CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 5 **CX/NFSDU 18/40/6-Add.2**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Fortieth Session

Berlin, Germany
26 – 30 November 2018

PROPOSED DRAFT GUIDELINE FOR READY-TO-USE THERAPEUTIC FOODS

Comments of Canada and United States of America

CANADA

1 General Comments:

Canada thanks South Africa, Senegal and Uganda for chairing the eWG and preparing the proposed draft guidelines for the use Ready-to-Use Therapeutic Foods (RUTF) in the management of severe acute malnutrition (SAM), for consideration by the Committee.

Canada generally supports the 22 recommendations and has provided comments for some of the recommendations in the following text.

Editorial Comments:

Canada suggests revising the title in the Proposed Draft Guideline for section 9 from "Manufacturing Practices and Good Hygiene Practices" to "**Good** Manufacturing Practices and Good Hygiene Practices"

2 Specific Comments:

Canada's Comments on Sections not Captured by the Recommendations:

Canada proposes the following minor edit to the text for the Contaminants Section of the draft proposed guideline:

[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* (CODEX STAN 193-1995), *Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for Residues of Veterinary Drugs in Foods* (CAC/MRL 2-2015) and Codex Maximum Residue Limits for Pesticides.

Canada's Comments on the Recommendations

Recommendation 1:

That CCNFSDU agree to the following text for the Preamble of the Guidelines for RUTF:

Children affected by severe acute malnutrition (SAM) need safe, palatable foods with a high energy content and adequate amounts of vitamins, minerals and other nutrients. Children with SAM need efficacious and timely treatment and RUTF is part of the care. RUTF are primarily intended for children with uncomplicated SAM from 6-59 months. Although RUTF may be given to other age groups with various forms of malnutrition at the implementation level, the primary focus for these guidelines is children with SAM from 6-59 months. Since RUTF are prescribed according to weight, National Authorities may decide to include the provision of RUTF in their national protocols for use by other age groups.

These guidelines provide guidance for the production and labelling of RUTF. The guidelines are intended to facilitate the harmonization of requirements for RUTF at the international level and may provide assistance to governments wishing to establish national regulations. The guidelines are also intended for use as an instrument designed to avoid or remove difficulties which may be created by diverging legal, administrative and technical approaches to RUTF and by varying definitions and nutrient compositions of RUTF. These guidelines should be used in accordance with technical recommendations of the relevant evidence and related Codex texts/documents by WHO, UNICEF and WFP[1]. Governments and other users should ensure adequate provisions are made for competent technical experts for the appropriate use of these guidelines.

1)

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;

2. 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;

3. World Health Organisation. 2013. Guideline: *Updates on the management of severe acute malnutrition in infants and children,* Geneva: World Health Organization;

4. World Health Organisation. 2003. *Global Strategy for Infant and Young Child Feeding*, Geneva: World Health Organization;

5. 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;

6. *Code of Ethics for International Trade in Food including Concessional and Food Aid Transactions* (CXC 20-1979);

7. 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.

Canada's Comments: Canada generally supports the proposed text in Recommendation 1; however, Canada questions the need for the reference to the *International code of marketing of breast-milk substitutes* in the footnote. Canada notes that RUTF are not intended to substitute breast-milk, and are not available at retail; therefore referencing this document is not necessary. Furthermore, the statement indicating that RUTF are not breastmilk substitutes and shall not be presented as such that is required on the label sufficiently addresses this concern.

Recommendation 2:

That CCNFSDU agree to the following texts for the Vitamins and Minerals section

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 metabolisable base. The non-metabolizable 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 vitamin and 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 and scientific evidence showing adequate stability and bioavailability in the finished product.]

Canada's Comments: Canada supports the addition of the proposed text in the closed brackets in Recommendation 2 to ensure that the chemical forms of the added vitamins and minerals are stable and bioavailable in the finished product.

Recommendation 3:

That CCNFSDU agree to the following texts for the Available Carbohydrates section

Available Carbohydrates[2]

The palatability of the RUTF can be increased by the addition of available carbohydrates. Available 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*.

2)Sucrose, plant starch, maltodextrin, should be the preferred carbohydrates in RUTF. Fructose, glucose and corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinized starches ~~[gluten-free]~~ by nature may be added. Any carbohydrate added for sweetness should be used sparingly.

Canada's Comments: Canada generally supports the text proposed in Recommendation 3. However, Canada notes the regulatory challenges associated with the enforcement of restricting carbohydrates added for sweetness, in addition to the need to add carbohydrate for sweetness in order to increase palatability of these products and to contribute to the high caloric requirements of these products.

Recommendation 4:

It is recommended that:

4.1 CCNFSDU take note and agree with the proposed list of food additives **(Table 1)** and their technological justification that are currently used in RUTF.

4.2 CCNFSDU agree that the electronic working group recommend a proposed list of food additives to the Committee for consideration on their technological justification.

Canada's Comments: Canada does not agree with Recommendation 4, although Canada has no objection to the step-wise approach in determining what food additives are appropriate for use in RUTFs, as suggested in the proposed approach on page 7 of the Discussion paper. Canada notes that step B of the proposed approach as per the discussion paper has not been completed, and therefore it is not yet appropriate to move to step C, as suggested in Recommendation 4.2. Furthermore, Canada notes that it must also be determined what Food Category applies to RUTF in the *General Standard for Food Additives* (CXS 192-1995).

Recommendation 5:

That CCNFSDU agree to the proposed text which reference Section 3 of the CXS 180-1991 on the use of other matrices in RUTF formulations as follows:

The Use of other Matrices in RUTF Formulation

RUTF may be manufactured with formulations different from the one laid down in these guidelines provided that these formulations comply with Section 3 of the *Standard for Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991).

Canada's Comments: Canada supports Recommendation 5; however, Canada notes that reference to CXS 180-1991 in the guideline may not be appropriate. Further discussion is required to determine how RUTF should be categorized, i.e. as Foods for Special Medical Purposes, Foods for Special Dietary Use, etc. Canada therefore proposes the addition of the text from Section 3 of the *Standard for Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991) directly into the proposed draft guideline:

The Use of other Matrices in RUTF Formulation

RUTF may be manufactured with formulations different from the one laid down in these guidelines provided that these formulations **are based on sound medical and nutritional purposes and their use has been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of ther persons for whom they are intended.**

Recommendation 6:

That CCNFSDU agree to the proposed text on energy and the energy values as follows:

Energy

Draft Text

The energy density of the formulated RUTF should be between 5.2 - to 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.

Energy Values

Unit	Minimum	Maximum	GUL
Kcal/100g	520	550	-

Canada's Comments: Canada supports the draft text for energy. Canada supports retaining the proposed energy values, as per the Joint Statement on Community-Based Management of Severe Acute Malnutrition 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, until there is sufficient evidence to revise the values for children with SAM.

Recommendation 7:

That CCNFSDU agree not to set the minimum and maximum/GUL values for carbohydrates.

Canada's Comments: Canada supports the proposal not to set the minimum and maximum/GUL values for carbohydrates based on the need for flexibility in order to meet the lipid and protein specifications for RUTF and the use of carbohydrates to achieve the final energy density requirements.

Recommendation 8:

That CCNFSDU agree to the proposed protein values in RUTF.

Protein should provide 10%-12% of the total energy.

Unit	Minimum	Maximum	GUL
g/100g	12.8	16.2	-
g/100kcal	2.3	3.1	-

Canada's Comments: Canada supports the proposed protein values in Recommendation 8, which are consistent with the Joint Statement on Community-Based Management of Severe Acute Malnutrition 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.

Recommendation 9:

That CCNFSDU agree to keeping the statement "at least 50% of protein is provided by milk products" in square brackets until there is further guidance from FAO on determining protein quality using PDCAAS.

["at least 50% of protein is provided by milk products"]

Canada's Comments: Canada supports recommendation 9.

Recommendation 10:

That CCNFSDU agree to the proposed text on fats/lipids and the proposed minimum and maximum fats/lipids values as follows:

Lipids should provide 45% to 60% of the total energy.

The level of linoleic acid should not be less than 333 mg per 100 kcal. The level of alpha-linolenic acid should not be less than 33mg/100kcal. The level of linoleic acid should ensure a ratio between linoleic acid and alpha-linolenic acid of between 5:1 and 15:1.]

Unit	Minimum	Maximum	GUL
g/100g	26	37	-
g/100kcal	5	6.7	-

Canada's Comments: Canada supports the minimum and maximum energy contribution from lipids as per recommendation 10, however Canada questions the additional text regarding essential fatty acids in recommendation 10, noting that they are addressed more specifically in Recommendation11.

Recommendation 11:

That CCNFSDU agrees to retaining the linoleic acid and alpha-linolenic acid values as stipulated in the

2007 Joint Statement in the current RUTF nutritional composition as follows:

Essential Fatty acids values

Linoleic Acid = 3-10% of total energy

The level of linoleic acid should not be less than 333 mg per 100 kcal

Alpha- linolenic acid = 0.3-2.5% of total energy

The level of alpha-linolenic acid should not be less than 33 mg per 100 kcal

Canada's Comments: Canada supports Recommendation 11.

Recommendation 12:

That CCNFSDU agree to the minimum, maximum and associated footnote for vitamin A as follows:

Unit	Minimum	Maximum	GUL
mg RE/100g	0.8	[1.1] OR [1.2]	-
mg/ RE/100kcal	0.15	[0.2] OR [0.22]	-
[2]µg RE/100kcal	150	[200] OR [220]	-

[2] 1µg RE = 3.33 IU Vitamin A = 1 µg trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

Canada's Comments: Canada prefers the maximum of 1.1 mg RE/ 100 g, as this proposed value aligns with the maximum Vitamin A level recommended in the Joint Statement on Community-Based Management of Severe Acute Malnutrition 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. However, Canada is not opposed to the higher maximum values, provided the rationale for the increased maximum is based on sound scientific advice provided by recognized authoritative scientific bodies.

Recommendation 13:

That CCNFSDU agree to the minimum, maximum/GUL and associated footnote for vitamin D as follows:

Unit	Minimum	Maximum	GUL
[3] µg/100 g	15	[20] OR [22]	[30]
[3] µg100 kcal	2.7	[3.6] OR [4]	-

[3] 1 µg cholecalciferol = 40 IU vitamin D

Canada's Comments: Canada prefers the maximum values of 20 µg/100 g Vitamin D and 3.6 µg100 kcals, as these values align with the maximum recommended Vitamin D levels in the Joint Statement on Community-Based Management of Severe Acute Malnutrition 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. However, Canada is not opposed to the higher Vitamin D maximum levels, provided the rationale is based on sound scientific advice provided by recognized authoritative scientific bodies.

Recommendation 14:

That CCNFSDU agree to the minimum and associated footnote for vitamin E as follows:

Unit	Minimum	Maximum	GUL
[4] mg/100 g	20	-	-
[4] mg α-TE /100 kcal	4	-	-

[4] 1 mg α-tocopherol = 1 mg RRR-α-tocopherol (d-α-tocopherol)

[4] 1 mg α-tocopherol =2.00 mg all-rac-α-tocopherol (dl- α-tocopherol)

Canada's Comments: Canada supports Recommendation 14.

Recommendation 15:

That CCNFSDU agree to the following recommendations for vitamin K, vitamin B1, vitamin B2, vitamin C, vitamin B6, vitamin B12, folic acid, niacin, pantothenic acid and biotin for RUTF as follows (table not included).

Canada's Comments: Canada supports the proposed nutrient values in Recommendation 15.

Recommendation 16:

That CCNFSDU agree to the following recommendations for sodium, potassium, calcium, phosphorus, magnesium, iron, zinc, copper, selenium and iodine for RUTF as follows:

(table not included)

Canada's Comments: Canada supports the proposed nutrient values in Recommendation 16.

Recommendation 17:

That CCNFSDU consider that the current formulation of RUTF, as well as the proposed nutrients as stipulated in the 2007 Joint Statement be the basis for RUTF formulation, unless there is scientific evidence on any additional nutrients that has been demonstrated to be safe and beneficial in meeting the nutritional requirements of SAM children.

Canada's Comments: Canada supports Recommendation 17.

Recommendation 18:

That CCNFSDU agree to the proposed text of " Processing Technologies" section of the Guidelines as follows:

In addition to the practices described below, Good Hygiene Practices (General principles of food hygiene CXC 1-1969) should be implemented to avoid cross contamination during the packing and storage of raw materials.

1. Preliminary Treatment of Raw Materials

Cereals, legumes, pulses and oilseeds should first be treated to obtain wholesome and clean raw materials of good quality. Such treatments include, but are not limited to:

- **Cleaning or washing**: to eliminate dirt, damaged grains, foreign grains and noxious seeds, insects and insect excreta and any adhering material.
- **Dehulling**: when necessary, pulses, legumes, oilseeds and certain cereals such as oats, barley, sorghum, millet and teff may be dehulled as completely as is feasible to reduce the fibre content to acceptable levels and to decrease, and/or if possible, to eliminate phytates, tannins and other phenolic materials, trypsin and chymotrypsin inhibitors which can lower the protein digestibility and amino acid bioavailability and mineral absorption**.**
- **Degermination:** where necessary and appropriate, degermination of wheat, corn, soy and other crops should be considered in order to reduce the phytate content.

2.Milling

- Milling or grinding of suitable raw materials should be carried out in such a way as to minimize the loss of nutritional value and to avoid undesirable changes in the technological properties of the ingredients.
- Dry raw materials may be milled together, if technologically feasible, or mixed after milling or grinding.
- Formulations containing milled cereals, legumes, pulses and/or oilseeds that have not been otherwise processed require adequate boiling to gelatinize the starch portions and/or eliminate anti-nutritional factors present in cereals, legumes and pulses. Boiling improves the digestibility and absorption of nutrients.
- The bulkiness of foods from food formulations containing dry ingredients obtained by milling of the raw materials can be reduced by adding, during the formulation, adequate amounts of enzymes such as alpha-amylase which, during the slow heating to boiling, predigest partially the

starch and reduce the amount of water needed for the preparation of the food.

3.Toasting

- Toasting (dry heating) enhances the flavour and the taste of the food through dextrinization of starch. It also improves digestibility and contributes to reducing the bulkiness of the formulated food. Moreover, it reduces microorganisms and enzyme activity and destroys insects, thus improving keeping qualities.
- Protein damage due to the Maillard reaction may occur in the presence of reducing carbohydrates. The toasting process should therefore be carefully controlled.
- Pulses as well as oilseeds such as soya beans, groundnuts and sesame seeds can be toasted as whole grains directly or after soaking.
- Toasted raw materials can be milled or ground for use as ingredients.
- [The use of appropriate enzymes may be considered to decrease anti-nutrients in ingredients.]

4. Sprouting, Malting and Fermentation

- Cereals and pulses can be induced to germinate by soaking or humidifying. It is necessary, however, to ensure that growth of mycotoxin producing microorganisms does not occur. The action of natural amylases contained in the grains results in the pre-digestion of the starchy portion of the grain (dextrinization) thus reducing the bulk of the food when prepared for feeding and, ultimately, increasing the nutrient density of the food. Sprouting**,** malting and fermentation can induce hydrolysis of phytates and decrease its inhibitory effect on mineral absorption, and may improve B vitamin content.
- During the germination process, the seed coat of the grain splits and can be removed by washing. The malted raw material is milled or ground after drying.

5. Other Processing Technologies

Whenever feasible, RUTF 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 or their raw materials include both thermal (e.g. roasting, steam treatment followed by a drying step) and non-thermal (e.g. antimicrobial fumigation) control measures. *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008) and *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CXG 63-2007) should be adhered to.

Canada's Comments: Canada supports the proposed text in Recommendation 18.

Recommendation 19:

- That CCNFSDU agree to the proposed draft text for "good manufacturing practices and good hygiene practices" section as follows:
- It is recommended that the products covered by the provisions of this 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).
- 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.

Canada's Comments: Canada supports Recommendation 19.

Recommendation 20:

That CCNFSDU agrees to the proposed text for "the methods of analysis and sampling" section of the guidelines as follows:

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), *General Standard for Contaminants*

and Toxins in Food and Feed (CXS 193-1995), *The Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997), *Code of Hygienic Practice for Low Moisture Foods* (CXC 75-2015), and other relevant Codex Alimentarius texts. When needed, specific methods of analysis should be developed in accordance with appropriate *Guidelines on Measurement Uncertainty* (CXG 54-2004), *Protocol for the Design, Conduct and Interpretation of Method Performance Studies* (CXG 64-1995), and Harmonized IUPAC.

Canada's Comments: Canada supports Recommendation 20.

Recommendation 21:

That CCNFSDU agrees to the proposed text for "packaging" section of the guidelines as follows:

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.

Canada's Comments: Canada supports Recommendation 21.

Recommendation 22:

That CCNFSDU agree with the proposed draft text for the "labelling" section of the guidelines as follows:

It is recommended that the labelling of RUTF for children from 6 to 59 months be in accordance with the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-991), ~~*Codex General Standard for the Labelling of Pre-packaged Foods* (CODEX STAN 1-1985)~~, the *General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses* (CXS 146-1985), ~~*Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997)~~ and *Guidelines on Nutrition Labelling* (CXG 2- 1985).

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. 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.

List of Ingredients

The list of ingredients shall be declared in accordance with Section 4.2 of the *Codex General Standard for the Labelling of Prepackaged Foods* (CXS 1 -1985).

Additional Mandatory Labelling Requirements

The following statements shall appear on the label of RUTF:

- "USE UNDER MEDICAL SUPERVISION" shall appear on the label in bold letters in an area separated from the written, printed, or graphic information.
- "For the dietary management of severe acute malnutrition" shall appear on the label.
- A prominent warning statement consisting of an explanatory statement in bold letters indicating that RUTF are for special medical purposes and may pose a health hazard when consumed by individuals who do not have the disease(s), disorder(s) or medical condition(s) for which the food is intended.
- The product is not to be used for parenteral, rectal or Nasogastric Tube (NG tube) administration.
- A statement indicating whether the product is or is not intended as the sole source of nutrition.
- A statement indicating that RUTF are not breastmilk substitutes and shall not be presented as such
- [Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for at least 24 months.]

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.

- The time in which the product should be consumed after opening should be clearly indicated.

Canada's Comments:

- Canada questions the proposed text that recommends labelling in accordance with the three Codex texts: *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) *Guidelines on Nutrition Labelling* (CXG 2- 1985). Canada notes that these three Codex texts provide different and conflicting labelling requirements. For example, (CXS 180-1991) makes reference to labelling requirements in accordance with (CXS 146-1985), except for Sections 4.3, 5.1, 5.2.2, 5.2.3 and 6 of that Standard. Referencing all of the above texts make it unclear what sections would apply to RUTF.
- Canada proposes the initiation of further discussion to determine what mandatory labelling statements should apply to RUTF from the aforementioned referenced Codex texts and further proposes that the labelling requirements for RUTF be laid out in the guideline specifically. Canada also proposes if necessary, referencing the relevant Codex texts in each subsection specifically, rather than referencing all of Codex texts at the beginning of the labelling section to reduce confusion of what labelling requirements apply to RUTF from each of the relevant Codex texts.
- Canada supports retaining the statement on exclusive breastfeeding on the label of RUTF

UNITED STATES OF AMERICA

Recommendation 1: Preamble

The United States supports a concise preamble that provides context for a technical guideline for RUTF. The United States prefers:

- In para 1, the first sentence "RUTF is an option used to manage severe acute malnutrition (SAM)". For some national authorities, the word treatment could imply RUTF is used as a drug.
- In para 2, use of the word 'guidelines' rather than 'requirements' because this is a Guideline not a Standard and notes that the purpose of the guideline is addressed in the 'Purpose' section;
- In para 2, delete the second and third sentences as the mission of Codex Alimentarius addressed in these sentences are implicitly addressed by the creation of a Codex text and dispute clauses are generally not included in Codex texts;
- In para 2, language is included to explain that technical recommendations are based on transparent and rigorous scientific review of relevant scientific evidence;
- RUTF labelling states that RUTF is not a breast milk substitute. The United States questions the need to include references pertaining to the marketing of breast milk substitutes because RUTF is not a breast milk substitute and is not available for retail sale and only used in food aid. Further, specific WHA resolutions are not identified thus it is unclear which resolutions are considered relevant. For footnote 1, the United States supports deletion of the "Code and subsequent and relevant WHA resolutions" as it is our view that they do not pertain to the temporary use of RUTF in a severely malnourished population.

US Proposed text:

RUTF is an option used to manage severe acute malnutrition (SAM)**.** The primary focus for these guidelines **pertains to the use of** RUTF for children with uncomplicated SAM from 6-59 months. **However,** RUTF may be given to other age groups with various forms of malnutrition at the implementation level. Since RUTF are prescribed according to weight, National Authorities may decide to include the provision of RUTF in their national protocols for use by other age groups.

These guidelines should be used in accordance with technical recommendations **based on transparent and rigorous review of** relevant **scientific** evidence and related Codex texts[1].

[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.

Recommendation 2: Vitamins and Minerals

The United States supports the proposed text below. The term 'micronutrients' is preferred as it is a more comprehensive term that includes minerals as well as vitamins. The inclusion of the last sentence is important to ensure that the chemical forms of micronutrients added during manufacturing are stable and bioavailable in the finished product.

> All added micronutrients vitamins 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 (CAC/GL 10-1979). Examples of minerals 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 micronutrients added to achieve the target level must be adjusted based on the chemical form and scientific evidence showing adequate stability and bioavailability in the finished product.

Recommendation 3: Available Carbohydrates:

The United States supports the proposed text; however, notes that while carbohydrates are used to improve palatability, they are also a source of energy and acknowledges that the Committee may wish to focus on its function to improve palatability.

The United States supports deletion of the footnote and suggests further discussion of the strength of evidence to support the exclusion of fructose and high fructose corn syrup in RUTF for children with SAM. The United States notes that the WHO Guideline for Sugars intake for adults and children state "These recommendations do not apply to individuals in need of therapeutic diets, including for the management of severe and moderate acute malnutrition. In addition, the references (Malik, 2015 and Hu 2010) cited to support the proposed footnote present epidemiological studies on sugar-sweetened beverages, not sugar and high fructose corn syrup conducted largely in adults. As simple sugars are being added to RUTF to increase palatability and contribute calories for short term management of SAM, the United States does not agree that the literature cited supports limiting the type of simple sugar allowed if they meet the intended purposes.

The United States also supports deletion of the last sentence in the footnote because regulatory enforcement of 'sweetness' would be challenging. As there is no definition or objective and standardized method of measurement for "sweetness", inclusion 'sweet ness" or similar phrases present unresolvable evaluation and enforcement issues.

> **Available Carbohydrates[2]**
>
> The palatability of the RUTF can be increased by the addition of available carbohydrates. Available 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*.

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[2] ~~Sucrose, plant starch, maltodextrin, should be the preferred carbohydrates in RUTF. Fructose, glucose and corn syrup as ingredients should be avoided in RUTF, because of potential adverse effects in SAM children. Only precooked and/or gelatinized starches [gluten-free] by nature may~~

~~be added. Any carbohydrate added for sweetness should be used sparingly.~~

Recommendation 4: Food Additives

The United States does not support recommendation 4.1 as proposed.

The United States would note that it is against standard Codex practice to list specific food additives in a Guideline. Rather than creating a positive list of food additives for the RUTF guidance document, the committee may consider simpler approaches that have previously been used in other guidance documents:

- The committee may consider making reference to the food additives permitted for use in another standard. As an example, Section 4.2.2 of the "Guidelines on Formulated Complementary Foods for Older Infants and Young Children" (CAC/GL 8-199) states that:

"Food additives and flavourings listed in the Standard for Processed Cereal-Based Foods for Infants and Young Children(CODEX STAN 74-1981)and the Standard for Canned Baby Foods (CODEX STAN 73-1981) may be used in Formulated Complementary Foods to the maximum limits given in those Standards." Section 4.2.2 of CAC/GL 8-199 also addresses carryover from raw materials or other ingredients. The benefit of the specific standards referenced above is that all of the additives listed in those standards have been confirmed by CCNFSDU as suitable for use in foods intended for infants and young children. However, the committee would need to review the additives listed in the referenced standards to ensure that the additives listed in that standard are sufficient to fulfill the required technological functions that are justified in RUTF.

- The committee may also consider a simple statement indicating the functional classes of food additives that may be used in RUTF (the current food additive list indicates the need for Anticaking agents, Antioxidants, Emulsifiers, Packaging gases, and Stabilizers). Such a statement could be combined with a restriction that the use of additives in RUTF be in line with Section 3 "General Principles for the Use of Food Additives" of the General Standard for Food Additives (GSFA, CODEX STAN 192-1995). If further specificity is necessary, the standard could allow all additives in Table 3 of the GSFA of the functional class needed for RUTF. (Table 3 additives are additives of low toxicological concern which the Joint Expert Committee on Food Additives (JECFA) have given an Acceptable Daily Intake of "not specified", indicating that the additive is of low toxicological concern and that there is no safety based reason to set a numeric use level for the use of the additive in a food).

As stated above, the United States is of the opinion that listing specific additives in a Guideline is not appropriate. However, the USA does offer the following comment on the food additive list discussed in CX/NFSDU 18/40/6. The design used for the creation of the food additive list for RUTF is a format that is not appropriate for food additive lists in current Codex texts. The list as currently put forward would not likely receive endorsement from the Codex Committee on Food Additives (CCFA) if forwarded to that committee. Issues with the list include:

- Only food additives that have an International Numbering System (INS) number and that have been evaluated for safety by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) should be included in the food additive list for a Codex text.
- It is not appropriate to list commercially available mixtures of ingredients in a Codex food additive list. Thus, NATA -5, Grindsted PS-209, Fortium APT 10, and NATA 1 should be removed from the list. If the additives within these formulations are necessary for RUTF, then the individual food additives should be listed in the table.
- The name of the food additives as they appear in the Codex text "Class Names and the International Numbering System for Food Additives" (CXG 36-1989) should be used in the food additive table. As an example, the food additive INS 471 is listed in the table as "Mono & diglycerides", however, it should be listed as it appears in CXG 36-1989 as "Mono- and di- glycerides of fatty acids."
- In order to avoid confusion, a consistent unit should be used to describe the maximum use level (e.g., mg/kg).
- It is not typical to include the approximate use level in a food additive list for a Codex text. While this information may be helpful in developing the list, it should ultimately be removed before the guidance is made final.
- Not all of the INS numbers or names used in the table are correct or appropriate.

- There is no “INS 306” currently listed in the INS list (CXG 36-1989). The food additive associated with this number “Tocoperhols rich extract” has not been included in the JECFA group ADI for Tocopherols.
- The entry for “Tocopherols” as INS 307 should include the three forms of tocopherol for which JECFA specifications exist that are currently grouped in the GSFA under the group heading “Tocopherols”: INS 307a d-alpha-Tocopherol; INS 307b Tocopherol concentrate, mixed; and INS 307c dl-apha-Tocopherol
- The food additive Lecithin should have the INS number “INS 322i” do differentiate it from other forms of lecithin included under the parent INS number 322.
- The current entry for INS 290 should be corrected to “Carbon dioxide”.
- INS 451 which is associated with the name “Sodium Triphosphates” in the table is actually a “parent” INS number (listed as “Triphosphates” in the INS list) includes both INS 451(i) “Pentasodium triphosphate” and INS 451(ii) “Pentapotassium triphosphate” in the GSFA. There are currently 28 phosphate food additives with the functional class of “Stabilizer” included under the group heading of “phosphates” in the GSFA. Are any of the other phosphates with stabilizer function suitable for use in RUTF?
- The full INS name for INS 551 is “Silicon dioxide, amorphous”. It should be listed as being used for the INS functional class of “anticaking agent” as “free flowing agent” is not a recognized functional effect in the INS.

Recommendation 5: The use of Other Matrices in RUTF

The United States view is that RUTF do not meet the definition of Foods for Special Medical Purposes and notes the diverging views of the eWG thus suggests that the Committee further discuss this issue. For this reason, the United States suggests the following edits rather than the reference to Section 3 of the *Standard for Labelling of and Claims for Foods for Special Medical Purposes* (CODEX STAN 180-1991) as we view RUTF as a food for special dietary uses for use in community based management of SAM.

The United States suggests:

RUTF formulations manufactured with ingredients other than those specified in this guideline [should be proven to suitable and safe for their intended purpose. Use of other ingredients should be demonstrated by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended.]

Recommendation 6:

That CCNFSDU agree to the proposed text on energy and the energy values as follows:

Energy

Draft Text

The energy density of the formulated RUTF should be between 5.2 - to 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.

Energy Values	Unit	Minimum	Maximum	GUL
	Kcal/100g	520	550	-

The United States Supports the proposed text on energy values. This range of energy delivery per 100g of ready to eat product is consistent with current literature. The United States notes that the combination of these sources of energy must ensure adequate rheology, palatability and fast delivery of calories to meet the needs of children with SAM.

Recommendation 7:

That CCNFSDU agree not to set the minimum and maximum/GUL values for carbohydrates.

The United States supports the Chairs recommendation of not setting minimum or maximum for carbohydrates, as flexibility is need to meet technical/formulation needs of the product.

Recommendation 8:

That CCNFSDU agree to the proposed protein values in RUTF.

Protein should provide 10%-12% of the total energy. **Unit**	**Minimum**	**Maximum**	**GUL**
g/100g	12.8	16.2	-
g/100kcal	2.3	3.1	-

The United States supports setting minimum and maximum levels of protein and also expressing those levels in terms of kcal/g. We suggest including the energy proportion in parenthesis, for clarity (68.5kcal/100g - 86.67kcal/100g).

Recommendation 9:

That CCNFSDU agree to keeping the statement "at least 50% of protein is provided by milk products" in square brackets until there is further guidance from FAO on determining protein quality using PDCAAS.

["at least 50% of protein is provided by milk products"]

The United States supports the chairs' recommendation. While milk protein provides higher bioavailability of key micronutrients that encourage linear growth and cognitive development such as Ca, P, Mg and Vitamin D[1] (Hess et al., 2015), the United States also recognizes that other local and culturally acceptable protein sources may be appropriate (provided that scientific evidence supports comparable effectiveness with RUTF formulations containing protein from milk products). Including a measure of protein quality that is internationally standardized and validated in collaborative studies may assist in providing flexibility with the statement in brackets.

Recommendation 10:

That CCNFSDU agree to the proposed text on fats/lipids and the proposed minimum and maximum fats/lipids values as follows:

Lipids should provide 45% to 60% of the total energy.

The level of linoleic acid should not be less than 333 mg per 100 kcal. The level of alpha-linolenic acid should not be less than 33mg/100kcal. The level of linoleic acid should ensure a ratio between linoleic acid and alpha-linolenic acid of between 5:1 and 15:1.] **Unit**	**Minimum**	**Maximum**	**GUL**
g/100g	26	37	-
g/100kcal	5	6.7	-

The United States agrees with the energy contribution from fat proposed here, however, suggests that the reference to essential fatty acids to be removed, and discussed further in the document under the section addressing "essential fatty acids".

Recommendation 11:

That CCNFSDU agrees to retaining the linoleic acid and alpha-linolenic acid values as stipulated in the 2007 Joint Statement in the current RUTF nutritional composition as follows:

Essential Fatty acids values

[1] Hess SY, Abbeddou S, Jimenez EY, Somé JW, Vosti SA, Ouédraogo ZP, et al. (2015) Small-Quantity Lipid-Based Nutrient Supplements, Regardless of Their Zinc Content, Increase Growth and Reduce the Prevalence of Stunting and Wasting in Young Burkinabe Children: A Cluster-Randomized Trial. PLoS ONE 10(3): e0122242. https://doi.org/10.1371/journal.pone.0122242

Linoleic Acid = 3-10% of total energy

The level of linoleic acid should not be less than 333 mg per 100 kcal

Alpha- linolenic acid = 0.3-2.5% of total energy

The level of alpha-linolenic acid should not be less than 33 mg per 100 kcal

The United States supports retaining the linoleic acid and alpha-linolenic acid values as stipulated in the 2007 Joint Statement. The United States queries the basis for the absolute values of linoleic acid and alpha-linolenic acid per 100 kcal and suggests the conversion be explained in text for clarity and accuracy.

Recommendation 12:

That CCNFSDU agree to the minimum, maximum and associated footnote for vitamin A as follows: **Unit**	**Minimum**	**Maximum**	**GUL**
mg RE/100g	0.8	[1.1] OR [1.2]	-
mg/ RE/100kcal	0.15	[0.2] OR [0.22]	-
2µg RE/100kcal	150	[200] OR [220]	-

The United States supports the proposed text and prefers 1.1 mg RE/100g and corresponding values expressed per 100 kcal as the maximum. 1.1 mg RE/100g is the estimated minimum content when the product contains the highest level possible at t0 (release time at manufacturer), and considering the RUTF maximum at 24 months shelf life, stored at 30C or under. With most products consumed well before their best-before date, vitamin A content when consumed is expected to be within this RUTF range most of the time.

Recommendation 13:

That CCNFSDU agree to the minimum, maximum/GUL and associated footnote for vitamin D as follows: **Unit**	**Minimum**	**Maximum**	**GUL**
3 µg/100 g	15	[20] OR [22]	[30]
3 µg100 kcal	2.7	[3.6] OR [4]	-

The United States supports the proposed text and min and max ranges for vitamin D. The United States supports the Chairs' recommendation of 22 ug/100g maximum level and does not oppose the corresponding proposed maximums as these ranges are wide enough to be technologically feasible and assist manufacturers in compliance.

Recommendation 14:

That CCNFSDU agree to the minimum and associated footnote for vitamin E as follows: **Unit**	**Minimum**	**Maximum**	**GUL**
4 mg/100 g	20	-	-
4 mg α-TE /100 kcal	4	-	-

The United States supports the proposed text and min and max ranges for vitamin E.

Recommendation 15:

That CCNFSDU agree to the following recommendations for vitamin K, vitamin B1, vitamin B2, vitamin C, vitamin B6, vitamin B12, folic acid, niacin, pantothenic acid and biotin for RUTF as follows:

The United States supports the proposed text and min and max ranges for these vitamins.

Recommendation 16:

That CCNFSDU agree to the following recommendations for sodium, potassium, calcium, phosphorus, magnesium, iron, zinc, copper, selenium and iodine for RUTF as follows:

The United States supports the proposed text and min and max ranges for these minerals.

Recommendation 17:

That CCNFSDU consider that the current formulation of RUTF, as well as the proposed nutrients as stipulated in the 2007 Joint Statement be the basis for RUTF formulation, unless there is scientific evidence on any additional nutrients that has been demonstrated to be safe and beneficial in meeting the nutritional requirements of SAM children.

The United States supports the Chair's recommendation as well as the text addressing scientific evidence for additional nutrients to provide flexibility for innovation and improvement of current formula.

Recommendation 18:

That CCNFSDU agree to the proposed text of " Processing Technologies" section of the Guidelines as follows:

In addition to the practices described below, Good Hygiene Practices (General principles of food hygiene CXC 1-1969) should be implemented to avoid cross contamination during the packing and storage of raw materials. ETC ETC…

The United States supports the proposed recommendation as it addresses the array of available technologies used in the production of RUTF.

Recommendation 19:

That CCNFSDU agree to the proposed draft text for "good manufacturing practices and good hygiene practices" section as follows:

It is recommended that the products covered by the provisions of this 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).

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.

The United States supports the proposed recommendation as all the processes proposed in the current guideline draft are common practice in the manufacturing of lipid-based food products. The use of both thermal and non-thermal processes to control microbial loads is also appropriate. We suggest the following edit for consistency when referencing Codex texts:

[These practices should be in accordance with the *Guidelines for the Validation of Food Safety Control Measures* (CAC/GL 69-2008)].

Recommendation 20:

That CCNFSDU agrees to the proposed text for "the methods of analysis and sampling" section of the guidelines as follows:

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), *General Standard for Contaminants and Toxins in Food and Feed* (CXS 193-1995), *The Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997), *Code of Hygienic Practice for Low Moisture Foods* (CXC 75-2015), and other relevant Codex Alimentarius texts. When needed, specific methods of analysis should be developed in accordance with appropriate *Guidelines on Measurement Uncertainty* (CXG 54-2004), *Protocol for the Design, Conduct and Interpretation of Method Performance Studies* (CXG 64-1995), and Harmonized IUPAC.

The United States supports the proposed text for this section. The United Sates proposes that a range of water activity (Aw) is included in these guidelines, since this parameter is more relevant than the moisture content because RUTF is a low moisture food. Controlling of water activity is necessary to prevent accelerated oxidation processes both for fat and fat-soluble vitamins.

We suggest including an Aw range of 0.2 - 0.45 in the Guideline. This is the range where the least oxidation occurs. If Aw is lower than 0.2 or higher than 0.45, the oxidation process exacerbates.

Recommendation 21:

That CCNFSDU agrees to the proposed text for "packaging" section of the guidelines as follows:

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.

The United States supports the language regarding packaging, as it is broad enough to allow for innovation and the identification of most cost-effective packaging solution. The United States supports the proposed recommendation as it addresses the safety, quality, and suitability for the intended use.

Recommendation 22:

That CCNFSDU agree with the proposed draft text for the "labelling" section of the guidelines as follows:

It is recommended that the labelling of RUTF for children from 6 to 59 months be in accordance with the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-991), *Codex General Standard for the Labelling of Pre-packaged Foods* (CODEX STAN 1-1985), the *General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses* (CXS 146-1985), *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997) and *Guidelines on Nutrition Labelling* (CXG 2- 1985).

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. 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.

List of Ingredients

The list of ingredients shall be declared in accordance with Section 4.2 of the *Codex General Standard for the Labelling of Prepackaged Foods* (CXS 1 -1985).

Additional Mandatory Labelling Requirements

The following statements shall appear on the label of RUTF:

 "USE UNDER MEDICAL SUPERVISION" shall appear on the label in bold letters in an area separated from the written, printed, or graphic information.

 "For the dietary management of severe acute malnutrition" shall appear on the label.

 A prominent warning statement consisting of an explanatory statement in bold letters indicating that RUTF are for special medical purposes and may pose a health hazard when consumed by individuals who do not have the disease(s), disorder(s) or medical condition(s) for which the food is intended.

 The product is not to be used for parenteral, rectal or Nasogastric Tube (NG tube) administration.

 A statement indicating whether the product is or is not intended as the sole source of nutrition.

 A statement indicating that RUTF are not breastmilk substitutes and shall not be presented as such.

 [Exclusive breastfeeding is recommended for the first 6 months of life, and continued breastfeeding is recommended for at least 24 months.]

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.

 The time in which the product should be consumed after opening should be clearly indicated.

The United States does not agree with the proposed text and supports further discussion of the proposed Codex texts to inform the labelling provisions for RUTF. The United States prefers omitting the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CODEX STAN 180-1991), as we do not view RUTF as a food for special medical purposes. Also, making reference to different standards that might contradict each other, as explained in Recommendation 1 comments can lead to confusion. For instance, if RUTF must be used "Under Medical Supervision", that would contradict the WHO/FAO statement on RUTF that states that "the product is to be consumed at home with minimum supervision".

The United States suggests keeping the "Declaration of Nutritive Value" to provide nutrient information on labelling for consumers and care providers.

Regarding the "Additional Mandatory Labelling Requirements" section, the United States supports further discussion of the approach to determine the mandatory statements that should be included in the labelling requirements for RUTF. The United States is not opposed to providing additional information on labelling, however, queries if the proposed text, implicitly describes a product that is not suitable for community based management of SAM (i.e. foods that can be eaten safely at home by a malnourished child with no medical complications and guided by appetite). Such labeling is inconsistent with the use of the product and difficult to comply with in community settings.

The United States supports breastfeeding and has assisted countries to promote, protect and support breastfeeding to reduce infant mortality and malnutrition for more than 45 years. However, the United States views bullets 5-7 as out of scope for a technical guideline for RUTF. RUTF is a product intended for emergency food relief for limited duration and not for retail sale thus the United States questions bullets 5-7 and suggests further discussion of statements that address whether the "product is or is not intended as a sole source of nutrition; and that they are not breastmilk substitutes; and recommended duration of exclusive breastfeeding and continued breastfeeding".