a food must be consumed before a certain date to ensure its safety and quality “Use–by Date” or “Expiration Date” should be used. IBFAN considers that these products should not be consumed after the expiration date, since there is no guarantee of the compliance with the required nutritional content of the standard, nor its microbiological and other quality and safety requirements. Since DRINK FOR YOUNG CHILDREN are intended for children from 12 to 36 months these precautions must be in place for this vulnerable population. 9.4.2 Where practicable, storage instructions shall be in close proximity to the date marking. 9.5 Information for use Add warnings about intrinsic contamination of powdered products. 9.5.1 Ready to use products in liquid form should be used directly. Concentrated liquid 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. ADD the following: Products in powdered form must contain a statement that the product is not sterile and preparation instructions must include that the product be reconstituted with safe water at 70 degrees centigrade according to the (WHO/FAO (2007) guidelines, “Safe preparation, storage and handling of powdered infant formula (http://apps.who.int/iris/bitstream/handle/10665/43659/978924 1595414_eng.pdf?sequence=1) and WHA resolutions WHA 58.32 (2005) and 61.20 (2008) as well as the Codex Alimentarius 'Code of hygienic practice for powdered formulae for infants and young children (2008), which provides relevant recommendations for the labeling of powdered infant formula and follow-up formula. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice. 9.5.2 Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that product remaining after feeding should be discarded, shall appear on the label. 9.5.3 The label shall carry clear graphic instructions illustrating the method of preparation of the product. 9.5.4 The directions should be accompanied by a warning and about the health hazards of inappropriate preparation, storage and use. 9.5.5 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label. 9.5.6 The label of DRINK FOR YOUNG CHILDREN shall include a statement that the product shall not be introduced to infants 12 months of age or less and is not to be used as the sole source of nutrition. 9.6 Additional Labelling Requirements The following text must be added to 9.6.3: 9.6. 1 The label of DRINK FOR YOUNG CHILDREN shall have no image, text or representation, including pictures of feeding bottles, that could undermine or discourage breastfeeding or which idealizes the use of DRINK FOR YOUNG CHILDREN. The term humanized, maternalized or other similar term must not be used on the label. 9.6.2 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 recommended to two years or beyond”; c) a statement that the product is not necessary as a nutritional requirement for young children and should only be used on advice of an	

independent health worker as to the need for its use and the proper method of use. (d) the statement; 'The use of this product must not replace breast-milk and lead to cessation of continued breastfeeding'. 9.6.1.3 recommend or promote bottle feeding; 9.6.1.4 undermine or discourage breastfeeding, that makes a comparison to breast-milk, or suggests that the product is similar, equivalent to or superior to breast-milk; 9.6.1.5 convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national or regional regulatory authorities. 9.6.3 The label shall have no pictures of infants, young children and women nor any other picture, text or represention that: 9.6.3.1 undermines or discourages breastfeeding or that makes a comparison to breastmilk or suggests that the product is similar, equivalent or superior to breastmilk. 9.6.3.2 might convey an endorsement or anything that may be construed as an endorsement by a professional or any other body, unless this has been specifically approved by relevant national or regional regulatory authorities. 9.6.4 Products shall be distinctly labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, and formula for special medical purposes, 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 on the labelling of the product. In summary IBFAN notes that the commonly used marketing strategy of cross-branding of products with infant formula through labelling and advertisements is a threat to breastfeeding and infant and child health. This marketing strategy is misleading and confusing and clearly designed to circumvent national regulations that cover the marketing of products for infants and young children. Cross branding on formulas and other feeding products for infants and young children over 6 months increases the risk of infants being fed with inappropriate products that do not meet their nutritional needs. "The practice of cross-promotion of breast-milk substitutes must be curbed." (WHO/UNICEF INFORMATION NOTE - Cross-promotion of infant formula and toddler milks, WHO, 2018).	
ISDI appreciates the opportunity to comment on the Circular Letter at Step 5 on the Review of the Standard for Follow-up Formula (section B) concerning the proposed draft scope, description and labelling for "drink/product for young children with added nutrients" or "drink for young children". ISDI recognizes the progress made at the 41st Codex Committee of Nutrition and Foods for Special Dietary Uses (CCNFSDU41) to frame the future Standard and wants to thank the Chair and co-chairs of the electronic working group for their extensive work. ISDI agrees with the adoption of the text of the proposed draft scope, description and labelling for "drink/product for young children with added nutrients" or "drink for young children", provided it is interpreted and implemented consistently in line with Codex principles. ISDI has comments in relation to the following sections: 1) ISDI is particularly concerned that the new section 9.6.5 in the ADDITIONAL LABELLING REQUIREMENTS is open to various interpretations without further qualification. This may lead to differences in interpretation and implementation contrary to Codex principles. ISDI is also concerned that 9.6.5 could establish a prohibition or restriction that is contrary to international obligations governing intellectual property rights (for example, the term "Images" could be understood to be a logo, a brand or a trademark). Therefore, ISDI proposes that further guidance is provided for proper implementation of the Standard in line with the intent clarified by the country (supported by some delegations) who introduced the new provision to limit the ability that products are labelled to make reference to other formula products in the range. 2) ISDI considers it is crucial CCNFSDU42 retains the sentence [which may contribute to the nutritional needs of young children] in the PRODUCT DEFINITION, section 2.1.1, concerning the role of the product. The product can help address nutrition deficiencies when young children transition to a family-based diet. 3) For consistency, ISDI requests that for the section 9.1.2, NAME OF THE PRODUCT, where CCNFSDU41 proposed: "drink/product for young children with added nutrients", or "drink for young children" that "product" wording also applies to "drink for young children". The names would then read: "Drink/product for young children with added nutrients" or "Drink/product for young children".	**International Special Dietary Food Industries**

ISDI looks forward to continuing the work on the proposed draft of the revised Standard that contributes to the health and well-being of older infants and young children while ensuring fair practice in food trade according to the Codex mandate.	
SECTION B: DRINK/PRODUCT FOR YOUNG CHILDREN WITH ADDED NUTRIENTS OR DRINK FOR YOUNG CHILDREN 1. SCOPE UNICEF acknowledges that the wording under this section has been agreed upon. 2.1.1 Product definition. UNICEF acknowledges that the wording has been agreed upon. This is despite UNICEF's position, expressed on several occasions, that the products in question ARE breast-milk substitutes as explained in the WHO Guidance on ending the inappropriate promotion of foods for infants and young children, whose recommendations were endorsed by the World Health Assembly (WHA 69.9, 2016). UNICEF would thus have preferred this to be stated clearly in 2.1.1, but reluctantly agreed to the compromise of a footnote stating that "in some countries these products are regulated as breast-milk substitutes", making it clear that Governments can (and in UNICEF's view should) include these products as breast-milk substitutes in national regulations to implement the International Code of Marketing of Breast-milk Substitutes and subsequent resolutions of the World Health Assembly. With regard to the text in square brackets, [which may contribute to the nutritional needs of young children], UNICEF would like to see the bracketed text deleted. The World Health Assembly stated clearly way back in 1986, when manufacturers started inventing these new products to try and get around the Code, that these products were not necessary. The text in brackets implies that these products do fulfill or contribute to some nutritional need of the young child and may thus have a role to play, which they do not. Indeed, recent evidence suggests that they contribute added sugars to the diet, an issue of major concern given the growing trend of childhood overweight and obesity. 2.1.2 – 2.2.1 UNICEF acknowledges that the text in these paragraphs has been agreed upon. 9. LABELLING UNICEF acknowledges that the text under this section has been discussed and agreed upon.	**UNICEF**

Proposed draft Guidelines for ready-to-use therapeutic foods (RUTF)

In reply to CL 2019/114-NFSDU

Comments from Argentina, Australia, Brazil, Burkina Faso, Canada, Chile, Colombia, Guatemala, Iraq, Malaysia, New Zealand, Panama, Peru, USA, EU Specialty Food Ingredients, IDF/FIL, International Baby Food Action Network, International Council on Amino Acid Science, International Special Dietary Food Industries, MSF and UNICEF

COMMENTS	**COUNTRY / OBSERVER NAME**
Argentina acuerda con el texto propuesto.	**Argentina**
Australia has no comments and supports progressing to adoption at Step 5.	**Australia**
General Comments Brazil appreciates the excellent work done by South Africa and Senegal and thanks for the opportunity to present the following comments. Specific Comments	**Brazil**

Brazil would like to suggest some amendments in the preamble, aiming to clarify that children with SAM from 6 to 59 months without medical complications need adequate treatment and care with the use of safe locally foods with adequate energy content and amounts of vitamins, minerals and other nutrients. Thus, RUTF may be used as an option when local food production is insufficient, water supply is inadequate or inaccessible or under emergency situations and should not undermine national nutrition recommendations and the use of culturally appropriate foods. We are also of the opinion that the importance of breastfeeding should be addressed in the preamble. We also suggest standardizing throughout the Guideline the text referring to the target population for which the product is intended, that is, children from 6 to 59 months with severe acute malnutrition without medical complications. 1. Preamble Children affected by severe acute malnutrition (SAM) need adequate treatment and care, including safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other nutrients. Children with SAM need efficacious and timely intervention and RUTF is one of the options for the dietary management of children with SAM from 6-59 months without medical complications, in specific situations of food insecurity when local food production is insufficient, water supply is inadequate or inaccessible or under emergency situations and should not undermine national nutrition recommendations and the use of culturally appropriate foods. It is critical that the use of RUTF does not undermine support for continued breastfeeding or to re-establish lactation. These guidelines should be used in accordance with technical recommendations that are based on the relevant evidence and related Codex texts/documents by WHO, UNICEF and WFP.	
[1. PRÉAMBULE Le Burkina Faso approuve le texte proposé 2. OBJET DES LIGNES DIRECTRICES Le Burkina Faso approuve les propositions mais attire l'attention sur l'inclusion dans les aspects nutritionnels et techniques de la production la prise en compte « des techniques de traitement des ATPE » dans le iii) Bonnes pratiques de fabrication qui avait été souligné durant le CCNFSDU41. 3. CHAMP D'APPLICATION sur Le Burkina Faso approuve le texte proposé 4. DESCRIPTION [4.1, 4.2] : Le Burkina Faso approuve les textes proposés 5. MATIÈRES PREMIÈRES ET INGRÉDIENTS APPROPRIÉS Le Burkina Faso approuve le texte proposé 5.1 Ingrédients et matières premières de base [5.1.1]: Le Burkina Faso approuve le texte proposé 5.1.2 Légumineuses et graines Le Burkina Faso approuve le texte proposé 5.1.3 Graisses et huiles Le Burkina Faso approuve le texte proposé 5.1.4 Céréales, racines, tubercules et leurs produits dérivés Le Burkina Faso approuve le texte proposé 5.1.5 Vitamines et sels minéraux Le Burkina Faso approuve le texte proposé 5.2 Autres ingrédients [5.2.1]: Le Burkina Faso approuve le texte proposé 5.2.2 Additifs alimentaires Le Burkina Faso approuve le texte et le tableau proposés 6. COMPOSITION NUTRITIONNELLE ET FACTEURS DE QUALITÉ Le Burkina Faso approuve le texte proposé 6.1 Énergie	**Burkina Faso**

Le Burkina Faso approuve le texte proposé 6.2 Protéines Le Burkina Faso approuve le texte proposé 6.3 Lipides Le Burkina Faso approuve le texte proposé et la suppression des crochets 6.4 Vitamines et sels minéraux Le Burkina Faso approuve le texte proposé 6.5 ACTIVITÉ HYDRIQUE Le Burkina Faso approuve le texte proposé 7. CONTAMINANTS Le Burkina Faso approuve le texte proposé 8. TECHNIQUES DE TRAITEMENT Le Burkina Faso approuve le texte proposé 9. BONNES PRATIQUES DE FABRICATION ET BONNES PRATIQUES D'HYGIÈNE Le Burkina Faso approuve le texte proposé 10. MÉTHODES D'ANALYSE ET D'ÉCHANTILLONNAGE Le Burkina Faso approuve le texte proposé 11. CONDITIONNEMENT Le Burkina Faso approuve le texte proposé 12. ÉTIQUETAGE Le Burkina Faso approuve le texte proposé [12.1, 12.2, 12.3, 12.4, 12.5] Le Burkina Faso approuve les textes proposés	
Canada thanks South Africa, Senegal and Uganda for chairing the eWG and for their extensive work to date on developing this guideline. Canada agrees that the text on the Proposed Draft Guidelines for Ready-to-use therapeutic foods (Appendix VI of REP20/NFSDU) is ready for adoption at Step 5 by CAC43.	**Canada**
Chile está de acuerdo con el avance del documento.	**Chile**
El texto está listo para su aprobación.	**Colombia**
Guatemala está de acuerdo con el texto de estas Directrices.	**Guatemala**
we agree with proposed draft guidance without any comments. Our regards.	**Iraq**
Malaysia supports this proposed draft.	**Malaysia**
New Zealand supports adoption of the text at Step 5 – we have no further comments at this stage	**New Zealand**
Panamá apoya el anteproyecto en discusión. Es un anteproyecto importante e interesante.	**Panama**
Perú está de acuerdo con todo lo propuesto en las secciones Preámbulo, Finalidad de las directrices, Ámbito de aplicación, Descripción, Materias primas e ingredientes apropiados, Composición nutricional y factores de calidad, Contaminantes, Tecnologías de elaboración, Buenas prácticas de fabricación y buenas prácticas de higiene, Métodos de análisis y muestreo, Envasado y Etiquetado Perú está de acuerdo con el nivel máximo de 1111 mg/100 kcal de Ácidos grasos omega 6 y con el nivel mínimo de 33 mg/100 kcal de Ácidos grasos omega 3. Respecto al magnesio para alimentos terapéuticos listos para el consumo, se está de acuerdo con las dosis más bajas, es decir dentro del rango 15 mg/100 Kcal a 45 mg/100 Kcal, considerando que se prescriben cantidades diversas para cada persona y en diferentes condiciones	**Peru**

de salud, inclusive pueden estar recibiendo magnesio a través de la alimentación. Concordamos que esto es debido a que estos productos pueden ser parte de otras formas de alimentación.	
Republic of Korea reviewed the proposed draft. We agreed current draft that has presented. No further comments at this time.	**Republic of Korea**
Generally, the United Stated Supports adoption of the text at step 5. However, the U.S. has a few comments and suggested edits with respect to some of the text which we would like included when the text is adopted. These edits and comments are below. The United States can support adoption of the preamble, with suggested edits for clarification. However, we do not support including all the reference documents in the footnote. We support references to technical based documents which complement and elaborate proper management of SAM and use of RUTF. The U.S. position is to delete the reference to the International Code of Marketing of BMS as we have already agreed RUTF is not a BMS and we do not support reference to the Codex Code of Ethics as this is not a technical document and the relevant technical aspects of the Code of Ethics have been addressed in the Guide-line. These guidelines should be used in accordance with technical recommendations of that are based on the relevant [insert: science based] evidence and related Codex texts [insert: as well as] documents by WHO, UNICEF and WFP. In Footnote #1, the United States recommends to delete the following text: Delete: "1981. International code of marketing of breast-milk substitutes, Geneva: World Health Organization and subsequent relevant WHA Resolutions on infant and young child feeding]; Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions (CXC 20-1979);" Regarding Section 5.2.1, the United States does not support adoption of section 5.2.1 Carbohydrates as shown. We have two comments. First, for clarity, it is our position that pre-gelatinized is sufficient as cooking gelatinizes starch which is the goal, to improve digestibility. Second, the U.S. is not clear of the scientific basis for excluding glucose and fructose and requests more documentation to support this. Sucrose rapidly digests into glucose and fructose for utilization. In Section 5.2.1, the U.S. suggests to delete "cooked and/or " from the following statement: "Only pre[delete: cooked and/or]-gelatinized starches may be added." In Section 5.2.1, the U.S. suggests to delete the following statement: delete: "Glucose and fructose should not be used." Regarding Section 6.1, the United States supports adoption of section 6.1 Energy with the following edit. We recommend including Protein as part of the energy source in addition to fats and oils. Note: under Section 6.2 Proteins, we specify that protein makes up 10-12% energy. In Section 6.1, the U.S. recommends to add the following text in square brackets: "The energy density of RUTF can be achieved during manufacturing by the addition of energy containing ingredients (i.e. fats and oils[insert: , protein] and/or digestible carbohydrates) and/or processing the basic raw materials and ingredients as indicated in Section 8." Regarding Section 6.2, the United States supports adoption of section 6.2 on proteins. However, for clarity regarding PDCAAS, we recommend stating the value as both > 0.9 or 90% based on a casein reference protein. In Section 6.2, the U.S. recommends deleting the following text in square brackets: "Protein quality should be determined using Protein Digestibility Corrected Amino Acid Score (PDCAAS), calculated according to the reference amino acid requirement and scoring patterns related to catch up growth of 10 g/kg/day in the target population [delete: for RUTF] which is children with SAM aged 6 to 59 months." In Section 6.2, the U.S. recommends the following text edits in square brackets:	**USA**

"For all RUTF formulations, the PDCAAS shall not be less than [insert: 0.9 or 90% based on a casein reference protein]." Regarding Section 7, the United States suggests we include radioactive materials in the list as these substances are emerging as a 4th category of human hazard. In Section 7, the U.S. recommends adding the following text in square brackets: The product should not contain contaminants or other undesirable substances (e.g. biologically active sub-stances, [insert: radioactive materials,] metal fragments) in amounts which may represent a risk to the health of children. Regarding Section 8 para. 1, the U.S. recommends the following insertions and deletions in square brackets: Processing technologies used for RUTF and their ingredients shall [insert: not compromise the nutritional value of RUTF] [delete: be validated to prove that they do- not alter the nutritional value of RUTF] and [delete: that they] [insert: should] allow [insert: for] the reduction of anti-nutritive factors. Milling or grinding, roasting, toasting are examples of processing technologies that can be used [delete: on ingredients] [insert: in the production of RUTF]. Regarding Section 8 para. 2, the U.S. recommends the following deletion in square brackets: [delete: Any technologies used should take into consideration the target group and any impact on the integrity of the nutrient content of the products. In addition to the practices described above,] Good Hygiene Practices should be implemented for manufacturing of RUTF, according to the General Principles of Food Hygiene (CXC 1-1969) and Code of Hygienic Practices for Low Moisture Foods (CXC 75-2015) to avoid cross contamination during the storage of raw materials and the manufacturing process. The United States has deleted the first sentence in Section 8 para. 2 as this information is already covered above and it is not necessary to repeat it again here. Regarding Section 11, the U.S. recommends adding the following text in square brackets: It is recommended that RUTF be packaged in such a way to safeguard the hygienic and other qualities including nutritional properties of the food for the duration of its defined shelf-life. [insert: Packaging should provide functionalities for ease and effective use.] Regarding Section 12 and "the additional statements shall appear on the label of RUTF", the U.S. has the following comments and recommended edits: a. Regarding the statement: "The product is not to be used for Nasogastric Tube (NG tube) administration", the United States would like to have clarity for the need for this statement as gastric administration for these products is not common and is not likely to be done. b. Regarding the statement: "The product should be used in conjunction with breast feeding ...", the United States recommends the following edits: "The product should be used in conjunction with breast feeding [insert: when possible]. [delete: The product should be used in conjunction with breastfeeding.]" The United States added in the text "when possible" recognizing that while continued breastfeeding is ideal, it is not always possible.	
Comment on Table A: Food Additives in RUTF Formulation We would like to point out that in case the Committee decides to change the nutritional profile towards higher levels of PUFA, the change may need to be reflected in the amount of tocopherols. For example, fish oil can contain up to 6000 mg/kg of tocopherol. Therefore, it will be necessary to calculate what amount of tocopherol would end up in the RUTF and whether that level is in line with the value of 10 mg/kg. Comment on the first sentence in section 5.2.2. Food Additives We believe that this sentence requires clarification: The provisions for food additives in the Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses are laid down in its part D. There we read:" For reason of stability and safe handling some vit-amins and other	**EU Specialty Food Ingredients**

nutrients have to be converted into suitable preparations…. For this purpose, the food additives included in the respective Codex standard may be used. In addition, the following food additives may be used…" The text is followed by a table listing these food additives. The respective Codex standards are CXS 72-1981, CXS 74-1981 and CXS 156-1987 – the additives permitted for direct addition in these standards are also permitted for use in nutrient preparations. We believe that the current text of the draft Guidelines may be incorrectly understood in a way that in addition to the food additives included in table A of the RUTF guidelines only the food additives included in the table in part D of the advisory list are permitted. In such case we would be concerned that the addition of vitamins in compliance with the RUTF Guidelines would not be possible. Therefore, we would propose the following amendment of the sentence: 'Only the food additives listed in this section and in the Advisory List of Nutrient Compounds For Use in Foods for Special Dietary Uses Intended for Infants and Young Children (CXG 10-1979), including those additives in respective Codex standards that the Advisory list refers to as acceptable for use in nutrient preparations, may be present in the foods described in section 4.1 of this Guideline'. We believe that this amended wording will assure consistency and certainty in the use of food additives for RUTF. Comment on Annex – Table: Nutritional Composition of RUTF n-6 Fatty acids In the section of lipids, for n-6 fatty acids, the text is in square brackets: [The level of linoleic acid should not be less than 333mg 316(strikeout) mg per 100 kcal and shall not be more than 1110 mg per 100 kcal]. Therefore, all values in the table should be in square brackets. Minimum: The minimum value in the table is 330 (without square brackets) whereas the text indicates two values, one being currently strikeout. Therefore, there is a need to align to the text or to the table. We believe that, with rounding rules, it would make sense to keep [330] mg/ 100kcal as minimum. Maximum: The table contains 2 values for the maximum ([1111] or [780]) whereas the text only indicates 1110 mg per 100 kcal]. We believe that, with rounding rules, it would make sense to keep [1110] mg/ 100kcal as maximum. n-3 Fatty acids The text for n-3 fatty acids is in square brackets as well for the minimum value: [The level of alpha-linolenic acid should not be less than 33 mg/100kcal.] According to the text, the maximum value should be removed from the table and the minimum should be [33] mg/ 100 kcal and should be kept in square brackets.	
IDF appreciates the opportunity to comment on the Circular Letter at Step 5 on proposed draft Guidelines for ready to use therapeutic foods IDF recognizes the progress made at the 41st Codex Committee of Nutrition and Foods for Special Dietary Uses (CCNFSDU41) to advance the development of the guidelines and wants to thank the Chair and co-chairs of the electronic working group for their extensive work. IDF agrees with the adoption of the text at step 5 as agreed upon during CCNFSDU41. IDF strongly supports the retaining of the reference of 50% of proteins from milk products to achieve high protein quality. This approach is aligned with the current scientific evidence as studies that have directly compared RUTF, which contain at least 50% of the protein from dairy versus other forms of RUTF, have shown they are more effective in the dietary management of children ages 6 to 59 months with severe acute malnutrition. Overall findings from studies indicate that RUTF containing lower amounts of dairy ingredients, i.e., dairy protein replaced with non-dairy protein sources, are not as effective for the treatment of SAM (Oakley et al 2010, Irena et al 2015, Bahwere et al 2016 &2014). In addition dairy foods deliver a nutrient-rich package that contains high quality protein, and the essential nutrients calcium, phosphorus, potassium, iodine, and vitamins B2 and B12. The proteins found in dairy are in many ways superior to plant proteins, providing a complete source of high-quality protein and better digestibility (Grace D et al, 2018). Nutrients in dairy work together complementing one another, as part of the dairy matrix (Thorning et al, 2017) . The nutrients from milk are	**IDF/FIL**

better absorbed than the added nutrients in fortified, plant-based products since these foods contain antinutritional compounds that inhibit the absorption of some nutrients. References -Bahwere P., Balaluka, B., Wells, JC, et al. 2016. Cereals and pulse-based ready-to-use therapeutic food as an alternative to the standard milk- and peanut paste-based formulation for treating severe acute malnutrition: a noninferiority, individually randomized controlled efficacy clinical trial. American Journal of Clinical Nutrition. 103(4):1145-1161. -Bahwere, P., Banda, T., Sadler, K., et al. 2014. Effectiveness of milk whey protein-based ready-to-use therapeutic food in treatment of severe acute malnutrition in Malawian under-5 children: a randomised, double-blind, controlled non-inferiority clinical trial. Maternal & Child Nutrition. 10(3):436-451. -Grace, D et al, "The influence of livestock-derived foods on nutrition during the first 1,000 days of life," CGIAR, 2018, https://cgspace.cgiar.org/handle/10568/92907 -Irena, AH., Bahwere, P., Owino, VO., et al. 2015. Comparison of the effectiveness of a milk-free soy-maize-sorghum-based ready-to-use therapeutic food to standard ready-to-use therapeutic food with 25% milk in nutrition management of severely acutely malnourished Zambian children: an equivalence non-blinded cluster randomised controlled trial. Maternal & Child Nutrition. 11(4):105-119. -Oakley, E., Reinking, J., Sandige, H., et al. 2010. A ready-to-use therapeutic food containing 10% milk is less effective than one with 25% milk in the treatment of severely malnourished children. Journal of Nutrition. 140(12):2248-2252. -Thorning TK et al. 2017. Whole dairy matrix or single nutrients in assessment of health effects: current evidence and knowledge gaps. Am J Clin Nutr, 105(5):1033-1045.	
IBFAN considers that the Guidelines are not ready for adoption. IBFAN has always maintained that there is no need for a Codex Guideline for RUTF – and that the risks of having one outweigh the benefits. If a Guideline is necessary then it should be produced by appropriate bodies such as WHO and UNICEF, whose remit is solely the pursuit of public health. While Codex has an important role in ensuring that all foods and commodities are as safe and nutrition as possible, it is not the appropriate forum for discussions about vulnerable malnourished children. Decisions at Codex invariably encourage increased global trade and are taken on the basis on politically and commercially influenced consensus, not on sound credible evidence. The Guidelines risks subverting "the UN Strategy to build capacity within countries to produce RUTF where needed, while ensuring appropriate use". The Guidelines fail to include safeguards to prevent the marketing of RUTF products and in so doing leave the door open for commercial exploitation that increases the risk of unnecessary and inappropriate use. The Guidelines may trigger diversion of public funds away from support for sustainable solutions such as breastfeeding and locally sourced, culturally appropriate, bio-diverse family foods. The Codex Standard covering Formulas for Special Medical Purposes (CODEX STAN 72 –1981) is not a sufficient safeguard, because FSMPs are designed to be sold on the open market. Categorisation as an FSMP has lead to an increase in inappropriate marketing of these products. The Codex process is not adequately safeguarded from conflicts of interest,thereforeundue influence from manufacturers and distributors of the products under discussion is likely to subvert the public health purpose. The Guidelines are likely to be used by manufacturers and distributors to put pressure on governments to accept imports of products that may not be needed or wanted. SPECIFIC COMMENTS: 1. PREAMBLE Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy, high nutrient content and adequate amounts of vitamins, minerals and other nutrients. Children with SAM need efficacious and timely treatment and RUTF is is one of the options for the dietary management and may be part of the care treatment. RUTF may be used are primarily intended for the treatment of children with uncomplicated SAM from 6-59 months. However, it is critical that its use does not undermine support for continued breastfeeding or to re-establish lactation, since this is the most important requirement for the rehabilitation of children suffering from malnutrition. RUTFs can be used as a treatment food while breastfeeding is sustained and family foods are gradually introduced. The portion size of RUFTs should be adapted to ensure optimal breastmilk intake. RUTFs can also be used for the feeding of malnourished older infants and young children in emergency situations. These guidelines should be used in accordance with technical recommendations that are based and updated on relevant and convincing evidence free from commercial influence, taking into account relevant Codex texts related to food safety and hygiene,	**International Baby Food Action Network**

and recommendations by WHO, UNICEF and WFP1. Governments and other users should ensure adequate provisions are made with competent technical experts to ensure that the use of these products is appropriate in the local context, does not undermine national nutrition recommendations and the use of bio-diverse, culturally appropriate foods. If RUTFs are considered appropriate, they should be used solely for treatment purposes and not for general use or the prevention of SAM. Steps must be taken to ensure that there is no spillover into the wider population and the black market. On no account should RUTF products be placed on the open market. The production and availability of these products must comply with the relevant provisions of the WHO International Code of Marketing of Breastmilk Substitutes, the subsequent relevant WHA resolutions including the WHA 69.9, its accompanying WHO Guidance on Ending the Inappropriate Marketing of Foods for Infants and Young Children and the Codex Guidelines on Nutrition and Health Claims, Paragraph 1,4 of which states that no nutrition and health claims should be made for foods for infants and young children. Nor should convenience claims be made for these products on labels or information materials. These guidelines should be used in accordance with technical recommendations of that are based on the relevant evidence and related Codex texts/documents by WHO, UNICEF and WFP1. 1) A Joint Statement by the World Health Organization, the World Food Programme, the United Nations System Standing Committee on Nutrition and the United Nations Children's Fund. 2007. Community-Based Management of Severe Acute Malnutrition; A Joint Statement by the World Health Organization and the United Nations Children's Fund. 2009. Child growth standards and the identification of severe acute malnutrition in infants and children, Geneva: World Health Organization; World Health Organisation. 2013. Guideline: Updates on the management of severe acute malnutrition in infants and children, Geneva: World Health Organization; World Health Organisation. 2003. Global Strategy for Infant and Young Child Feeding, Geneva: World Health Organization; World Health Organisation. [1981. International code of marketing of breast-milk substitutes, Geneva: World Health Organization and subsequent relevant WHA Resolutions on infant and young child feeding]; Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions (CXC 20-1979); Food and Agriculture Organisation and World Health Organisation. 2016. FAO/WHO Microbial safety of lipid-based ready-to-use foods for management of moderate acute malnutrition and severe acute malnutrition, Rome: Food and Agriculture Organisation.] 2. PURPOSE OF THE GUIDELINES To provide guidance on technical and nutritional aspects of the production of Ready to Use Therapeutic Foods for children from the age of 6 to 59 months with severe acute malnutrition, including i. Nutritional Composition ii. Raw Materials and Ingredients iii. Good Manufacturing Practices iv. Microbiological and Chemical Contaminant Criteria v. Methods of Analysis and Sampling vi. Appropriate use of these products for the treatment of SAM vii. Provisions for Packaging and Labelling 3. SCOPE The provisions of these guidelines apply to Ready to Use Therapeutic Foods for children from age 6 to 59 months with severe acute malnutrition. Ready-to-Use Supplementary Foods (RUSF), micronutrient supplements2, processed cereal based foods3, formulated complementary foods for older infants and young children4, canned baby foods5 are not covered by these guidelines. 2)Guidelines for Vitamin and Mineral Food Supplements (CXG 55-2005) 3Standard for Processed Cereal-Based Foods for Infants and Young Children (CXS 74-1981) 4Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CXG 8-1991) 5Standard for Canned Baby Foods (CXS 73-1981) 4. DESCRIPTION 4.1 Ready-to-Use Therapeutic Foods (RUTF) are foods for special medical purposes and are high-energy and contain adequate protein and other essential nutrients for the dietary management of children from 6 to 59 months with severe acute malnutrition without medical complications with appetite in conjunction with supports to sustain breastfeeding for the recommended two years or beyond. These foods should be soft or crushable and should be easy for children to eat without any prior preparation. 4.2 Severe Acute Malnutrition is defined by weight for height (or length) less than –3 Z-score of the median WHO growth standards, or by mid upper arm circumference (MUAC) <11.5 cm, or by the presence of bilateral oedema. 5. SUITABLE RAW MATERIALS AND INGREDIENTS RUTF are made of ingredients embedded in a lipid-rich matrix e.g. paste or biscuit, resulting in an energy and nutrient-dense food. The following raw materials, many of which can be sourced locally, are suitable ingredients for the production of RUTF under the specified conditions given below. Any formulation of RUTF shall comply with Section 3 of the Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CXS 180-1991) including the specification that their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended. 5.1 Basic Raw Materials and Ingredients	

5.1.1 Milk and other Dairy Products Milk and other dairy products used in the manufacturing of RUTF must comply with the Standard for Milk Powders and Cream Powder (CXS 207-1999) and the Standard for Whey Powders (CXS 289-1995), and other Codex milk and milk product standards as well as other guidelines and Codes of Practice recommended by Codex Alimentarius Commission, which are relevant to these products. Relevant codes of practice include the Code of Hygienic Practice for Milk and Milk Products (CXC 57-2004) and the Code of Hygienic Practices for Low-Moisture Foods (CXC 75-2015). 5.1.2 Legumes and Seeds Legumes and seeds such as soybeans, lentils, chickpeas, cowpeas, beans, peanut, sesame and other types of legumes and seeds must comply with the relevant Codex Alimentarius texts when used in the manufacturing of RUTF. Legumes and seeds must be appropriately processed to reduce, as much as possible, the anti-nutritional factors normally present, such as phytate, lectins (haemagglutenins), trypsin, chymotrypsin inhibitors and phytoestrogens. Field beans or Faba beans (Viciafaba L) should not be used in the formulation of RUTF because of the danger of favism. 5.1.3 Fats and Oils Fats and oils used in the manufacturing of RUTF must comply with the relevant Codex Alimentarius texts. Fats and oils are incorporated as technologically feasible for the purpose of achieving the energy density and providing essential fatty acids. Care must be taken to avoid oxidized fat which will adversely affect nutrition, flavour and shelf life. Partially Hydrogenated fats and oils should not be used in RUTF. 5.1.4 Cereals, Roots and Tubers and their derived Products All milled cereals, roots and tubers and their derived products suitable for human consumption may be used provided that they are processed in such a way that the fibre content is reduced, when necessary, and that the effects of anti-nutritional factors such as phytates, tannins or other phenolic materials, lectins, trypsin, and chymotrypsin inhibitors which can lower the protein quality and digestibility, amino acid bioavailability and mineral absorption are removed or reduced, whilst retaining maximum nutrient value. 5.1.5 Vitamins and Minerals Vitamin and mineral forms used must be soluble and easily absorbed by patients with SAM. Children with SAM have low or absent gastric acid which means that they should not be given inorganic salts of minerals that are insoluble or requiring an acid gastric environment for absorption, in order to avoid metabolic acidosis. It is important that RUTF should have a mineral composition that leads to a moderate excess of non-metabolizable buffer base. The non-metabolizable buffer base can be approximated by the formula: estimated absorbed millimoles (sodium + potassium + calcium + magnesium) - (phosphorus + chloride). All added vitamins and minerals must be in accordance with the Advisory Lists of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children (CXG 10-1979). Examples of mineral forms for RUTF formulation can be found in the WHO Management of severe malnutrition: A manual for physicians and other senior health workers (1999). The amount of vitamins and minerals added to achieve the target level must be adjusted based on the chemical form, interaction, and impaired absorption with other nutrients and non-nutrients and scientific evidence showing adequate stability and bioavailability in the finished product. 5.2 Other Ingredients 5.2.1 Carbohydrates Carbohydrates are used to achieve energy requirements in balance with proteins and lipids. Plant starch, lactose, maltodextrin and sucrose are the preferred carbohydrates in RUTF. Free sugars should be limited and should not exceed 20% 10% of total energy. Only precooked and/or gelatinized starches may be added. Glucose and fructose should not be used. Carbohydrates must adhere to the relevant Codex Alimentarius texts. Honey should not be used in RUTF due to the risk of infant botulism from Clostridium botulinum. 5.2.2 Food Additives and Flavours The only food additives permitted for this vulnerable population, should be those necessary for the safety of the product. Food Additives listed in Table A of the guideline if necessary for food safety requirements must only be used at the specified maximum use level. NOTE: IBFAN is not convinced that the additives listed in Table meet this requirement. Flavourings, artificial or natural must not be permitted. Genetically modified ingredients and those produced by bio-engineering are not permitted. Table A: Food Additives in RUTF Formulation Only the food additives listed in this Section or in the Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children (CXG 10-1979) may be present in the foods described in section 4.1 of this Guideline . Other than by direct addition, an additive may be present in RUTF as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions: a) The additive is acceptable for use in the raw materials or other ingredients (including food additives) according to the General Standard for Food Additives (CXS 192-1995) b) The amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum use level specified in the General Standard for Food Additives (CXS	

192-1995); and c) The food into which the additive is carried over does not contain the additive in greater quantity than would be introduced by the use of the raw materials or ingredients under proper technological conditions or good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the General Standard for Food Additives (CXS 192-1995). 6. NUTRITIONAL COMPOSITION AND QUALITY FACTORS The nutritional composition of RUTF shall comply with the requirements set out in the table in the Annex. Furthermore, the following requirements shall be complied with. 6.1 Energy The energy density of the formulated RUTF should be between 5.2 - 5.5 kcal per gram. The energy density of RUTF can be achieved during manufacturing by the addition of energy containing ingredients (i.e. fats and oils and/or digestible carbohydrates) and/or processing the basic raw materials and ingredients as indicated in Section 8. 6.2 Proteins Protein should provide 10% to 12% of the total energy. Protein quality should be determined using Protein Digestibility Corrected Amino Acid Score (PDCAAS), calculated according to the reference amino acid requirement and scoring patterns related to catch up growth of 10 g/kg/day in the target population for RUTF which is children with SAM aged 6 to 59 months. For all RUTF formulations, the PDCAAS shall not be less than 90. The PDCAAS shall be calculated using, appropriate digestibility values and the reference amino acid pattern as stipulated in the Report of the FAO Expert Working Group: Protein quality assessment in follow-up formula for young children and ready to use therapeutic foods (2018). High quality protein will be achieved with RUTF formulations containing a minimum of 50% of protein from milk products. In formulations with lower PDCAAS scores, the quality and/or quantity of protein should be adjusted to achieve the desired value. The addition of limiting amino acids, solely in the L-form, shall be permitted only in amounts necessary to improve the protein quality of the RUTF. 6.3 Lipids Lipids should provide 45% to 60% of the total energy. [The level of linoleic acid should not be less than 333mg 316 mg per 100 kcal and shall not be more than 1110 mg per 100 kcal. The level of alpha-linolenic acid should not be less than 33 mg/100kcal.] [and shall not be more than 280 mg per 100kcal.] The level of linoleic acid should ensure a ratio between linoleic acid and alpha-linolenic acid of between 5:1 1:1 and 15:1. 6.4 Vitamins and Minerals RUTF should contain the vitamins and minerals presented in the annex: Nutritional Composition of RUTF. RUTF should comply with the minimum and maximum or guidance upper levels in the annex. 6.5 WATER ACTIVITY RUTF is a low-moisture food with a water activity of 0.6 or below. 7. CONTAMINANTS It is recommended that the products covered by the provisions of these guidelines and the ingredients used in such products comply with the General Standard for Contaminants and Toxins in Food and Feed (CXS 193-1995), Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for Residues of Veterinary Drugs in Foods (CXM 2-2015) and Codex Maximum Residue Limits for Pesticides. Further guidance is given by codex Codes of practice and should be adhered to. The product should not contain contaminants or other undesirable substances (e.g. biologically active substances, metal fragments) in amounts which may represent a risk to the health of children. Aflatoxin levels should be kept to below 10ppb, 8. PROCESSING TECHNOLOGIES Processing technologies used for RUTF and their ingredients shall be validated to prove that they do not alter the nutritional value of RUTF and that they allow the reduction of anti-nutritive factors. Milling or grinding, roasting, toasting are examples of processing technologies that can be used on ingredients. Any technologies used should take into consideration the target group and any impact on the integrity of the nutrient content of the products. In addition to the practices described above, Good Hygiene Practices should be implemented for manufacturing of RUTF, according to the General Principles of Food Hygiene (CXC 1-1969) and Code of Hygienic Practices for Low Moisture Foods (CXC 75-2015) to avoid cross contamination during the storage of raw materials and the manufacturing process. RUTF and/or their raw materials should be treated with a validated microbial reduction treatment in order to inactivate pathogens such as Salmonella, noting that some pathogens have increased heat resistance characteristics at reduced water activities in food matrices. Commonly used microbial reduction treatments that could be applied to RUTF and/or their raw materials include both thermal and non-thermal control measures. For additional information on validation of control measures, refer to the Guidelines for the Validation of Food Safety Control Measures (CXG 69-2008). Additionally, refer to the Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM) (CXG 63-2007). 9. GOOD MANUFACTURING PRACTICES AND GOOD HYGIENE PRACTICES It is recommended that the products covered by the provisions of these guidelines be prepared and handled in accordance with the appropriate sections of the General Principles of Food Hygiene (CXC 1-1969), and Code of Hygienic Practice for Low-Moisture Foods (CXC 75-2015), and other relevant Codex texts. The product should	

comply with any microbiological criteria established in accordance with the Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CXG 21-1997). The ingredients and final product should be prepared, packed and held under sanitary conditions and should comply with relevant Codex texts. 10. METHODS OF ANALYSIS AND SAMPLING It is recommended that methods of analysis and sampling of RUTF be in accordance with the Recommended Methods of Analysis and Sampling (CXS 234-1999). 11. PACKAGING It is recommended that RUTF be packaged in such a way to safeguard the hygienic and other qualities including nutritional properties of the food for the duration of its defined shelf-life. The packaging materials shall be made only of substances which are safe and suitable for their intended uses. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging materials, that standard shall apply. 12. LABELLING It is recommended that the labelling of RUTF for children from 6 to 59 months with SAM be in accordance with the Standard for the Labelling of and Claims for Foods for Special Medical Purposes (CXS 180-1991), the General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses (CXS 146-1985), and Guidelines on Nutrition Labelling (CXG 2- 1985). These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation. A WARNING that these products must only be used for the treatment of SAM and strictly under medical supervision. A STATEMENT that potable drinking water must be available for children receiving RUTF treatment A STATEMENT that these products are not to be sold on the open market or commercially promoted in any way. 12.1 The Name of the Food The name of the food to be declared on the label shall indicate that the food is a Ready-To-Use Therapeutic Food for Children from 6 to 59 months with SAM. The appropriate designation indicating the true nature of the food should be in accordance with national legislation. The age from which the product is recommended for use shall appear in close proximity to the name of the food. 12.2 List of Ingredients The list of ingredients shall be declared in accordance with Section 4.2 of the General Standard for the Labelling of Prepackaged Foods (CXS 1 -1985). 12.3 Additional Mandatory Labelling Requirements Provisions of section 4.4 and 4.5 of the Standard for the Labelling of and Claims for Food for Special Medical Purposes only to indicate that it may be used for the treatment of SAM (CXS 180-1991) shall apply. There should be no nutrition or health claims for these products. 12.4 The following additional statements shall appear on the label of RUTF: The product is not to be used for Nasogastric Tube (NG tube) administration. The product should be used in conjunction with breastfeeding. Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for up to two years or beyond. 12.5 Instructions for use The label should indicate clearly from which age the product is recommended for use. This age shall not be less than six months for any product. Feeding instructions shall be given; preferably accompanied by graphical presentations. Serving sizes must be indicated for the ages of older infants and young children in 3 month incremental stages to ensure that breastmilk intakes are not compromised. The time within which the product should be consumed after opening should be clearly indicated. Storage and packaging instructions to minimize spoilage and contamination. ANNEX Table: Nutritional Composition of RUTF	
Comments on Annex (Nutritional Composition): The minimum and maximum levels of minerals and vitamins were adopted from the current RUTF specifications (2007). Since RUTF CODEX Guidance is now covering alternative types of RUTF, we believe the nutrition composition ranges need to accommodate all RUTF types. Specifically, we have noticed that maximum levels of Fe and Zn need to be increased to comply with current novel RUTF specifications (Iron: 10-35 mg, Zinc: 10-20 mg per 100g, total energy of 520-550 kcal). We propose maximum levels are 6.7mg/100kcal (Iron) and 3.7 mg/100kcal (Zinc) in plant- and cereal-based RUTF recipes. Science: Reduced bioavailability of zinc and iron: It has been known that absorption of some micronutrients will be decreased in plant-based materials. The review paper by Gibson RS et al. has specifically shown the negative impact of phytate on zinc and iron absorption (Gibson RS, Food and Nutrition Bulletin 2010 vol.31, no.2 (suppl) S134-S146). Science: safety aspects: Lopriore C et al. (AJCN 2004；80:978-81) provided a justification for the proposed content of iron and zinc, documenting that the levels proposed (though higher than UN secs) had been successfully used before. Furthermore, Akomo P et al. (BMC Public Health 2019;19:806) observed no adverse effects of an RUTF recipe containing the above “high” levels of zinc and iron. Limiting the anti-nutrient factors in plant	**International Council on Amino Acid Science**

ingredients is an alternative approach to resolving the issue. However, considering the affordability and availability of plant-based ingredients, we believe iron and zinc content enhancements is a more feasible approach.	
IRUFA would like to thank the CCNFSDU Chair and the Chair and co-chairs of the eWG for all the progress made to frame the future Guideline. IRUFA supports the text of the Guidelines at step 5 noting further discussion and amendments will be possible at step 6.	**International Ready to Use Foods Association**
ISDI welcomes the preparation of the draft Guidelines and acknowledges all the progress made in the last years at the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to frame the future Guideline. We would like to thank the CCNFSDU Chair and the Chair and co-chairs of the eWGs established to focus on specific aspects of this Guideline. ISDI supports the text of the Guidelines at step 5 noting further discussion and amendments will be possible at step 6. As a consequence, ISDI strongly supports the adoption of the proposed draft Guidelines for ready-to-use therapeutic foods at step 5 (REP20/NFSDU Appendix VI) by the Codex Alimentarius Commission in July 2020. We look forward to continue to work on the proposed draft Guidelines at Step 6.	**International Special Dietary Food Industries**
MSF generally agrees with the provisions of the draft. MSF would like to emphasize the attention to the current review on evidence of the Efficacy, safety, and effectiveness of ready-to-use therapeutic foods (RUTF) with reduced milk-protein content, lead by WHO. (https://www.who.int/nutrition/topics/callforauthors-review-RUTF-protein-sources/en/). This review will contribute to the update of the recommendations provided in the 2007 UN Joint Statement. As the proposed draft guideline is based on this WHO document to be soon updated, MSF would like to have this mentionned.	**MSF**
UNICEF finds the text is ready for adoption as a draft guideline. It broadly meets the overall aims of texts developed by Codex to protecting consumers' health and addresses a gap in normative texts for an essential commodity used to save children's lives. The guideline will be a useful tool for national governments and procuring agencies, and is drafted to allow for local adaption and innovation in years to come. UNICEF has editorial and technical comments that we would like the e-working group to consider in the next circulating draft, to further improve this draft. 1.Editorial comment : the WHO and other technical recommendations and guidelines will be updated in the future, so we suggest through out the text where appropriate, 'and updated guidance' or similar can be added. 2. Technical comment: In recent publications by WHO, the term severe acute malnutrition (SAM) has been replaced with severe wasting. UNICEF suggests that the term Severe Acute malnutrition (SAM) is replaced with 'severe wasting' in the relevant sections of the text so as to reflect this up to date terminology	**UNICEF**

Codex Committee on Food Hygiene

Comité du Codex sur l'Hygiène Alimentaire

Comité del Codex sobre Higiene de los Alimentos

Proposed Draft Guidance for the Management of Biological Foodborne Outbreaks

In reply to CL 2019/112-FH

Comments from Argentina, Canada, Chile, Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Honduras, Iraq, Peru, Senegal, Thailand, United Kingdom, Uruguay, USA

COMMENTS	**COUNTRY / OBSERVER NAME**
Argentina acuerda que el documento se remita al 43.º período de sesiones de la CAC para su adopción en el trámite 5 (Apéndice III); y establecer un GTP, que se reuniría coincidiendo con la celebración de la 52.ª reunión del CCFH para examinar todas las observaciones recibidas y preparar una propuesta revisada para su examen por el plenario. Asimismo, se sugiere eliminar la mención a los piensos en todo el documento. En todo el documento en español se sugiere traducir "recall" como "retiro" en lugar de "retirada".	**Argentina**
Canada has not additional comments on the proposed draft text and supports its adoption at Step 5.	**Canada**
Chile quiere agradecer el trabajo realizado por el CCFH en el **ANTEPROYECTO DE ORIENTACIONES PARA LA GESTIÓN DE BROTES BIOLÓGICOS TRANSMITIDOS POR LOS ALIMENTOS en trámite 5.** **Comentarios específicos:** **PARRAFO O SECCIÓN ORIGINAL** Definiciones: 22. Lote: Una cantidad determinada de ingredientes o de un alimento que se pretende que tenga un carácter y una calidad uniformes, dentro de unos límites establecidos, que se produce, envasa y etiqueta en las mismas condiciones y al que el operador de la empresa alimentaria asigna un número de identificación de referencia único. También puede denominarse "partida". **CAMBIO PROPUESTO** 22. Lote: Una cantidad determinada de ingredientes o de un alimento que se pretende que tenga un carácter y una calidad uniformes, dentro de unos límites establecidos, que se produce, envasa y etiqueta en ~~las mismas~~ condiciones **esencialmente iguales** y al que el operador de la empresa alimentaria asigna un número de identificación de referencia único. También puede denominarse "partida". **RATIONALE** “las mismas condiciones pueden llevar a que un lote pueda abarcar la producción de toda una semana o más tiempo mientras yo mantenga las mismas condiciones a diferencia de cuando las condiciones deben ser esencialmente iguales, incrementa la especificidad de las condiciones lo que restringe el tiempo de producción bajo las mismas condiciones al que le puedo llamar lote.	**Chile**

El texto se encuentra listo para su aprobación en el trámite 5/8.	**Colombia**
Costa Rica apoya el avance del texto en el tramite 5/8.	**Costa Rica**
Cuba agradece la oportunidad de expresar sus comentarios y en principio apoya el documento ANTEPROYECTO DE ORIENTACIONES PARA LA GESTIÓN DE BROTES BIOLÓGICOS TRANSMITIDOS POR LOS ALIMENTOS para su aprobación en el trámite 5 en la próxima reunión del CAC.	**Cuba**
Ecuador agradece el trabajo realizado, con relación al documento “Anteproyecto de orientaciones para la gestión de brotes biológicos transmitidos por los alimentos”, el país señala que no tiene observaciones; ya que los criterios técnicos descritos están bien estructurados, considerando que está listo para su aprobación.	**Ecuador**
En seguimiento a la solicitud de observaciones en CL 2019/112/OCS-FH de responder si el texto está listo para su aprobación o no, El Salvador ha analizado los cambios que han sufrido dichas orientaciones tras el debate en el seno del CCFH51, disponibles en el apéndice III del Rep20/FH. A pesar que en El Salvador no se dispone de todas las consideraciones que presentan las orientaciones para emplear los métodos analíticos que se presentan, específicamente cuando se utilice la SGC y tomando en cuenta las modificaciones hechas al párrafo 50, sobre la preocupación expresada en el CCFH51, respecto al sentido obligatorio que tenía este apartado, y se modificó dejando apertura a los países sobre este tema ("en el caso de usar la SGC"). El Salvador apoya el avance de la presente directriz de acuerdo al trámite interno del Codex Alimentarius, tal como se expresó en el CRD18 del CCFH51. Se considera que está lista para su aprobación en el siguiente periodo de sesiones de la Comisión del Codex Alimentarius (CAC).	**El Salvador**
Honduras sugiere remplazar la palabra rastreo por trazabilidad en todo el documento: Análisis de brotes: Un análisis basado en la información disponible sobre el brote transmitido por los alimentos, así como sobre los datos históricos pertinentes. Se utiliza para prever si cabría esperar más casos en las circunstancias dadas y para completar la información de rastreo que señala a una fuente y comprarla con la información epidemiológica del brote. Rastreabilidad/rastreo de productos: La capacidad de seguir el movimiento de un alimento a través de la(s) etapa(s) concreta(s) de su producción, elaboración y distribución. "Rastreo/rastreabilidad hacia atrás" se refiere a seguir el flujo hacia su origen o fuente y "rastreo/rastreabilidad hacia adelante" se refiere a seguir el flujo hacia su distribución final o punto de consumo. Sustituir la palabra CON por ENTRE: **REDES INTERNACIONALES DE ALERTA E INTERCAMBIO DE INFORMACIÓN ~~CON~~ ENTRE ELLAS** Se deberían utilizar métodos analíticos validados para aislar e identificar los agentes causales. Los métodos analíticos tradicionales (como el aislamiento de patógenos) o la reacción en cadena de la polimerasa (PCR) utilizados para la vigilancia y el seguimiento son indispensables para detectar e investigar cualquier brote, pero a menudo no permiten establecer en forma concluyente una relación entre los distintos casos en seres humanos, ni entre los casos en seres humanos y la supuesta fuente alimentaria. En algunos casos, la información básica de tipificación, como el serotipo, puede ser suficiente para permitir establecer dicha vinculación~~.~~. Cuando se ~~requiere una mejor~~ requiera mejorar la tipificación ~~a los~~ bacteriana o viral para fines de ~~investigar~~ investigación de un brote, ~~se puede~~ los países pueden recurrir a ~~los cada vez más empleados~~ métodos de tipificación molecular o genética~~.~~. Honduras sugere agregar este parrafo 52. Así mismo, las autoridades competentes de cada país podrán autorizar a laboratorios de la academia para que brinden colaboración en los análisis que se requiera.	**Honduras**

No se observa con claridad un intercambio de información de arriba hacia abajo (de la Red Nacional a Redes locales), o la comunicación al público de cuál fue el resultado del análisis y gestión de brotes. Agregar este item - Protocolo de muestreo protocolo de muestreo Información sobre las muestras tomadas – artículos, lugares de muestreo, etc.	
We agree with proposed draft of guidance without any comments. our regards.	**Iraq**
Perú agradece a la Secretaria del Codex. INTRODUCCION/1 Dice: 1. Las enfermedades transmitidas por los alimentos abarcan un amplio espectro de enfermedades y constituyen un importante problema de salud pública. Son consecuencia de la ingestión de alimentos contaminados con peligros biológicos (enfermedades biológicas transmitidas por los alimentos) o productos químicos (enfermedades químicas transmitidas por los alimentos). La contaminación de los alimentos puede producirse en cualquier etapa del proceso, desde la producción hasta el consumo y puede ser resultado de la presencia de peligros zoonóticos en la producción animal o procedentes de las personas que manejan los animales, de la contaminación ambiental, a través de los equipos, el agua, el suelo o el aire. Debe decir: Las enfermedades transmitidas por los alimentos abarcan un amplio espectro de enfermedades y constituyen un importante problema de salud pública. Las enfermedades transmitidas por los alimentos son generalmente de carácter infeccioso o tóxico y son causadas por bacterias, virus, parásitos o sustancias químicas que penetran en el organismo a través del agua o los alimentos contaminados. Las sustancias químicas que plantean más riesgos para la salud son las toxinas naturales y los contaminantes ambientales. La contaminación de los alimentos puede producirse en cualquier etapa del proceso, desde la producción hasta el consumo y puede ser resultado de la presencia de peligros zoonóticos en la producción animal o procedentes de las personas que manejan los animales, de los ingredientes de la contaminación ambiental, a través de los equipos, el agua, el suelo o el aire. Sustento: Se precisa los peligros biológicos y los químicos Los ingredientes también podrían ser fuente de contaminación biológica y/o, química. Parrafa 4 Dice: El Codex Alimentarius ha publicado varias guías para las empresas alimentarias y para las autoridades competentes sobre sobre prácticas de higiene para garantizar la inocuidad de los alimentos. Tales directrices se centran en la prevención, la vigilancia y las medidas correctivas en caso de que se produzcan desviaciones en los procesos de producción. A pesar de los esfuerzos por alcanzar un alto nivel de higiene, continúan ocurriendo brotes de enfermedades transmitidas por alimentos. Debe decir: El Codex Alimentarius ha publicado varias guías para las empresas alimentarias y para las autoridades competentes sobre prácticas de higiene para garantizar la inocuidad de los alimentos. Tales directrices se centran en la prevención, la vigilancia y las medidas correctivas en caso de que se produzcan desviaciones en los procesos de producción. A pesar de los esfuerzos por alcanzar un alto nivel de higiene, continúan ocurriendo brotes de enfermedades transmitidas por alimentos. Sustento: Palabra repetida "sobre" Párrafo 11 Dice: Estas directrices también describen el papel que desempeñan las autoridades competentes a nivel local, nacional y, cuando corresponda, regional (por ejemplo, grupos de países), así como la colaboración entre ellas en estructuras de redes formalizadas. Se incluyen directrices sobre la colaboración y la comunicación con los operadores de empresas alimentarias y otras partes interesadas antes y durante los brotes	**Peru**

transmitidos por los alimentos, así como sobre las medidas posteriores a los brotes y la revisión de la gestión del brote una vez que se ha declarado que ha finalizado. Se aborda asimismo el mantenimiento de las estructuras y los métodos de capacitación para mejorar la respuesta por parte de las redes. Debe decir: Estas directrices también describen el papel que desempeñan las autoridades competentes a nivel local, nacional y, cuando corresponda, regional (por ejemplo, grupos de países), así como la colaboración entre ellas en estructuras de redes formalizadas. Se incluyen directrices sobre la colaboración y la comunicación con los OEA y otras partes interesadas antes y durante los brotes transmitidos por los alimentos, así como sobre las medidas posteriores a los brotes y la revisión de la gestión del brote una vez que se ha declarado que ha finalizado. Se aborda asimismo el mantenimiento de las estructuras y los métodos de capacitación para mejorar la respuesta por parte de las redes. Sustento: Para uniformizar con otros documentos Párrafo 22 Dice: Lote: Una cantidad determinada de ingredientes o de un alimento que se pretende que tenga un carácter y una calidad uniformes, dentro de unos límites establecidos, que se produce, envasa y etiqueta en las mismas condiciones y al que el operador de la empresa alimentaria asigna un número de identificación de referencia único. También puede denominarse "partida". Debe decir: Lote: Una cantidad determinada de ingredientes o de un alimento que se pretende que tenga un carácter y una calidad uniformes, dentro de unos límites establecidos, que se produce, envasa y etiqueta en las mismas condiciones y al que el operador de la empresa alimentaria asigna un número de identificación de referencia único. También puede denominarse "batch". Sustento: Para un mejor entendimiento del texto se corrigió término Párrafo 24 Dice: Seguimiento: La realización de análisis rutinarios para detectar la contaminación microbiológica, por ejemplo, de alimentos, a partir de los cuales se pueden determinar datos de prevalencia. Debe decir: Seguimiento: La realización de análisis rutinarios para detectar la contaminación microbiológica, por ejemplo, en alimentos, a partir de los cuales se pueden determinar datos de prevalencia. Sustento: Para entendimiento del texto se corrigió. Párrafo 25 Dice: Análisis de brotes: Un análisis basado en la información disponible sobre el brote transmitido por los alimentos, así como sobre los datos históricos pertinentes. Se utiliza para prever si cabría esperar más casos en las circunstancias dadas y para completar la información de rastreo que señala a una fuente y comprarla con la información epidemiológica del brote. Debe decir: Análisis de brotes: Un análisis basado en la información disponible sobre el brote transmitido por los alimentos, así como sobre los datos históricos pertinentes. Se utiliza para pronosticar si se deben esperar más casos en las circunstancias dadas y para completar la información de rastreo que señala a una fuente y comprarla con la información epidemiológica del brote. Sustento: Para entendimiento del texto se corrigió. Párrafo 38 Dice: Se deberían elaborar de antemano plantillas y herramientas estándar, que deberían incluirse en los procedimientos estándar para que los participantes en la red las utilicen. Algunos de ellos se enumeran a continuación:	

• Plantilla(s) para recopilar y mantener actualizada la información que describe el brote - epidemiología descriptiva; • Cuestionario(s) estandarizado(s) para la elaboración de hipótesis; • Plantilla(s) de cuestionarios de cohortes y de casos y controles. Así, las redes podrían adaptarlas a la situación concreta del brote y utilizar los cuestionarios sin demora. La creación de cuestionarios estandarizados con esta finalidad se puede realizar de forma electrónica mediante el uso de alguna de las soluciones de software gratuitas disponibles en Internet. Los datos se pueden analizar electrónicamente a través de un programa estadístico estándar; • Plantilla(s) para informar sobre el brote y el resultado de las investigaciones; y • Una plantilla para solicitar una evaluación rápida de riesgos a la que se hace referencia en la Sección E y en el Anexo II. El nivel nacional de la red debería contar con una conexión permanente con las redes mundiales, entre otras, con INFOSAN y, cuando proceda, con las redes de alerta regional. Estas redes mundiales o nacionales cuentan con puntos de contacto nacionales de emergencia en la mayoría de los países. Si existe un punto de contacto nacional (persona o institución), se lo debería incorporar activamente a las investigaciones a nivel nacional sobre brotes transmitidos por los alimentos. El punto de contacto de estas redes de alerta puede ayudar a reunir y recopilar información y a presentar información coordinada sobre los brotes transmitidos por los alimentos que estén ocurriendo. Debe decir: Se deberían elaborar de antemano plantillas y herramientas estándar, que deberían incluirse en los procedimientos estándar para que los participantes en la red las utilicen. Algunos ejemplos se detallan a continuación: • Plantilla(s) para recopilar y mantener actualizada la información que describe el brote - epidemiología descriptiva; • Cuestionario(s) estandarizado(s) para la elaboración de hipótesis; • Plantilla(s) de cuestionarios de cohortes y de casos y controles. Así, las redes podrían adaptarlas a la situación concreta del brote y utilizar los cuestionarios sin demora. La creación de cuestionarios estandarizados con esta finalidad se puede realizar de forma electrónica mediante el uso de alguna de las soluciones de software gratuitas disponibles en Internet. Los datos se pueden analizar electrónicamente a través de un programa estadístico estándar; • Plantilla(s) para informar sobre el brote y el resultado de las investigaciones; y • Una plantilla para solicitar una evaluación rápida de riesgos a la que se hace referencia en la Sección E y en el Anexo II. Sustento: Para entendimiento del texto se corrigió. Párrafo 42 Dice: El nivel nacional de la red debería contar con una conexión permanente con las redes mundiales, entre otras, con INFOSAN y, cuando proceda, con las redes de alerta regional. Estas redes mundiales o nacionales cuentan con puntos de contacto nacionales de emergencia en la mayoría de los países. Si existe un punto de contacto nacional (persona o institución), se lo debería incorporar activamente a las investigaciones a nivel nacional sobre brotes transmitidos por los alimentos. El punto de contacto de estas redes de alerta puede ayudar a reunir y recopilar información y a presentar información coordinada sobre los brotes transmitidos por los alimentos que estén ocurriendo. Debe decir: El nivel nacional de la red debería contar con una conexión permanente con las redes mundiales, entre otras, con INFOSAN y, cuando proceda, con las redes de alerta regional. Estas redes mundiales o nacionales cuentan con puntos de contacto nacionales de emergencia en la mayoría de los países. Si existe un punto de contacto nacional (persona o institución), se lo debería incorporar activamente a las investigaciones a nivel nacional sobre brotes transmitidos por los alimentos. El punto de contacto de estas redes de alerta puede ayudar a enviar información coordinada sobre brotes en curso transmitidos por alimentos. Sustento Para entendimiento del texto se corrigió. Párrafo 43 Dice: La información procedente de las redes mundiales puede resultar útil para la labor de las redes nacionales, incluso si los brotes descritos no se refieren al país en cuestión, por lo que siempre se debería tener en cuenta si la información relativa a un brote podría ser útil para otros	

países y, por lo tanto, se debería compartir. Debe decir: La información procedente de las redes mundiales puede resultar útil para la labor de las redes nacionales, incluso si los brotes descritos no se refieren al país en cuestión, por lo que siempre se debería tener en cuenta si la información relativa a un brote podría ser útil para otros países y, por lo tanto, compartirla. Sustento: Para entendimiento del texto se corrigió. E. EVALUACIÓN RÁPIDA DE RIESGOS - ESTRUCTURAS PARA EVALUAR LOS RIESGOS/ 55 Una parte fundamental de la preparación para los brotes es disponer de estructuras que permitan una evaluación rápida de riesgos. Deberían incluir lo siguiente, sin limitarse a ello: • Listas de evaluadores de riesgos y expertos en peligros específicos disponibles con la indicación de su ámbito de competencia; • Instrucciones en las que se establezca claramente lo que se espera de estos evaluadores de riesgos y expertos en la materia, indicando el ámbito de aplicación de cualquier evaluación rápida de riesgos, teniendo en cuenta el corto plazo del que se dispone para la realización de la evaluación, o una plantilla lista para ser utilizada en dicha evaluación rápida de riesgos. • Se ofrecen ejemplos de solicitudes en el Anexo II. Anexo II Ejemplos de solicitudes de evaluaciones rápidas de riesgos El objetivo de una evaluación rápida de riesgos es responder a una pregunta concreta o evaluar un elemento de riesgo específico en relación con un brote. • Una estructura para la presentación directa e inmediata de información procedente de la investigación del brote a los asesores sobre riesgos y para que estos soliciten más aclaraciones a los investigadores o a los operadores de empresas de alimentos implicados, cuando sea necesario; • Disponibilidad de datos (regionales/nacionales/locales) sobre el consumo, los hábitos de consumo y el tamaño de las raciones, que estén lo más actualizados posible; • Procedimientos para ponerse rápidamente en contacto con los operadores de empresas alimentarias, lo que incluye el mantenimiento de la información de contacto. Debe Decir: Una parte fundamental de la preparación para los brotes es disponer de estructuras que permitan una evaluación rápida de riesgos. Deberían incluir lo siguiente, sin limitarse a ello: • Listas actualizadas de especialistas en evaluación de riesgos y de expertos en peligros específicos, con la indicación de su ámbito de competencia, • Instrucciones en las que se establezca claramente lo que se espera de estos evaluadores de riesgos y expertos en peligros específicos, indicando el ámbito de aplicación de cualquier evaluación rápida de riesgos, teniendo en cuenta el corto plazo del que se dispone para la realización de la evaluación, o una plantilla lista para ser utilizada en dicha evaluación. • Se ofrecen ejemplos de solicitudes en el Anexo II. Anexo II Ejemplos de solicitudes de evaluaciones rápidas de riesgos El objetivo de una evaluación rápida de riesgos es responder a una serie de preguntas concretas o evaluar elementos de riesgo específico en relación con un brote. Sustento: Mejora de redacción, para una mejor comunicación y comprensión en español. A.IDENTIFICACIÓN E INVESTIGACIÓN DE BROTES TRANSMITIDOS POR LOS ALIMENTOS – SALUD HUMANA/ 62 Dice: Un brote transmitido por los alimentos normalmente es identificado por: • Un sistema nacional o regional de vigilancia cuando ocurre un grupo de casos humanos con un tipo de infección idéntico o estrechamente relacionado que probablemente sea transmitido por los alimentos; o por	

• Las autoridades de control alimentario cuando informan sobre una enfermedad relacionada con empresas alimentarias o productos específicos. La información se puede obtener tanto a partir de reclamaciones de los consumidores, de información del sector de salud pública o de las propias empresas alimentarias, por ejemplo, de un restaurante que recibe reclamaciones de sus clientes. La gestión de los brotes se ve beneficiada cuando los sectores de control de los alimentos, veterinario y agrícola son capaces de intercambiar y combinar, entre ellos y con el sector de salud pública, datos de laboratorio sobre vigilancia y seguimiento a fin de identificar una coincidencia entre una cepa clínica aislada de origen humano y una fuente alimentaria Debe decir: Un brote transmitido por los alimentos normalmente es identificado por: • Un sistema nacional o regional de vigilancia cuando ocurre en un grupo humano con un tipo de infección idéntico o estrechamente relacionado que probablemente sea transmitido por los alimentos; o por • Las autoridades de control alimentario cuando informan sobre una enfermedad relacionada con empresas alimentarias o productos específicos. La información se puede obtener tanto a partir de reclamos de los consumidores, de información del sector de salud pública o de las propias empresas alimentarias, por ejemplo, de un restaurante que recibe reclamos de sus clientes. La gestión de los brotes biológicos se ve beneficiada cuando los sectores de control de los alimentos y sectores veterinarios y agrícolas son capaces de intercambiar y combinar, entre ellos y datos de laboratorio sobre vigilancia y seguimiento de brotes, con el sector de salud pública, a fin de identificar una coincidencia entre una cepa clínica aislada de origen humano y una fuente alimentaria. Sustento: Mejora de redacción, para una mejor comunicación y comprensión en español. Párrafo 75 Dice: La gestión de los brotes se ve beneficiada cuando los sectores de control de los alimentos, veterinario y agrícola son capaces de intercambiar y combinar, entre ellos y con el sector de salud pública, datos de laboratorio sobre vigilancia y seguimiento a fin de identificar una coincidencia entre una cepa clínica aislada de origen humano y una fuente alimentaria Debe decir: La gestión de los brotes biológicos se ve beneficiada cuando los sectores de control de los alimentos y sectores veterinarios y agrícolas son capaces de intercambiar y combinar, entre ellos y datos de laboratorio sobre vigilancia y seguimiento de brotes, con el sector de salud pública, a fin de identificar una coincidencia entre una cepa clínica aislada de origen humano y una fuente alimentaria. Sustento: La traducción no es clara. Se sugiere reestructurar el párrafo. Párrafo 78 Dice: SNC Debe decir: La abreviatura no ha sido traducida Párrafo 80 Dice: El nivel de contaminación puede ser de bajo, por lo que las posibilidades de detección son limitadas. Debe decir: El nivel de contaminación puede ser bajo, por lo tanto, la posibilidad de detección es limitada. Sustento: Error en la traducción Párrafo 81 Dice: Por otra parte, las pruebas analíticas deberían contar siempre con el respaldo de información epidemiológica, como la obtenida en las entrevistas de casos humanos, ya que la coincidencia entre alimentos y cepas humanas no significa necesariamente que el alimento sea la verdadera fuente de la enfermedad.	

Debe decir: Por otra parte, las pruebas analíticas deberían contar siempre con el respaldo de información epidemiológica, así como aquella obtenida en las entrevistas de casos humanos, ya que la coincidencia entre alimentos y cepas humanas no significa necesariamente que el alimento sea la verdadera fuente de la enfermedad. Sustento: La traducción no es clara. Se sugiere reestructurar el párrafo. Párrafo 99: Dice: La revisión se debería difundir ampliamente en el marco del sistema, para compartir las lecciones aprendidas. Lo ideal sería que la difusión incluyese información como la siguiente: Debe Decir: La revisión se debería difundir ampliamente en el marco del sistema, para compartir las lecciones aprendidas. Idealmente, la difusión incluiría información como: Sustento: Mejora de redacción, para una mejor comunicación y comprensión en español *EN TODO EL DOCUMENTO MODIFICAR: Producto alimentario por producto alimenticio Retirada de producto por retiro de producto.	
Le Sénégal supporte l'adoption du document à l'étape 5 Nous rappelons aussi la nécessité d'inclure INFOSAN au niveau des réseaux internationaux et le secteur privé au niveau des Réseaux natioanaux dans l'ANNEXE I du draft qui décrit la structuration des réseaux gérant les épidémies d'origine alimentaire au plan international et national où la coopération, la coordination et la transparence sont essentielles pour une gestion efficace des épidémies.	**Senegal**
Thailand has no further comment for the Draft at Step5.	**Thailand**
The United Kingdom supports the adoption of the proposed Draft Guidance for the Management of Biological Foodborne Outbreak at step 5	**United Kingdom**
Comentarios generales del documento: Uruguay entiende que el borrador de documento requiere una mayor discusión entre los países. Entendemos que debería revisarse la redacción a lo largo del documento, a fin de evitarse la utilización de expresiones que confieran al documento un carácter mandatario. Por otro lado, entendemos que persisten aspectos del documento que son técnicamente muy valiosos para la gestión de brotes biológicos transmitidos por los alimentos, pero que no reflejan el estado del arte de los países menos desarrollados y no aplicables, por lo tanto, en el futuro inmediato, como, por ejemplo, la recomendación de la utilización de la secuenciación genómica completa.	**Uruguay**
The United States supports the adoption of the Draft Guidance for the Management of Biological Foodborne Outbreaks at Step 5, as our significant concerns have been addressed.	**USA**

Ad hoc Codex Intergovernmental Task Force on Antimicrobial Resistance

Groupe intergouvernemental spécial du Codex sur la résistance aux antimicrobiens

Grupo de Acción Intergubernamental Especial sobre Alimentación Animal

Proposed draft revised Code of Practice to Contain and Minimize Foodborne Antimicrobial Resistance (CXC 61-2005)

In reply to CL 2020/04-AMR

Comments from Algeria, Brazil, Chile, China, Colombia, Cook Islands, Costa Rica, Cuba, Ecuador, Egypt, European Union, Iraq, Malaysia, Republic of Korea, Thailand, United Kingdom, Uruguay, USA, Consumer Goods Forum, International Feed Industry Federation and OIE

COMMENTS	COUNTRY / OBSERVER NAME
Il est proposé de rajouter les définitions relatives à l 'antibiorésistance et la biosécurité. **3. Définitions** Il est proposé d 'ajouter les définitions relatives à "l 'antibiorésistance" et à "la biosécurité" **4. Principes généraux visant à réduire au minimum et maîtriser la résistance aux antimicrobiens** Il est constaté un non-respect de l 'ordre chronologique des principes généraux. De ce fait , il est jugé utile de revoir ce classement pour une meilleure compréhension. **Préparation d'un résumé des caractéristiques de chaque produit antimicrobien** Il est proposé ce qui suit: -Remplacer au niveau du paragraphe 23 "les autorités réglementaires "par les autorités compétentes " Les interactions du produit et ~~son~~ son utilisation chez des populations spécifiques pour chaque produit antimicrobien autorisé, lorsqu'elles sont disponibles; Il est recommandé de reformuler le cinquième point comme suit: les interactions du produit et son "mode" d 'utilisation chez des populations spécifiques, lorsqu'elles sont disponibles. 26. Lorsque l'évaluation des données collectées à partir d'un programme de pharmacovigilance et d'autres programmes de surveillance après autorisation, y compris, le cas échéant, la surveillance ciblée de la résistance aux antimicrobiens des agents pathogènes présents dans les animaux ou les plantes/cultures, suggère que les conditions d'usage stipulées dans l'autorisation de mise sur le marché de l'agent antimicrobien examiné devrait être révisées, les autorités réglementaires devraient mettre tout en œuvre pour procéder à cette réévaluation. Il est recommandé de remplacer "les autorités réglementaires " par "les autorités compétentes ". 28. Les autorités compétentes devraient empêcher que les médicaments illégaux et les formulations non approuvées n'entrent dans les systèmes de distribution.	**Algeria**

Il est proposé de reformuler le paragraphe 28 comme suit: Les autorités compétentes devraient empêcher" l 'entrée " des médicaments illégaux et les formulations non approuvées dans les systèmes de distribution. 35. Les autorités compétentes devraient élaborer des procédures efficaces de collecte et d'élimination sans risque des agents antimicrobiens non utilisés, de qualité inférieure et contrefaits, commercialisés illégalement ou périmés. Remplacer le Chiffre 35 par le chiffre 34 et de reformuler ce paragraphe comme suit: -Les autorités compétentes devraient élaborer des procédures efficaces de collecte et d 'élimination sans risque des agents antimicrobiens "périmés" ou non utilisés, de qualité inférieure et contrefait, commercialisés illégalement. 38. L'exportation d'agents antimicrobiens devrait être limitée aux produits conformes aux normes de qualité telles que précisées dans la loi du pays importateur. Il est proposé de remplacer au niveau du paragraphe 38 "la loi du pays importateur "par "La réglementation du pays importateur". 46. Les grossistes et détaillants distribuant des agents antimicrobiens d'importance médicale ne devraient le faire que sur ordonnance d'un vétérinaire ou sur ordre d'un professionnel de la santé des plantes/cultures ou d'une autre personne dûment formée et autorisée conformément à la législation nationale. Tous les produits distribués devraient être correctement étiquetés. Il est proposé de déplacer la phrase du paragraphe 46 "tous les produits distribués devraient être correctement étiquetés ". au titre 5.2 dès lors que la conformité de l 'étiquetage est la responsabilité des fabricants. 47. Les distributeurs devraient tenir des enregistrements détaillés des antimicrobiens d'importance médicale fournis, conformément aux réglementations nationales, pouvant faire état des éléments suivants : Il y a lieu de rajouter au niveau du paragraphe 47 un point relatif à la "quantité vendue". D'éviter d'utiliser des agents antimicrobiens périmés et de se débarrasser de tous les agents antimicrobiens inutilisés ou périmés, conformément aux dispositions figurant sur l'étiquette du produit et à la législation nationale; Il est proposé de reformuler le point 7 du paragraphe comme suit: "d 'éviter d 'utiliser des agents antimicrobiens périmés et de se débarrasser de tous les agents antimicrobiens inutilisés ou périmés, conformément aux dispositions "de la réglementation " nationale. Les informations pertinentes sur les animaux et plantes/cultures traités (nombre, âge, poids); Compléter ce point 10 m par le mot "espèce".	
Brazil recognizes the efforts of all members during the Sessions of the Task Force and supports the adoption at Step 5 of the revised Code of Practice to Contain and Minimize Foodborne Antimicrobial Resistance, as presented in REP20/AMR, Appendix II.	**Brazil**
In response to the circular letter, Chile would like to manifest its gratitude with the TFAMR 7 in developing this document which will have great utility for members countries. We look forward to seeing the complete document for its adoption at step 8. Chile doesn't have any specific comments to the revised Code of Practice to Contain and Minimize Foodborne Antimicrobial Resistance (CXC 61-2005) and recommend its adoption at step 5 by the Codex Alimentarius Commission.	**Chile**

China would like to thank the excellent work and continue efforts of the working groups in TFAMR7. China agree that the proposed draft revised Code of Practice is now ready for adoption at step 5. Thanks for the opportunity to submit the comments from Chinese expert group. 52. For food-producing animals, the appropriate use of medically important antimicrobial agents in therapeutic practice is a clinical decision that should be based on the experience of the prescribing veterinarian~~,~~ and epidemiological and clinical knowledge and, if available, based on adequate diagnostic procedures. When a group of food-producing animals~~,~~ which may have been exposed to pathogens, they may need to be treated without recourse to a laboratory confirmed diagnosis based on antimicrobial susceptibility testing to prevent the development and spread of clinical ~~disease~~disease under the direction of veterinarians. The population treatment for prevent the development and spread of clinical disease should be under the direction of veterinarians. 57. Medically important antimicrobials should not be used off-label for plants/crops, except off-label use for emerging disease control,under the direction of plant/crop health professionals, in accordance with national legislation. The off-label use for emerging disease control should be under the direction of plant/crop professionals. Record the antimicrobial susceptibility testing ~~results; when~~ results and genomic ~~information,~~ information when available; Record the antimicrobial used, the dosage and the duration; • investigate adverse reactions to antimicrobial agents, including lack of expected efficacy, and report it, as appropriate, to the competent authorities (through a pharmacovigilance system, if available). The investigation of adverse reaction should be listed as a separate bullet. To use antimicrobial agents in the species, for the uses and at the doses and duration on the approved labels and in accordance with the prescription, product label instructions or the advice of a veterinarian, plant/crop health professional or other suitably trained person authorized in accordance with national legislation familiar with the food-producing animals or the plant/crop production site; t~~To~~ o ensure sound management of wastes and other materials to minimize dissemination of excreted antimicrobial agents, resistant microorganisms and resistance determinants into the environment where they may contaminate food; Keep the format consistent for all the bullets. t~~To~~ o address on-farm biosecurity measures and take infection prevention and control measures as appropriate and as provided in the *OIE Terrestrial and Aquatic Animal Health Codes*; Keep the format consistent for all the bullets. t~~To~~ o participate in training on issues related to antimicrobial resistance and the responsible use of antimicrobial agents as described in paragraph 32, as appropriate; Keep the format consistent for all the bullets. t~~To~~ o assist the relevant authorities in surveillance programs related to antimicrobial use and antimicrobial resistance, as appropriate. Keep the format consistent for all the bullets.	**China**
Estamos de acuerdo con la aprobación de documento.	**Colombia**
We are yet to finalize with Ministry of Health as the appropriate agency who handles Food-borne AMR. before progressing on the proposed draft. Due to the COVID -19 global out break all work on codex work has been suspended indefinite.	**Cook Islands**

Costa Rica appreciates the opportunity to provide comments and to participate in the EWG on the Draft of the revision of the Code of Practice to minimize and contain food-borne antimicrobial resistance (CXG 61-2005). Additionally, we thank the GTE leaders and co-leaders for the excellent work done. General observations: The Draft revision of the Code of Practice to minimize and contain resistance to food-borne antimicrobials (CXG 61-2005) in is generally harmonized with our national regulations within the scope of in the food chain. However, we respectfully requested to the EWG to recall a general and additional review of the use of "antimicrobial agent", which in some paragraphs may not be the appropriate its use and should be changed to "antimicrobial product". According our country, as in others countries, the marketing and use authorization is granted from the Competent authority to the “veterinary product” wich presents the dossier for evaluation and which in its formulation contents an “antimicrobial agent”. For example, in section 3 definition of “Marketing license”; and in paragraph 4, in which it is recalled that the direct use of animals is as a "veterinary product" in which it contains an antimicrobial agent. Specific observations: 1. About "[Principle 6: Antimicrobial agents of medical importance should be used only for therapeutic purposes (treatment / control / metaphylaxis or disease prevention / prophylaxis).]" Position: Our country considers that it is pertinent to eliminate the Principle 6 of the document. Justification: It is a principle that is detailed and clarified under a responsibly therapeutic use in the principle 7. Maintaining principle 6 can cause confusion for general readers of the Code of Practice by being repetitive on purpose that carries principle 7. Besides, repeating principles with differents words can dilute the value of other principles, especially in this document where there are a wide variety of principles.	**Costa Rica**
Cuba revisó el documento referido en la solicitud de observaciones sobre el Anteproyecto de revisión del Código de prácticas para reducir al mínimo y contener la resistencia a los antimicrobianos transmitida por los alimentos (CXC 61-2005) en el trámite 5, y apoyamos los cambios propuestos, no se tienen señalamietos al respecto.	**Cuba**
8. El presente documento está concebido para ofrecer un marco para el desarrollo de medidas destinadas a mitigar el riesgo de RAM transmitida por los alimentos, que los países pueden aplicar como parte de su estrategia nacional sobre la RAM, según su capacidad, en función de sus prioridades y capacidades nacionales, y en un plazo de tiempo razonable. Algunos países pueden servirse de una implementación progresiva para aplicar debidamente elementos de este documento en forma proporcional al riesgo de RAM transmitida por los alimentos. Dicho enfoque no se debería utilizar para crear obstáculos injustificados al comercio. Ecuador apoya este párrafo considerando que da la directriz de restricción progresiva. **Uso terapéutico:** La administración o aplicación de agentes antimicrobianos para el tratamiento, el control/metafilaxis o la prevención/profilaxis de enfermedades.**]** Ecuador solicita eliminar la prevención/profilaxis de enfermedades en el concepto de uso terapéutico. **Principio 1 bis:** Considerando que este documento tiene por objeto brindar orientaciones para la gestión del riesgo a los efectos de abordar los riesgos de RAM transmitida por los alimentos para la salud humana, la sanidad animal y la sanidad vegetal, se deberían tener en cuenta las normas pertinentes de la OIE y de la CIPF. Ecuador solicita la inclusión de estos términos en el glosario: OIE y CIPF	**Ecuador**

Principio 12: Únicamente deberían prescribir, administrar o aplicar antimicrobianos de importancia médica los veterinarios, los profesionales de la sanidad de plantas/cultivos u otras personas debidamente capacitadas y autorizadas de conformidad con la legislación nacional o, en su defecto, dichas acciones deberían realizarse bajo su dirección. Ecuador solicita se elimine de importancia médica **Principio 5:** El uso responsable y prudente de los agentes antimicrobianos no incluye el uso para estimular el crecimiento de agentes antimicrobianos que se consideren de importancia médica. Los agentes antimicrobianos que no se consideren de importancia médica no deberían utilizarse para estimular el crecimiento, a menos que se hayan evaluado los riesgos potenciales para la salud humana mediante procedimientos coherentes con las *Directrices para el análisis de riesgos de resistencia a los antimicrobianos transmitida por los alimentos*. Ecuador apoya este párrafo considerando que da la directriz de restricción progresiva de antimicrobianos de importancia médica. Y de manera posterior la restricción UAM de los que NO se consideran de importancia médica. **Principio 6:** Los agentes antimicrobianos de importancia médica deberían utilizarse únicamente con finalidad terapéutica (tratamiento/control/metafilaxis o prevención/profilaxis de enfermedades).**]** Ecuador solicita incluir; o, en determinadas circunstancias, para la prevención, investigación y conservación, previo conocimiento y autorización del ente de control gubernamental **Principio 7:** Se sugiere el siguiente texto considerando que los agentes antimicrobianos de importancia médica se puede utilizar con fines terapéuticos o profilácticos, en determinadas circunstancias con supervisión profesional y previo conocimiento y autorización del ente de control gubernamental. ... "cuando se disponga de ellas, lo cual incluye las restricciones en proporción con el riesgo y respaldadas por la evidencia científica. Previo conocimiento y autorización del ente de control gubernamental" **Principio 7 bis:** Cuando se utilicen para el control de enfermedades/metafilaxis, los agentes antimicrobianos de importancia médica únicamente deberían usarse en función de los conocimientos epidemiológicos y clínicos y del diagnóstico de una enfermedad específica, y se debería contar con una supervisión profesional, una dosificación y una duración adecuadas. Se solicita eliminar porque está incluido en los párrafos anteriores. **Principio 10:** El seguimiento y la vigilancia del uso de agentes antimicrobianos, así como la incidencia o prevalencia, y, en determinadas pautas, los microorganismos resistentes transmitidos por los alimentos y los determinantes de la resistencia se encuentran entre los factores críticos a tener en cuenta a la hora de desarrollar medidas de gestión del riesgo y de evaluar la eficacia de las medidas de gestión del riesgo aplicadas. El uso de agentes antimicrobianos en seres humanos, animales destinados a la producción de alimentos y plantas/cultivos, y la transmisión de patógenos y de genes de resistencia entre los seres humanos, los animales destinados a la producción de alimentos, las plantas/los cultivos y el ambiente son factores adicionales a tener en cuenta en el proceso de análisis del riesgo de RAM transmitida por los alimentos que se describe en las *Directrices para el análisis de riesgos de resistencia a los antimicrobianos transmitida por los alimentos*. PRINCIPIO 10: Dentro los factores críticos a considerar al desarrollar medidas de gestión de riesgos, así como la evaluación de la efectividad de la implementación de dichas medidas, son el monitoreo y vigilancia del uso de agentes antimicrobianos; la incidencia o prevalencia; y en particular, las tendencias de los microorganismos resistentes a los antimicrobianos transmitidos por los alimentos y los determinantes de resistencia. Otros factores adicionales a considerar, según el documento “Directrices para el análisis de riesgos de antimicrobianos transmitidos por alimentos”, son el uso de agentes antimicrobianos en: humanos, animales productores de alimentos, y plantas/cultivos; así como la transmisión de patógenos y genes de resistencia entre humanos. 21. Las autoridades competentes deberían evaluar el potencial de los agentes antimicrobianos de importancia médica que se utilizan a lo largo de la cadena alimentaria para seleccionar la RAM transmitida por los alimentos, teniendo en consideración las *Directrices para el análisis de riesgos*	

de resistencia a los antimicrobianos transmitida por los alimentos, la *Lista de la OMS de antimicrobianos de importancia crítica para la medicina humana*, la *Lista de la OIE de agentes antimicrobianos de importancia veterinaria* o las listas nacionales, cuando se disponga de ellas. Se puede colocar investigaciones de otros países no únicamente las autoridades competentes. 31. La publicidad y promoción de los antimicrobianos debería realizarse de conforme a las recomendaciones reglamentarias específicas para el producto. Cuando se publiciten antimicrobianos se debería solicitar que se haga énfasis en cuestiones relacionados con la buena práctica de manejo de antimicrobianos por ejemplo . Respetar el período de carencia y retiro 41. Es responsabilidad de los fabricantes y los titulares de autorizaciones de comercialización dar publicidad únicamente a los agentes antimicrobianos con arreglo a las disposiciones de los párrafos 30 y 31, y abstenerse de hacer publicidad indebida de agentes antimicrobianos directamente a los productores. Ecuador no está de acuerdo, a razón que los titulares de registro tienen la autorización de publicitar anti microbianos siempre y cuando se respeten las disposiciones de los párrafos 30 y 31 descritos en este documento.	
Egypt agrees to adopt the proposed draft revised Code of Practice at Step 5 and taking into consideration the following points: 1-Therapeutic use : Egypt agrees to leave this definition in square brackets for further consideration at its next session 2- "Principle 5: Responsible and prudent use of antimicrobial agents does not include the use for growth promotion of antimicrobial agents that are considered medically important. Antimicrobial agents that are not considered medically important should not be used for growth promotion unless potential risks to human health have been evaluated through procedures consistent with the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance": Egypt disagrees with Principle 5 as presented and TFAMR07 is reported that Egypt registered its reservation on this principle with Russian Federation, Thailand and India and Egypt will welcome the opportunity to continue the discussion of principle 5 in the coming years. Norway asked for further consideration of phasing-out antimicrobials used as growth promoters 3- [Principle 6: Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease).] Egypt agrees to leave this definition in square brackets for further consideration at its next session.	**Egypt**
Reply of the European Union and its Member States to CL 2020/04/OCS –AMR: Request for Comments on the Proposed Draft Revised Code of Practice to Contain and Minimize Foodborne Antimicrobial Resistance (CXC 61-2005) at Step 5 Mixed Competence European Union Vote The EU and its Member States (EUMS) would like to recall their reservations on principles 5 and 7 as currently written in the proposed draft Revision of the Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (CXC 61-2005) submitted for adoption at step 5: Concerning Principle 5, given the threat that antimicrobial resistance represents for global public health, the EUMS strongly believe that new antimicrobial agents should not be granted marketing authorisation for growth promotion and that the use for growth promotion of those antimicrobials that are already authorised should be phased out worldwide, at a bare minimum. There is a growing international consensus also at scientific level that the use of antimicrobials for growth promotion should be phased out since it represents an important causal factor contributing	**European Union**

to the emergence of resistance and co- and cross resistance to antimicrobials and, most importantly, to the medically important antimicrobials. The OIE in 2018 endorsed the phasing out of antimicrobial agents for growth promotion giving priority to medically important antimicrobials. In May 2019, the Secretary General of the UN in his report to the General Assembly embraces the recommendations of the Interagency Coordination Group on Antimicrobial Resistance (IACG). Like OIE, the IACG recommends the phasing out of antimicrobial agents for growth promotion in the framework of implementation of the One Health approach at global level. Concerning Principle 7, the EUMS do not support the prophylactic use of medically important antimicrobials. To promote the prudent use of all antimicrobials and in view of the risk of resistance and co- and cross resistance to medically important antimicrobials, clear and strong restrictions must apply on the prophylactic use of antimicrobials in animals. This includes a ban on the preventive use of antibiotics in groups of animals, allowing only individual animals to be administered antibiotics prophylactically and only in exceptional cases. All antibiotics should be covered by these restrictions on prophylactic use, including those listed to be of the highest priority among those of the High Critical Importance under the WHO CIA List and those of Veterinary Critical Importance under the OIE List of antimicrobial agents of veterinary importance. The work of Codex should aim at being ambitious in line with the Codex mandate ensuring protection of public health and consistent with FAO, WHO and OIE.	
we agree with proposed draft revision of the Code of Practice without any comments. Regards.	**Iraq**
Malaysia support the term therapeutic included as inclusive of prevention, control, and treatment in the Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance. The rationale are as follows: The document strengthens efforts to address AMR along the food chain through the application of science and a practical One Health approach. The document advances the credibility of Codex by maintaining scientific integrity through utilizing risk assessment to inform food safety decisions and focus on interventions that matter. The document provides text to all countries to more confidently pursue AMR mitigation efforts relative to local conditions, without adverse trade impacts.	**Malaysia**
Republic of Korea agrees to submit this proposed draft to CAC43 for adoption at step5.	**Republic of Korea**
Thailand does not oppose the adoption of the draft revised Code of Practice to Contain and Minimize Foodborne Antimicrobial Resistance (CXC 61-2005) at Step 5. However, we would like to reserve our position to refuse principle 5 with regard to the application of antimicrobial agents for growth promotion as indicated in the final sentence of the said principle. Rationale: To ensure that antimicrobial agents are used prudently and responsibly, the use of antimicrobial growth promoters in the food-producing animals should not be used in any circumstances.	**Thailand**
In response to Codex circular letter CL 2020/04/OCS-AMR, the UK would like to support progressing the draft revised Code of Practice to adoption. We welcome the significant step forward that this document represents through some difficult discussions and agreed compromises at TFAMR7.	**United Kingdom**
Uruguay agradece la oportunidad de comentar el documento y opina que está listo para su aprobación en el trámite 5.	**Uruguay**
The United States fully supports advancing the proposed draft revised Code of Practice to Contain and Minimize Foodborne Antimicrobial Resistance (CoP) to Step 5. The United States would like to acknowledge the hard work of the Codex ad hoc Intergovernmental Task Force on Antimicrobial Resistance in building consensus over three years through multiple electronic and physical working groups in addition to three Task Force meetings. The draft CoP helps to reinforce key areas at the global level and across sectors. This is no small feat as it is challenging to come to common understanding on an issue when there are human, animal, crop, and environmental contexts, varying use of terminology in different countries and sectors, and the scientific landscape on the issue is constantly changing. Further, determining those areas that are both within	**USA**

Codex mandate and beyond added to the complexity of the task. The draft CoP supports the need for the international community to have a common understanding of terms, general principles to be followed to help minimize antimicrobial resistance, and roles and responsibilities of various actors in the food chain to minimize antimicrobial resistance. The draft CoP also expands work done in the original 2005 CoP beyond use of antimicrobials in animal food production to address other relevant sectors in the food chain. The United States looks forward to continuing the work in the Electronic Working Group and at the physical meeting of the Task Force on the few remaining issues to enable the Task Force to advance the Guidance at its next session to Step 8. This includes bracketed text regarding definition of the term "therapeutic use," its accompanying principle, principle 6, and inclusion of the term, "therapeutic" in paragraph 54 regarding proper use of antimicrobial drugs in therapeutic regimens.	
GFSI welcomes the work of the taskforce and: ● the emphasis on the risk-based approach. ● the responsibility of food processors clearly stated ● the specific need to work together with professional associations for the training and the development of guidelines. ● the need for the control of advertising by antimicrobials producers (point 41 and 42) ● the acknowledgment that safe and effective alternatives exist (Principle 2) and think they should be promoted	**Consumer Goods Forum**
The proposed text from the Seventh Meeting of TFAMR significantly improves the existing Codex guidance on this matter and provides practical, science-driven input for Member Countries and food chain stakeholders, including the feed industry. The document represents a carefully developed set of practical provisions to address an important One Health challenge implementable by the different stakeholders, while supporting compliance with trade obligations. Therefore, the International Feed Industry Federation (IFIF) supports adoption at Step 5 of the Codex Proposed draft revision of the Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (CXC 61-2005). IFIF encourages the next TFAMR to limit its work to the provisions in the brackets for finalising the document.	**International Feed Industry Federation**
52. For food-producing animals, the appropriate use of medically important antimicrobial agents in therapeutic practice is a clinical decision that should be based on the experience of the prescribing veterinarian~~,~~ and epidemiological and clinical knowledge and, if available, based on adequate diagnostic procedures. When a group of food-producing animals~~,~~ which may have been exposed to pathogens, they may need to be treated without recourse to a laboratory confirmed diagnosis based on antimicrobial susceptibility testing to prevent the development and spread of clinical disease. Seems that English semantic might need to be edited. Evidence-based therapeutic guidelines, such as species or sector-specific guidelines on the responsible and prudent use of antimicrobial agents, if available; Should be open for discussion either in the Electronic Working Group, or next TFAMR Record the antimicrobial susceptibility testing results; when genomic information, when available; Seems that English semantic needs to be edited To use antimicrobial agents only when necessary, under the supervision of a veterinarian or plant/crop health professional when required, and not as a replacement for good management and farm hygiene practices, or other disease prevention methods; Should be clarified either in the Electronic Working Group or next TFAMR to isolate sick animals and dispose of dead or dying animals or plants/crops promptly under conditions approved by competent authorities; related to food safety? or animal health?	**OIE**

FAO/WHO Coordinating Committee for Africa

Comité FAO/OMS de coordination pour l'Afrique

Comité Coordinador FAO/OMS para África

Proposed draft standard for dried meat

In reply to CL 2019/104-AFRICA

Comments from Burkina Faso, Eritrea, Iraq, Morocco, Zambia and IUFOST

COMMENTS	COUNTRY / OBSERVER NAME
1. CHAMP D'APPLICATION Le Burkina Faso approuve le texte proposé 2. DESCRIPTION Le Burkina Faso approuve le texte proposé 3. FACTEURS ESSENTIELS DE COMPOSITION ET DE QUALITÉ 3.1 Ingrédients essentiels [3.1.1, 3.2, 3.2.1] : Le Burkina Faso approuve le texte proposé 4. [ADDITIFS ALIMENTAIRES] Le Burkina Faso approuve le texte et les tableaux proposés 5. CONTAMINANTS Le Burkina Faso approuve le texte proposé 6. HYGIÈNE Le Burkina Faso approuve le texte proposé 7. CRITÈRES PHYSIQUES ET CHIMIQUES Le Burkina Faso approuve le texte et le tableau proposés 8. EMBALLAGE ET ÉTIQUETAGE [8.1, 8.2] : Le Burkina Faso approuve les textes proposés 9. TRANSPORT ET ENTREPOSAGE Le Burkina Faso approuve le texte proposé 10. MÉTHODES D'ANALYSE ET D'ÉCHANTILLONNAGE Le Burkina Faso approuve le tableau proposé	**Burkina Faso**
The raw meat used for processing the product shall be obtained from animals specified in the Scope above that have passed the ante-mortem and post-mortem inspection by a competent authority.This standard should be adopted at step 5.	**Eritrea**
Scope covers dried meat obtained from cattle, camel, sheep, goat, poultry, donkey, horse and farmed game intended for direct human consumption or for further processing . so what about Islamic Countries ? some of thesis animals shall didn't Halal according to Islamic rules.so we disagree with scope of proposal standard. Regard.	**Iraq**
1. CHAMP D'APPLICATION La norme porte sur la viande séchée de bovins, de chameau, de mouton, de chèvre, de volaille, ~~d'âne,~~ de cheval et de gibier d'élevage destinée à la consommation humaine directe ou à une transformation ultérieure.	**Morocco**

Justificatif : *Il faudrait exclure la viande asine du champs d'application du projet de norme vu que :*

- *La majorité des pays africains ne consomment pas cette viande, d'ailleurs dans la 1ère version du projet de norme aucune des spécialités présentées par les pays n'est d'origine asine ;*
- *Cette espèce pourrait présenter une contrainte si nous voulons proposer à ce que cette norme deviennent internationale*
- *Pour des raisons religieuses, la viande asine est prohibée dans plusieurs pays africains.*

3. FACTEURS ESSENTIELS DE COMPOSITION ET DE QUALITÉ

3.1 Ingrédients essentiels

3.1.1 Viande maigre crue

La viande maigre crue utilisée pour cette transformation doit être d'un seul type de viande et son arôme doit être caractéristique de ce type. Les matières premières utilisées pour préparer ces produits doivent être sans danger pour la consommation humaine et ne comporter ni odeur indésirable, ni corps étranger, ni poussière, ni signe de pourriture.

La viande crue utilisée pour transformer le produit doit provenir d'animaux qui ont été inspectés avant et après abattage par une autorité compétente. Il est aussi recommandé que la viande doit provenir d'animaux abattus conformément aux lignes directrices de la norme du Codex Alimentarius CAC/GL 69/2008, dans des établissements conformes à la réglementation en vigueur en matière d'hygiène des denrées alimentaires. Ladite viande doit provenir d'un abattoir ou atelier de découpe agréé par l'Autorité Compétente du pays et accompagnée d'un certificat sanitaire vétérinaire.

3.~~2~~ 3 Facteurs essentiels de qualité

Les ingrédients doivent être propres, sains et salubre, de bonne qualité et aptes à la consommation humaine. Les ingrédients doivent être manipulés conformément à la dernière édition des Codes d'usages en matière d'hygiène du Codex Alimentarius qui leur correspondent respectivement.

3.~~2~~.~~1~~ Ingrédients facultatifs

Ce sont les agents de salage, à savoir le sel de qualité alimentaire, les épices et condiments et l'huile alimentaire.

4. [ADDITIFS ALIMENTAIRES]

Les additifs alimentaires utilisés dans les produits visés par la présente norme doivent être conformes à la Norme générale pour les additifs alimentaires (CXS 192-1995) .

Justificatif : *Il est préférable de privéligier la proposition ci-dessus car la Norme Générale pour les additifs alimentaires (CXS 192-1995) est sujette à plusieurs révision et on ne peut pas à chaque fois reprendre la présente norme pour faire les adaptations necessaires.* ***Il serait plus judicieux de supprimer les tableaux*** *ci-dessous.*

~~Les antioxidants, conservateurs, stabilisants, régulateurs d'acidité et séquestrants utilisés conformément à la Norme générale pour les additifs alimentaires (CODEX STAN 192-1995) dans la catégorie d'aliments 08.2. (Viande, volaille et gibier compris, transformée, en pièces entières ou en morceaux) sont acceptables dans les aliments conformes à la présente norme.~~

~~Catégorie d'aliments n° 08.2~~	~~Viande, volaille et gibier compris, transformée, en pièces entières ou en morceaux~~	~~Fonction technologique (Tableau un)~~

~~Additif~~	~~SIN~~	~~Limite maximale~~	
~~Hydroxyanisole butylé~~	~~320~~	~~200~~	~~Antioxydant~~
~~Hydroxytoluène butylé~~	~~321~~	~~100~~	~~Antioxydant~~
~~Gallate de propyle~~	~~310~~	~~200~~	~~Antioxydant~~
~~Butylhydroquinone tertiaire~~	~~319~~	~~100~~	~~Antioxydant~~
~~Tocophérols~~	~~307 a, b, c~~	~~500~~	~~Antioxydants~~
~~Diacétate de sodium~~	~~262 ii)~~	~~1 000~~	~~Régulateur d'acidité, conservateur, séquestrant~~

~~Catégorie d'aliments n° 08.2.1~~	~~Viande, volaille et gibier compris, transformée non cuite~~		~~Fonction technologique (Tableau un)~~
~~Additif~~	~~SIN~~	~~Limite maximale~~	
~~Arginate d'éthyle laurique~~	~~243~~	~~200 mg/kg~~	~~Conservateurs~~

~~Catégorie d'aliments n° 08.2.1.1~~	~~Viande, volaille et gibier compris, saumurée (y compris salée)~~		~~Fonction technologique (Tableau un)~~
~~Additif~~	~~SIN~~	~~Limite maximale~~	
~~Sorbates~~	~~200, 202 et 203~~	~~2 000 mg/kg~~	~~Conservateurs~~

~~Catégorie d'aliments n° 08.2.1.2~~	~~Viande, volaille et gibier compris, saumurée (y compris salée) et séchée~~		~~Fonction technologique (Tableau un)~~
~~Additif~~	~~SIN~~	~~Limite maximale~~	

~~Benzoates~~	~~210-213~~	~~1 000 mg/kg~~	~~Antioxidant, conservateurs et séquestrant~~
~~Citrates d'isopropyle~~	~~384~~	~~200 mg/kg~~	~~Antioxidant, conservateurs et séquestrant~~
~~Natamycine (Pimaricine)~~	~~235~~	~~6 mg/kg~~	~~Conservateurs~~
~~Sorbates~~	~~200, 202 et 203~~	~~2 000 mg/kg~~	~~Conservateurs~~

~~**Catégorie d'aliments n° 08.2.2.2**~~	~~Viande, volaille et gibier inclus, traitée thermiquement, en pièces entières ou en morceaux~~		~~**Fonction technologique (Tableau un)**~~
~~ARGINATE D'ÉTHYLE LAURIQUE~~	~~243~~	~~2 00 mg/kg~~	
~~NISINE~~	~~234~~	~~25 mg/kg~~	
~~NITRITES~~	~~249, 250~~	~~25 mg/kg~~	
~~PHOSPHATES~~	~~338; 339(i)-(iii); 340(i)- (iii); 341(i)-(iii); 342(i)- (ii); 343(i)-(iii); 450(i)-(iii),(v)-(vii), (ix); 451(i),(ii); 452(i)-(v); 542~~	~~1320 mg/kg~~	
~~SACCHARINES~~	~~954(i)-(iv)~~	~~500 mg/kg~~	
~~SORBATES~~	~~200, 202, 203~~	~~200 mg/kg~~	
~~STÉAROYL LACTYLATES~~	~~481(i), 482(i)~~	~~2000 mg/kg~~	

~~SUCROESTERS D'ACIDES GRAS~~	~~473~~	~~5000 mg/kg~~	
~~SUCROGLYCÉRIDES~~	~~474~~	~~5000 mg/kg~~	

~~**Catégorie d'aliments n° 08.2.1.3**~~	~~**Viande, volaille et gibier compris, fermentée**~~		~~**Fonction technologique (Tableau un)**~~
~~Sorbates~~	~~200, 202 et 203~~	~~2 000 mg/kg~~	~~Conservateurs~~

L'emploi des substances aromatisantes doit être conforme aux *Directives pour l'emploi des aromatisants* (CAC/GL 66-2008).

5. CONTAMINANTS

4.1 .Les produits visés par la présente norme doivent respecter les limites maximales de la *Norme générale pour les contaminants et les toxines présents dans les produits de consommation humaine et animale* (CXS 193-1995).

4.2 Les produits visés par les dispositions de la présente norme doivent être conformes aux limites maximales de résidus pour les pesticides fixés par la Commission du Codex Alimentarius et les *Limites maximales de résidus de médicaments vétérinaires dans les aliments* indiquées dans le document CXL 2-2015.

A pictorial presentation of the food animal from which the meat is derived should be presented on the label for easy identification by the consumer. Local name should be accompanied by the common name of the animal. E.g Segwapa- 'Kudu' Nevertheless, Zambia agrees to the text in the standard	**Zambia**
Much dried meat produced in Africa is from wild animals that have been killed without any pre- or post-mortem inspection. The draft standard does not make any provision for these products, but they are dried meat and are available on the market in many countries of Africa. This draft standard should take this into account to avoid trade problems between products meeting this standard and similar products that are from other sources of meat.	**IUFOST**

FAO/WHO Coordinating Committee for North America and South West Pacific

Comité FAO/OMS de coordination pour l'Amérique du Nord et le Pacifique Sud-Ouest

Comité Coordinador FAO/OMS para América del Norte y el Pacífico sudoccidental

Proposed draft regional standard for fermented noni fruit juice

In reply to CL 2020/15-NASWP

Comments from Australia, Canada, Cook Islands, Ecuador, Iraq, New Zealand, Solomon Islands, USA and CCTA

COMMENTS	**COUNTRY / OBSERVER NAME**
General Comments or Summary Comments Both Annex A and Annex B assume a competent chemical laboratory technician/chemist familiar with both ISO17025 requirements and principles and techniques associated to Thin Layer Chromatography. Both Annex provide only a concise or abridged method and do not constitute fully documented analytical methods in their own right. On this basis performance of the methods should ideally be undertaken by a trained and assessed operator working in a 17025 compliant laboratory environment and in detailed reference to References 2 & 1 respectively, Potterat O, et al. and/or References 5 & 3 respectively, West BJ, Deng S. Recommend that a statement to this effect preface each Annex. Note in relation to recognition of methods; It is likely there will be jurisdictions/economies wherein there will be a preference to apply contemporary instrumental techniques in place of the technique principles listed in table 10.1 for the determination of ethanol, scopoletin and deacetylasperulosidic acid. For example; gas chromatography (GC) for ethanol and liquid chromatography (LC) for scopoletin and deacetylasperulosidic acid. Such techniques, when well performed, are technically superior to the more expedient techniques provided for in the Standard and could enable quantitative determination of scopoletin and deacetylasperulosidic acid rather than a qualitative presence/absence. **ANNEX A and B** **'1.2** Noni juice is filtered through a 0.45 µm membrane filter and then purified by solid-phase extraction (SPE) with Waters OASISS® extraction cartridges, or similar solid-phase extraction cartridge. [SPE cartridges is first equilibrated with water, followed by methanol. The samples are then loaded onto the cartridge and washed with 5% MeOH, followed by 100% MeOH. The MeOH eluate is retained for TLC analysis.]' Recommend 'Noni juice" be replaced by "Noni juice or fermented noni juice" as follows; Noni juice or fermented noni juice is filtered through a 0.45 µm membrane filter and then purified by solid-phase Recommend a minimum volume or volume range be specified as guidance in relation to the volumes of both 5% and 100% methanol used in the wash and elution steps of the process. Recommend the word "similar" be replaced with "equivalent" as follows; Waters OASISS® extraction cartridges, or similar equivalent solid-phase extraction cartridge. **3.1 THIN LAYER CHROMATOGRAPHY** Recommend include an indicative development time expected Recommend inclusion of images, if possible, for a developed standard and a typical developed plate for a purified fermented noni juice eluate indicating the deacetylasperulosidic acid migration present on the plate	**Australia**

"Canada supports the adoption of the Draft Regional Standard for Fermented Noni Fruit Juice at Step 5".	**Canada**
Cook Islands support step 5 on the proposed draft regional standards for fermented Noni Fruit Juice.	**Cook Islands**
El Ecuador agradece a los países que aportaron en la elaboración de la propuesta de revisión de la "norma regional para el zumo (jugo) de noni fermentado"; en este sentido y luego de haber realizado el análisis técnico correspondiente de dicha norma, el país informa que está de acuerdo con el documento propuesto y apoya el avance del mismo al siguiente trámite.	**Ecuador**
We agree with proposed draft of regional standard without any comments. Regards.	**Iraq**
New Zealand supports this draft of the regional standard for Fermented Noni Fruit Juice. New Zealand appreciates the opportunity to comment on CL 2020/15/OCS-NASWP 01/20 Request for Comments at Step 5 on the proposed draft Regional Standard for Fermented Noni Fruit Juice. We thank Tonga for the strong progress they have made on the draft Standard.	**New Zealand**
General comments were made on the paragraph 3 or section 3.2 for d). Deacetylasperulosidic acid - present and e). Scopoletin - present and paragraph 10 or section 10 for Method of Analysis - Identification of scopoletin and Deacetylasperuloisidic acid. refer to general comments. Scopoletin and Deacetylasperulosidic acid - according to the Proposed Draft Regional Standard for fermented Noni Juice, scopoletin is measured as "PRESENT". This is identification but should it be measured by how much presence in the Noni juice. Also the thin layer chromatography only identifies the sample by presence and absent. However, these are only general comments. On behalf Solomon Islands (CCP), Noni is one of our new products in Solomon Islands needing these requirements and would really support this draft and for further progress to another stage.	**Solomon Islands**
United States would like to provide the following comments in response to CL2020/15-CCNASWP at Step 5 on the proposed draft Regional Standard for Fermented Noni Fruit Juice. Specific Comments The United States believes that the name "Fermented Noni Juice" and "Fermented Noni Fruit Juice," which seem to have been used interchangeably, are not exactly the same. In fact, the agenda for the 20th Session of the CCNASWP meeting (September 2020) referred to it "Fermented Noni Juice" whereas the final report of that meeting used the term "Fermented Noni Fruit Juice." This may not seem like a big change, but we believe the draft standard should revert back to the earlier name: "Fermented Noni Juice" wherever the name appears, for the following reasons: • The typical naming convention for juices does not include the word "fruit" or "vegetable." For example, the common or usual name for apple juice is "apple juice" not "apple fruit juice." The common or usual name for beet juice would be "beet juice" not "beet vegetable juice." If beverages are named as proposed, we question whether consumers will think the product is a fruit juice containing other fruits in addition to fermented noni juice. • Noni does not appear to be something that consumers are accustomed to eating as a fruit in the United States. However, the part of the tree typically used for juice is botanically a fruit. • We did not find any evidence of products sold as noni fruit juice in the United States. We also note that there were not many noni juice labels available for review. Most products were positioned as dietary supplements. In addition, Since Annex C has been removed, we propose amending the following language in the second sentence in section 2.3: "The resultant 100% fermented noni juice is pasteurized or otherwise treated with validated processing methods (e.g., High Pressure Processing) to eliminate pathogens of public health significance".	**USA**

c) Éthanol ~~>~~ < 0,5 pour cent v/v **1.2** Noni juice is filtered through a 0.45 µm membrane filter and then purified by solid-phase extraction (SPE) with Waters ~~OASISS®~~ OASIS® extraction cartridges, or similar solid-phase extraction cartridge. [SPE ~~cartridges~~ cartridge is first equilibrated with water, followed by methanol. The samples are then loaded onto the cartridge and washed with 5% MeOH, followed by 100% MeOH. The MeOH eluate is retained for TLC analysis.] **1.2** Filtrer le jus de noni sur une membrane filtrante de 0,45 µm puis purifier par extraction en phase solide au moyen de cartouches Waters ~~OASISS®~~ OASIS® ou de cartouches d'extraction en phase solide similaires. [Les cartouches d'extraction en phase solide sont d'abord ~~équilibrée~~ équilibrées avec de l'eau, puis du méthanol. Les échantillons sont ensuite chargés sur la cartouche et lavés avec du méthanol à 5 pour cent, puis du méthanol à 100 pour cent. L'éluat méthanolique est conservé pour l'analyse par CCM.] **1.2** El jugo de noni se pasa por un filtro de membrana de 0,45 µm y, a continuación, se purifica por extracción en fase sólida con cartuchos de extracción Waters ~~OASISS®~~ OASIS® o cartuchos de extracción en fase sólida similares. [Los cartuchos de extracción en fase sólida se equilibran con agua y luego metanol. A continuación, las muestras se cargan en el cartucho y se lavan con metanol al 5 %, seguido de metanol al 100 %. El eluido de metanol queda retenido para el análisis por cromatografía en capa fina.] Ponga 5 µL de las soluciones de muestra y de la solución de referencia en una placa de gel de sílice [60 F254] para cromatografía en capa fina, secada previamente a 110 ºC durante 15 minutos en un horno de secado. [Eluya la placa con una fase móvil que contenga una solución ~~más baja~~ de diclorometano, metanol y agua (13:6:1, v/v/v).] Rocíe la placa con una solución de anisaldehído al 2 % y ácido sulfúrico y etanol al 10 % y después caliéntela en el horno a 110 ºC durante un minuto para revelar el color azul. Identifique el ácido deacetilasperulosídico en las muestras comparando los colores y los valores del factor de retención con la referencia.	**CCTA**

Proposed draft regional standard for Kava products for use as a beverage

In reply to CL 2020/16-NASWP

Comments from Australia, Cook Islands, Ecuador, Iraq, New Zealand, Solomon Islands, USA

COMMENTS	COUNTRY / OBSERVER NAME
Australia thanks you for the opportunity to comment on this document. We suggest the Quality criteria specification and Methods of analysis need to be clearer and consistent about where the method details are provided, what the actual 'provision' is, and provide specifications that that provision need to meet as 'Noble kava varieties' . Suggested comments have been provided in the document. **3.5 Quality criteria** "Of Noble kava variety [and with a suitable kavalactones composition[1]];" We suggest - Of Noble kava variety, based on meeting the criteria of 'Absorbance of acetonic extracts' (less or equal to 0.9 Absorbance units) and with a suitable Total kavalactone composition1. **METHODS OF ANALYSIS AND SAMPLING** We suggest the following for Section 8 Methods of Sampling and Analysis for • Provision - Noble kava varieties – with Absorbance of acetonic extracts Comment: We suggest the Provision is specified as in Lebot V, Legendre L (2016) Section 2.3 & 3.1, as the 'UV absorbance of acetonic extracts' with the one refinement in the principle being 'measured at 440 nm', and that the specification for 'Noble Kava Varieties' of 'Absorbance <0.9 Absorbance units' is moved to section 3.5 as above. So the Table in Section 8 could appear as presented below. *Provision:* ~~Noble kava varieties~~ Absorbance of acetonic extracts *Method:* Lebot V, Legendre L (2016), Comparison of kava (Piper methysticum Forst.) varieties by UV absorbance of acetonic extracts and high-performance thin-layer chromatography. Journal of Food Composition and Analysis 48:25-33. http://dx.doi.org/10.1016/j.jfca.2016.01.009 ~~Lebot V, Michalet S, Legendre L. (2019). Kavalactones and flavokavins profiles contribute to quality assessment of kava (Piper methysticumG.Forst.), the traditional beverage of the Pacific. Beverages 2019, 5, 34; https://doi.org/10.3390/beverages5020034~~ Comment: Section 2.1, 2.2 & 2.3. *Principle:* High performance thin layer chromatography ~~and/or~~ UV absorbance of acetonic extracts measured at 440 nm (less or equal to 0.9) comment: Principle to just read: UV absorbance of acetonic extracts measured at 440 nm • Provision - Moisture – Comment: the current reference 'The Fiji Kava Standard 2017. Section 8.1' actually in turn references 'AOAC 925.45'. However this AOAC 925.45 method is for 'Loss on Drying (Moisture) in sugars' which then lists four different techniques for different applications, so the exact method and technique should be specified. To do this would require a select of either 'AOAC 925.45A(Vacuum drying)', or 'AOAC 925.45B	**Australia**

(Drying at atmospheric pressure)', or 'AOAC 925.45C (Drying on Pumice Stone)', or 'AOAC 925.45D (Drying on Quartz Sand)'. In the table below we have used 'AOAC 925.45A(Vacuum drying)' as a conservative choice, as the AOAC 925.45B 3 hours at 100oC may degrade the Kava product. So the Table in Section 8 could appear as presented below. *Method:* ~~. Section 8.1~~ AOAC 925.45A(Vacuum drying) • Provision – Flavokavins – Comment: Please ensure the section '3.5 Quality criteria' and section 8 'Provisions' match. Currently section '3.5 Quality criteria' specified 'Total kavalactones' via the footnote 1. While the 'Provision' in section 8 is for 'Flavokavins' (note, 'Total kavalactones' and 'Flavokavins' are two different groups of compounds in Kava). The High performance thin layer chromatography methodology for 'Total kavalactones' is described by Lebot V, Michalet S, Legendre L. (2019). Section 2.1, 2.2, 2.3, and 3.1. So the Table in Section 8 could appear as presented below. *Method:* ~~Lebot V, Legendre L (2016), Comparison of kava (Piper methysticum Forst.) varieties by UV absorbance of acetonic extracts and high-performance thin-layer chromatography. Journal of Food Composition and Analysis 48:25-33. http://dx.doi.org/10.1016/j.jfca.2016.01.009 and~~ Lebot V, Michalet S, Legendre L. (2019). Kavalactones and flavokavins profiles contribute to quality assessment of kava (Piper methysticumG.Forst.), the traditional beverage of the Pacific. Beverages 2019, 5, 34; Comment: Add to the end of this Section 2.1, 2.2, 2.3, 3.1	
Cook Islands support step 5 on the proposed draft regional standards for kava products for use as a beverage.	**Cook Islands**
Ecuador expresa su agradecimiento por la invitación a presentar sus observaciones sobre el Anteproyecto de norma regional para los productos a base de kava que se utilizan como bebida mezclados con agua; sin embargo el país comunica que en la actualidad no elabora productos a base de kava, razón por la cual no podría aportar con información al respecto.	**Ecuador**
We agree with proposed draft of regional standard without any comments. Regards.	**Iraq**
New Zealand supports this draft of the regional standard for kava products for use as a beverage. The draft Standard provides a clear pathway for determining kava varieties. New Zealand is mindful of the principles and approach we have used to develop kava under the Australia New Zealand Food Standards Code (Standard 2.6.3). The draft Standard is robust and durable, and we see no reason for the Standard not to be agreed at Step 5/8. New Zealand appreciates the opportunity to comment on CL 2020/16/OCS-NASWP 01/20 Request for Comments at Step 5 on the proposed draft Regional Standard for Kava products for use as a beverage when mixed with water. We thank Vanuatu for the strong progress they have made on the draft Standard.	**New Zealand**
Solomon Islands (CCP) has supported the Proposed Draft Regional Standards for Kava. A comment has been made but that will be further reviewed by the review control panel. (3.2 Production and post-harvest handling). On behalf of Solomon Islands (CCP), we support the draft as it is. we submit our comments for your further review. General comments on 3.2 Production and Post-harvest handling Inclusion of Basal stems and sentence structure eg. The roots, rhizomes and/or basal stems are harvested, washed and peeled. when tissues have been exposed to sunlight, they may be sliced, dried or fresh. Dried kava may also be ground into powder.	**Solomon Islands**

The United States has safety concerns about the consumption of kava products for use as a beverage when mixed with water and about compounds present in kava, based upon the most recent scientific studies. The United States does not support final adoption of this standard and recommends that an updated safety assessment be conducted based on peer-reviewed scientific articles and preferably involving more than one author. We are providing a partial list of relevant studies for consideration. These references are not meant to represent a complete assessment of the safety of kava, they are examples of studies that point to safety concerns. Specific Comments: In Section 1, Scope, the draft states, "The standard does not apply to the final kava beverage as such, or kava products used for medicinal purposes, or as ingredients in foods (other than as provided in this Standard) or other tradable product, or for any other purposes." The United States believes that the statement "other than as provided in this Standard," should be removed. This standard does not provide for use as an ingredient in food. Section 3.5, Quality criteria, mentions that "Kava products shall be: of known Noble variety [and with a suitable kavalactones composition]." Following that statement there is a footnote that lists the total amount (in g/kg) of kavalactones in fresh and dry products. However, safe levels of kavalactones have not been determined, and the United States is uncomfortable with establishing levels, even in the context of quality. Section 8, Methods of Analysis and Sampling, The United States has remaining concerns with the methods listed for analyzing kavalactones. The analytical methods in the current draft were updated to include another citation from the same authors. However, the addition of another citation by the same authors of the original citation does not change our concerns. The United States prefers validated methods, particularly when a method is being used to determine compounds with safety concerns. Additionally, there is a method listed for flavokavins but flavokavins are not discussed in the body of the standard. Kava References 1. Anke, J., and Ramzan, I. 2004 Kava hepatotoxicity: are we any closer to the truth? Planta Med. 70:193–196. 2. Becker et al. 2019 Liver transplantation and the use of KAVA: Case report. Phytomedicine 56:21-26. 3. Behl et al. 2011 Liver toxicity and carcinogenicity in F344/N rats and B6C3F1 mice exposed to Kava Kava. Food and Chemical Toxicology 49: 2820–2829. 4. Brown et al. 2007 Traditional kava beverage consumption and liver function tests in a predominantly Tongan population in Hawaii. Clinical Tox. 45, 549–556. 5. Brown-Joel et al. 2018 Inflammatory sebotropic reaction associated with kava kava ingestion. JAAD Case Rep. 4(5): 437–439. 6. Bodkin R et al. 2012 Rhabdomyolysis associated with kava ingestion. Am J Emerg Med. 30(4): 635.e1-3 7. Cairney S, Maruff P, Clough AR, Collie A, Currie J, Currie BJ. 2003a. Saccade and cognitive impairment associated with kava intoxication. Hum Psychopharmacol. 18:525-33. 8. Cairney et al. 2003 Saccade and cognitive function in chronic kava users. Neuropsychopharmacology (2003) 28, 389–396. 9. CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (US FOOD AND DRUG ADMINISTRATION) Consumer advisory: Kava-containing dietary supplements may be associated with severe liver injury (document issued March 25, 2002). http://www.cfsan.fda.gov/~dms/aadskvahtml. 10. Hepatic Toxicity Possibly Associated with Kava-Containing Products --- United States, Germany, and Switzerland, 1999—2002 https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5147a1.htm 11. Christl, SU et al. 2009 Toxic Hepatitis after consumption of traditional kava preparation. Journal of Travel Medicine, Volume 16, Issue 1, 55–56. 12. Chua et al. 2016 Kavain, the major constituent of the anxiolytic kava extract, potentiates GABAA receptors: functional characteristics and molecular mechanism. PLoS One. 11(6): e0157700. 13. Clayton NP, Yoshizawa K, Kissling GE, Burka LT, Chan PC, Nyska A. 2007. Immunohistochemical analysis of expressions of hepatic cytochrome P450 in F344 rats following oral treatment with kava extract. Exp Toxicol Pathol. 58:223-36. 14. Clouatre, D.L. (2004) Kava kava: examining new reports of toxicity. Toxicol. Lett. 150 85–96.	**USA**

15. Clough AR, Bailie RS & Currie B (2003) Liver function test abnormalities in users of aqueous Kava extracts, Journal of Toxicology: Clinical Toxicology, 41:6, 821-829.
16. Clough AR, Jacups SP, Wang Z, et al. 2003 Health effects of kava use in an eastern Arnhem Land community. Intern Med J 33: 336-340.
17. Côté CS, Kor C, Cohen J, Auclair K. 2004 Composition and biological activity of traditional and commercial kava extracts. Biochem Biophys Res Commun 322, Issue 1, 147-152.
18. Coulter D., et al., 2007. Assessment of the risk of hepatotoxicity with kava products. World Health Organization. Accessed Feb 18, 2020. https://apps.who.int/iris/bitstream/handle/10665/43630/9789241595261_eng.pd
19. Denham A., McIntyre M., Whitehouse J. (2002) Kava-the unfolding story: report on a work-in-progress, J. Altern. Complement. Med. 8, 237–263.
20. Donadio V, Bonsi P, Zele I, Monari L, Liguori R, Vetrugno R, Albani F, Montagna P. 2000 Myoglobinuria after ingestion of extracts of guarana, Ginkgo biloba and kava. Neurol Sci. 21:124.
21. Duffield AM, et al. (1989) Identification of some human urinary metabolites of the intoxicating beverage kava. J. Chromatogr. 475:273-281.
22. Duffield PH, Jamieson DD, Duffield AM.: (1989) Effect of aqueous and lipid-soluble extracts of kava on the conditioned avoidance response in rats. Arch. Int. Pharmacodyn. Ther. 301:81-90.
23. Escher, M., et al. (2001) Hepatitis associated with Kava, a herbal remedy for anxiety, BMJ 322:139.
24. FDA. 2002. Letter to health care professionals: FDA issues consumer advisory that Kava products may be associated with severe liver injuries. http://www.cfsan.fda.gov/~dms/ds-ltr29html.
25. Fu PP, Xia Q, Guo L, Yu H, Chan PC. 2008 Toxicity of kava kava. J Environ Sci Health. Part C Environ Carcinog Ecotoxicol Rev. 26(1):89-112.
26. Guo L, Li Q, Xia Q, Dial S, Chan PC, Fu P. 2009 Analysis of gene expression changes of drug metabolizing enzymes in the livers of F344 rats following oral treatment with kava extract. Food Chem Toxicol. 47:433-442.
27. Guo et al. 2010. Gene expression profiling in male B6C3F1 mouse livers exposed to kava identifies--changes in drug metabolizing genes and potential mechanisms linked to kava toxicity. Food Chem. Tox. 48:686-696.
28. Gurley B J, Gardner S F, Hubbard M A, Williams D K, Gentry W B, Khan I A, Shah A. 2005. In vivo effects of goldenseal, kava kava, black cohosh, and valerian on human cytochrome P450 1A2, 2D6, 2E1, and 3A4/5 phenotypes. Clin Pharmacol Ther. 77, 415-426.
29. Guro-Razuman S., Anand P., Hu Q., Mir R. 1999 Dermatomyositis-like illness following kava-kava ingestion. J Clin Rheumatol. 5:342–345.
30. Gow P.J., Connelly N.J., Hill R.L., Crowley P., Angus P.W. (2003) Fatal fulminant hepatic failure induced by a natural therapy containing kava, Med. J. Aust. 178: 442–443.
31. Hannam S et al. 2014 Kava dermopathy in Fiji: an acquired ichthyosis? Int J Dermatol. 53(12):1490-1494.
32. He XG, Lin LZ, Lian LZ. 1997. Electrospray high performance liquid chromatography mass spectrometry in phytochemical analysis of kava (Piper methysticum) extract. Planta Med. 63(1):70–4.
33. Humberston CL1, Akhtar J, Krenzelok EP. 2003: Acute hepatitis induced by kava kava. J. Toxicol. Clin. Toxicol. 41(2):109-113.
34. Huynh J.C., Asgari M.M., Moore M.M. 2014 Sebotropic eruption associated with use of oral kava kava supplement. Clin Exp Dermatol. 39:816–818.
35. Jamieson DD, Duffield PH. 1990. Positive interaction of ethanol and kava resin in mice. Clinical and Experimental Pharmacology and Physiology 17:509–14.
36. Jhoo JW, Ang CY, Heinze TM, Deck J, Schnackenberg LK, Beger RD, Dragull K, Tang CS. 2007 Identification of C-glycoside flavonoids as potential mutagenic compounds in kava. J Food Sci. 72:C120-5.
37. Keledjian J, Duffield PH, Jamieson DD, Lidgard RO, Duffield AM. 1988 Uptake into mouse brain of four compounds present in the psychoactive beverage kava. J Pharm Sci. 77(12):1003-6.
38. Kraft et al. 2001. Fulminant liver failure after administration of the herbal antidepressant Kava-Kava. Deutsche Medizinische Wochenschrift (1946), 31 Aug 2001, 126(36):970-972 German with English translation on the same page.
39. Lim ST, Dragull K, Tang CS, Bittenbender HC, Efird JT, Nerurkar PV. 2007 Effects of kava alkaloid, pipermethystine, and

kavalactones on oxidative stress and cytochrome P450 in F-344 rats. Toxicol Sci. 97:214-221.
40. Mathews JD, Riley MD, Fejo L, Munoz E, Milns NR, Gardner ID, Powers JR, Ganygulpa E, Gununuwawuy BJ. 1988. Effects of the heavy usage of kava on physical health: summary of a pilot survey in an aboriginal community. Med. J. Aust. 148:548-555.
41. Mathews JM, Etheridge AS, Black SR. 2002. Inhibition of human cytochrome P450 activities by kava extract and kavalactones. Drug Metab Dispos. 30:1153-1157.
42. Mathews JM, Etheridge AS, Valentine JL, Black SR, Coleman DP, Patel P, So J, Burka LT. 2005. Pharmacokinetics and disposition of the kavalactone kawain: interaction with kava extract and kavalactones in vivo and in vitro. Drug Metab Dispos. 33:1555-1563.
43. Meseguer E, et al. 2002 Life-threatening parkinsonism induced by kava-kava. Mov Disord. 2002 17(1):195-196.
44. Narayanapillai et al., 2014 Flavokawains A and B in Kava, not dihydromethysticin, potentiate acetaminophen-induced hepatotoxicity in C57BL/6 Mice. Chem. Res. Toxicol. 27, 1871-1876.
45. Parker JA 2014 Hepatitis A outbreak associated with kava drinking. Commun Dis Intell Q Rep. 38(1): E26-28.
46. Patra KK, Coffey CE 2004 Implications of Herbal Alternative Medicine for Electroconvulsive Therapy J ECT
47. 20 (3), 186-194.
48. Poolsup N, Li Wan Po A, Knight TL. 2000. Pharmacogenetics and psychopharmacotherapy. J Clin Pharm Ther. 25:197-220.
49. Raduege KM et al. 2004 Anesthetic considerations of the herbal, kava J Clinical Anesthesia Vol 16, Issue 4, 305-311.
50. Rzepecki AK, Wald J, Amin B, Leung E, Choi E, Balagula Y. 2018 Kava-induced acute cutaneous toxicity: An increasingly recognized characteristic clinicohistologic pattern. JAAD Case Rep. 10;4(10):1037-1038.
51. Russmann S, Lauterburg BH, Helbling A. 2001. Kava hepatotoxicity. Ann Intern Med. Jul 3;135(1):68-69.
52. Russmann S et al. 2003 Hepatic injury due to traditional aqueous extracts of kava root in New Caledonia. Eur J Gastroenterol Hepatol. 15:1033-1036.
53. Russmann S, Lauterburg BH, Barguil Y, Choblet E, Cabalion P, Rentsch K, Wenk M. 2005. Traditional aqueous kava extracts inhibit cytochrome P450 1A2 in humans: Protective effect against environmental carcinogens? Clin Pharmacol Ther. 77:453-454.
54. Rychetnic L, Madrano CM. 2011 The health and social effects of drinking water-based infusions of kava: A review of the evidence. Drug Alcohol Rev 30: 74–83.
55. Sarris J 2013 Kava in the treatment of generalized anxiety disorder: a double-blind, randomized, placebo-controlled study. J Clin Psychopharmacol 33: 643-648.
56. Sarris J, Stough C, Teschke R, Wahid ZT, Bousman CA, Murray G, Savage KM, Mouatt P, Ng C, Schweitzer I. 2013 Kava for the treatment of generalized anxiety disorder RCT: analysis of adverse reactions, liver function, addiction, and sexual effects. Phytother Res. 27(11):1723-8.
57. Sarris J et al. 2020 Kava for generalised anxiety disorder: A 16-week double-blind, randomised, placebo-controlled study. Aust N Z J Psychiatry. Mar;54(3):288-297.
58. Schelosky L, Raffauf C, Jendroska K, Poewe W 1995 Kava and dopamine antagonism. J Neurol Neurosurg Psychiatry, 58 (5), 639-640.
59. Schmidt P, Boehncke WH 2000. Delayed-type hypersensitivity reaction to kava-kava extract. Contact Dermatitis 42:363-364.
60. Schmidt M, Nahrstedt A, 2002. Is kava hepatotoxic? Available from: (www.uni- muenster.de/Chemie.pb/Kava/pdf/Review.pdf).
61. Shimoda LM, et al. 2012 Pacific island 'Awa (Kava) extracts, but not isolated kavalactones, promote proinflammatory responses in model mast cells. Phytother Res. 26(12):1934-41.
62. Singh YN. 1992 Kava: an overview. J Ethnopharmacol. 37:13-45.
63. Singh, Y. N. and Devkota, A. K. (2003). Aqueous kava extracts do not affect liver function tests in rats. Planta Med. 69, 496–499.
64. Singh YN. 2005. Potential for interaction of kava and St. John's wort with drugs. J Ethnopharmacol.100:108–13.
65. Smith K, Leiras C 2018 The effectiveness and safety of Kava Kava for treating anxiety symptoms: A systematic review and analysis of randomized clinical trials. Complementary Therapies in Clinical Practice 33: 107–117.
66. Sorrentino, L., Capasso, A., Schmidt, M., 2006. Safety of ethanolic kava extract: results of a study of chronic toxicity in rats. Phytomedicine 13, 542–549.
67. Stickel F, et al 2003. Hepatitis induced by Kava (Piper methysticum rhizoma). J. Hepatol. 39(1):62-67.
68. Tang J, Dunlop RA, Rowe A, Rodgers KJ, Ramzan I. 2011 Kavalactones Yangonin and Methysticin induce apoptosis in human

hepatocytes (HepG2) in vitro. Phytother Res. 25:417-23.
69. Tarbah F, Mahler H, Kardel B, Weinmann W, Hafner D, Daldrup T. 2003 Kinetics of kavain and its metabolites after oral application. J Chromatogr B Analyt Technol Biomed Life Sci. Jun 5;789(1):115-130.
70. Teschke R., et al. 2008 Kava hepatotoxicity: a clinical survey and critical analysis of 26 suspected cases. Eur J Gastroenterol Hepatol 20:1182–1193.
71. Wainiqolo I., et al. 2015 Is driving under the influence of kava associated with motor vehicle crashes? A systematic review of the epidemiological literature. Aust N Z J Public Health. 39(5):495-499.
72. Wainiqolo I., et al. 2016 Driving following Kava Use and Road Traffic Injuries: A Population-Based Case-Control Study in Fiji (TRIP 14). PLoS One.11(3): e0149719.
73. Wanwimolruk S, Bhawan S, Coville PF, Chalcroft SC. 1998 Genetic polymorphism of debrisoquine (CYP2D6) and proguanil (CYP2C19) in South Pacific Polynesian populations. Eur J Clin Pharmacol. 54:431-435.
74. Whittaker, P., Clarke, J.J., San, R.H., Betz, J.M., Seifried, H.E., de Jager, L.S., Dunkel, V.C., 2008. Evaluation of commercial Kava extracts and Kavalactone standards for mutagenicity and toxicity using the mammalian cell gene mutation assay in L5178Y mouse lymphoma cells. Food Chem. Toxicol. 46, 168–174.
75. Xia Q., et al. 2012 Phototoxicity of kava - formation of reactive oxygen species leading to lipid peroxidation and DNA damage. Am J Chin Med. 40(6):1271-88.
76. Yamashita H, et al. 2016 Chemical exacerbation of light-induced retinal degeneration in F344/N rats in National Toxicology Program rodent bioassays. Toxicologic Pathol. 44(6):892-903.
77. Yamashita H, et al. 2018 Reduced disc shedding and phagocytosis of photoreceptor outer segment contributes to Kava Kava Extract-induced retinal degeneration in F344/N Rats. Toxicol Pathol. 46(5):564-573.
78. Yamazaki Y, Hashida H, Arita A, Hamaguchi K, Shimura F. 2008. High dose of commercial products of kava (Piper methysticum) markedly enhanced hepatic cytochrome P450 1A1 mRNA expression with liver enlargement in rats. Food Chem Toxicol. 46:3732-3738.
79. Yang, X.; Salminen, W.F. 2011 Kava extract, an herbal alternative for anxiety relief, potentiates
80. acetaminophen-induced cytotoxicity in rat hepatic cells. Phytomedicine 18, 592–600.
81. Zhou, P., Gross, S., Liu, J.-H., Yu, B.-Y., Feng, L.-L., Nolta, J., Sharma, V., Piwnica-Worms, D., Qiu, S. X. 2010 Flavokawain B, the hepatotoxic constituent from kava root, induces GSH-sensitive oxidative stress through modulation of IKK/NF-κB and MAPK signaling pathways. FASEB J. 24(12): 4722–4732.
82. Zou L, Harkey MR, Henderson GL. 2002. Effects of herbal components on cDNA-expressed cytochrome P450 enzyme catalytic activity. Life Sci. 71:1579-89.
83. Zou L, Henderson GL, Harkey MR, Sakai Y, Li A, (2004) Effects of kava (Kava-kava, Awa, Yagona, Piper methysticum) on cDNA-expressed cytochrome P450 enzymes and human cryopreserved hepatocytes. Phytomedicine 11; 285–294.
84. Zou L, Harkey MR, Henderson GL. 2005 Synthesis, in vitro, reactivity, and identification of 6-phenyl-3-hexen-2-one in human urine after kava-kava (Piper methysticum) ingestion. Planta Med. 71:142-6.