

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS



WORLD  
HEALTH  
ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

**Agenda Item 7**

**CX/NFSDU 09/31/7  
September 2009**

## **JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

### **CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES Thirty first Session**

**Robert Schumann Hall, Museum Kunst Palast, Düsseldorf, Germany  
2 – 6 November 2009**

#### **DISCUSSION PAPER ON THE PROPOSAL TO REVISE THE CODEX GUIDELINES ON FORMULATED SUPPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN (CAC/GL 8-1991)**

**Prepared by Ghana**

#### **I. Introduction**

Ghana submitted a proposal at the 30<sup>th</sup> session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to revise the Guidelines on Formulated Supplementary Foods for Older Infants and Young Children. Following discussions at that meeting, the Committee agreed to establish an electronic working group, led by Ghana to prepare revised proposals taking into account comments and concerns raised for consideration at the next session of the Committee.

Member countries of the electronic Working Group were as follows: Argentina, Australia, Brazil, Burundi, Finland, Ghana, Kenya, Mexico, South Africa, Tanzania, The Gambia, United States of America, World Health Organization, IBFAN and IAFCO.

The report was therefore prepared to address the comments raised at CCNFSDU session in 2008 and to provide a revised version of the project plan.

Based on feedback from members of the EWG and awareness of new knowledge related to Formulated Complementary Foods (FCF), the work is proposed to expand from revising only Section 6 (which was the stated intent at the Codex meeting in 2008 in South Africa – paragraph 143 in ALINORM 09/32/26) to revising the title and content of the Guidelines to refer to Formulated Complementary Foods as well as Sections 4, 5, 6 and 9 and the Annex.

## **II. Background**

The term “formulated complementary foods” (FCF) refers to foods suitable for feeding older infants (aged 6-11 months) and young children (aged 12-36 months) as a complement to breast milk or breast milk substitutes. FCFs include porridges, ready-to-use products such as pastes and compressed bars, and food-based fortificants for use in the home. Food-based home fortificants typically contain high quality protein (e.g. milk proteins, soy proteins), high-quality vegetable oil, and (micro) nutrients, and are added to local foods to improve the nutrient density and content of these foods or eaten alone to improve both macronutrient and micronutrient intake.

The purpose of the Codex Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (1991) is to “provide guidance on nutritional and technical aspects of the production of formulated supplementary foods for older infants and young children.” Since these Guidelines were published, new evidence has become available regarding energy and nutrient requirements from complementary foods.

The 1991 Guidelines already include important ingredients such as milk and/or milk products (important for growth) in the list of suitable raw materials and ingredients for formulated complementary foods (FCF). The Guidelines also address technologies for processing pulses, oilseeds, and cereals to reduce anti-nutrients, and provide guidance on vitamins and minerals that are most frequently deficient in the diets of older infants and young children.

## **III. The Problem**

Several aspects of the present Guidelines are no longer consistent with new recommendations on feeding older infants and young children. The current recommended quantity of FCF, given in the Guidelines (CAC/GL 08-1991) is too large for breastfed and non-breastfed children 6–11 months, 12-36 months of age and leaves almost no room for breast milk or other milks and local foods. Furthermore, the recommended levels of fortification of vitamins and minerals are too low. Additional guidance is also needed on the ratio of linoleic to alpha-linolenic acids, anti-nutrients such as phytate, avoidance of trans-fatty acids, types/forms of dairy products that can be used in FCF, and energy percentage from fat. Additionally Reference Nutrient Intakes (RNI) for children 7–12 months and 1–3 years of age have also been updated and therefore the Guidelines need to reflect these updates as well.

## **IV. What can be achieved by revising these Guidelines**

1. Guide and support the formulation, labeling, and recommended serving size and daily quantity, of diverse types of FCFs (porridges, ready-to-use products such as pastes and compressed bars, and food-based home fortificants);
2. Encourage optimal formulation and use of FCFs;
3. Assist governments in improving the quality of the foods used in feeding programs as well as those sold for use by older infants and young children;
4. Ensure fair practices in international food trade so that products which do not meet the specified quality criteria would be accurately positioned but not inappropriately represented as a FCF

and

5. Lessen impediments to international trade by providing clear guidance for foods used in feeding programs for young children.

The proposed revision focuses on both breastfed and non-breastfed older infants and young children. From 6 months of age, both breastfed and non-breastfed infants and young children need high-quality complementary foods in addition to human or other milk. Complementary foods are not breast milk substitutes and are intended to complement, not replace, breast milk. In environments where local complementary foods are missing or inadequate in essential nutrients, FCF are important sources of these nutrients. Thus, revising the 1991 Guidelines would guide the formulation and recommended daily quantity and serving size of FCF to provide these essential nutrients based on a better understanding of optimal infant and young child feeding and updated nutrient requirements.

#### V. Key differences between India and Ghana proposals

1. The India proposal focuses on the revision of the **Standard for processed cereal based foods** for infants and young children in developing countries, whereas the Ghana proposal focuses on the revision of the **Guidelines on formulated supplementary foods** for older infants and young children. . Ghana is pursuing a revision to the guidelines because these particular Guidelines (CAC/GL 08-1991) are of most relevance to the FCFs, their formulation and recommended daily quantity and serving size.

2. Even though there is an overlap in some of the raw ingredients (e.g. cereals, legumes) used to manufacture the products covered by the two proposals, the proposal by Ghana includes a greater diversity of FCFs within its scope. Processed cereal-based foods are only one type of FCF. The proposal by Ghana additionally covers ready-to-use products such as pastes and compressed bars, and food-based fortificants for use in the home.

3. The revision of the Guidelines proposed by Ghana includes changes to serving size, fortification level, ingredients and processing methods. By contrast, the India proposal focuses only on changes in specifications cereal and protein content and energy density.

#### VI. Responses to the Points of Concern

The specific concerns related to this proposal and recorded in ALINORM 09/32/26 are presented below *in italic font*, with responses following each point of concern in plain font.

*148. ....The Observers indicated further that foods referred to in the two proposals were usually distributed by aid agencies and were not commercially available. The Observers also expressed concern that such products if introduced commercially could damage breastfeeding programmes and reduce the use of traditional foods.*

While many complementary foods including FCF are distributed by aid agencies, there is a substantial production and sale of porridge mixes for infants and young children through the commercial sector involving both international and regional/local companies. Such foods are available, for example, in Côte d'Ivoire, Nigeria, Kenya, Ghana, South Africa, Uganda, and China. In Ghana, at least 4 local companies produce porridge mixes and in Uganda, at least 3 local companies distribute such foods. There is also sale

of ready-to-eat FCF in the form of pastes and bars.

The proposed revision of the Guidelines is intended to protect breastfeeding because the Guidelines currently recommend serving sizes that are too large for children 6–11 months and 12-36 months of age. For children in this age range, such large volumes of food can displace breast milk from their diet, and can also interfere with consumption of local foods, thereby decreasing diet diversity. Thus revised Guidelines that optimally improve the quality of FCF will help to support, not damage breastfeeding, thus helping protect this valuable resource.

*149. The Delegation of the European Community while acknowledging that the two proposals intended to tackle very serious problems associated with malnutrition and under-nourishment, noted that several questions remained on both proposals such as*

***(a) Who are the intended population for the products?***

The intended population for these foods is infants and young children aged 6-11 months and 12-36 months whose diets are lacking in or provide insufficient quantities of certain nutrients. This includes those who are consuming breast milk or breast milk substitutes and other foods available in the country where the product is sold. FCF are intended to improve the quality of diet for older infants and young children — this includes normally growing children at risk of malnutrition and moderately malnourished children. Infants less than 6 months of age are explicitly not targeted because the use of complementary foods is not suitable for this age group.

***(b) The proposal of Ghana targeted specifically breastfed infants and did not address the situation of non-breastfed children***

The Ghana proposal targets both breastfed and non-breastfed infants and young children. The ultimate goal associated with the use of FCF is to prevent energy and nutrient deficiencies and reverse or prevent growth faltering and malnutrition in both breastfed and non-breastfed children.

Exclusive breastfeeding provides optimal nutrition in the first six months of life and continued breastfeeding up to at least two years provides a source of high-quality protein, fat and nutrients. From 6 months of age, both breastfed and non-breastfed infants and young children need high-quality complementary foods in addition to human and other milk. When local complementary foods are missing or inadequate in essential nutrients, FCF are important sources of these nutrients. For example, when animal-source foods are lacking in the local diet, FCF can provide nutrients such as iron and zinc that would otherwise be inadequate. The revision of the Guidelines would guide the formulation and recommended daily quantity and serving size of FCF to provide essential nutrients based on a better understanding of optimal infant and young child feeding and updated nutrient requirements.

The revision of smaller serving sizes for the younger age group is intended to avoid interfering with breast milk intake and to allow consumption of a diverse diet, which includes locally available foods, by both breastfed and non-breastfed children. Both breastfed and non-breastfed children should consume local foods in addition to breast milk or other milks and FCF and should not rely solely on FCF to meet their nutritional needs.

***(c) The true nature of these cereal-based foods or supplements was unclear***

FCFs include porridges, ready-to-use products such as pastes and compressed bars, and food-based fortificants for use in the home. Food-based home fortificants typically containing high quality protein (e.g. milk proteins, soy proteins), high-quality vegetable oil, and (micro) nutrients are added to local foods to improve the nutrient density and content of these foods.

FCF are eaten along with breast milk or breast milk substitutes (or animal milks where breastfeeding has stopped) and home-prepared complementary foods. The diverse range of FCF finished products are made from any combination of ingredients including cereals, legumes, pulses, fat, peanuts, sugar, dried dairy products such as powdered milk or whey, essential fatty acids, fish meal, protein concentrates, amino acids, enzymes, and vitamins and minerals.

*(d) The composition requirements of these foods needed to be clarified as well as the channels for distribution of these products (commercially available or not) and if commercially available, how risk of confusion by potential users would be avoided and how the work of WHO/UNICEF/FAO/WFP/UNHCR could contribute to the consideration of the proposed work.*

The updated composition requirements are highlighted in the attached project document and take into consideration recommendations of the 2008 WHO/UNICEF/WFP/UNHCR Consultation on the Dietary Management of Moderate Malnutrition. The recommendations are summarized in the Food and Nutrition Bulletin (volume 30, Number 2, June 2009, S236-55) and given in the proceedings of the Moderate Malnutrition meeting

([http://www.who.int/nutrition/publications/moderate\\_malnutrition/mm\\_report/en/index.html](http://www.who.int/nutrition/publications/moderate_malnutrition/mm_report/en/index.html)).

Channels of distribution for these products include market-based (commercial) as well as government- or NGO-supported feeding programmes. The revised Guidelines can inform and guide the manufacture of FCF, especially as orders are placed by governments and international organizations such as WFP. As mentioned earlier, infant porridge mixes are already commercially available, supplied by both international and regional/local companies.

Commercial products that meet the proposed revised Guidelines would be identified as foods for special dietary use and would be required to be labeled accordingly. This should differentiate FCF from other currently available products.

## **VII. The Relation between This Proposal and Other Proposals for Foods for Malnourished Children**

India is proposing the addition of a “Part B” to the revised Codex standard for processed cereal based foods for infants and young children entitled “processed cereal based foods for infants and young children in developing countries.” This was discussed during the 30<sup>th</sup> CCNFSDU in 2008. The key goal of the proposal by India is to improve nutritional status by ensuring (1) at least 50% cereal content in cereal-based foods, (2) at least 12% protein, and (3) energy density of at least 4 kcal/g on dry weight basis. Ghana’s proposal for a revision of the Guidelines does not address minimum cereal content, emphasizes protein quality defined by a minimum PDCAAS score of 70 and no less than 10% of the total energy from protein, and argues for the same minimum energy density as the India proposal of 4 kcal/g. The key differences between the India and Ghana proposals have been presented earlier in this paper (see **Key differences between India and Ghana proposals**). In summary, the proposal by Ghana focuses on improving the formulation and recommended serving size of the wide range of foods that together constitute FCF.

**PROPOSAL FOR NEW WORK FOR REVISION OF THE GUIDELINES ON  
FORMULATED SUPPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG  
CHILDREN (CAC/GL 08-1991)**

The title of the Guidelines uses the term “supplementary” however, the term “complementary” is proposed to be used in this document in preference to “supplementary” (the term in use at the time the 1991 Guidelines were developed) or “weaning” for foods used in addition to breast milk because these foods complement what breast milk provides for infants over 6 months of age.

Since the 1991 Guidelines were published, new international, evidence-based recommendations regarding energy requirements and nutrient needs from complementary food including formulated complementary foods (FCF) for older infants and young children have been established.

In addition, FCF have expanded in recent years from porridges to several types of food-based products including

- a) Ready-to-use products such as pastes and compressed bars
- b) Food-based home fortificants typically containing high quality protein (e.g. milk proteins, soy proteins), high-quality vegetable oil, and (micro) nutrients.

These foods can be eaten directly or mixed with local complementary foods, thus improving the overall quality of local complementary foods.

### **1. Purpose and scope of the revision**

The main purpose of the proposed revision is to update the Guidelines with regard to nutritional aspects of formulated complementary foods for older infants and young children, based on relevant science-based recommendations and updated Reference Nutrient Intakes (RNI) for children 7–12 months and 1–3 years of age. The proposed revision has five aims to:

- a) Revise energy and nutrient densities and recommended serving size and daily quantity of FCF for infants and young children
- b) Strengthen the Guidelines on the importance of key ingredients
- c) Update the Guidelines on effective processing methods to reduce or eliminate anti-nutrients
- d) Amend labeling provisions to include the type of fat used and the amount of linoleic acid and alpha-linolenic acid
- e) Amend the name and content of the Guidelines to reflect current terminology

Not included in the scope of the proposed revision are non-food-based micro- or multi-nutrient powders used in the home (e.g. Sprinkles).

## 2. Relevance and timeliness

These 1991 Guidelines are outdated with current evidence and need to be updated. The current recommended quantity of FCF, given in the Guidelines (CAC/GL 08-1991) is too large for breastfed and non-breastfed children 6–36 months of age and leaves almost no room for breast milk or other milks and local foods. Furthermore, the recommended levels of fortification of vitamins and minerals are too low. Additional guidance is also needed on the ratio of linoleic to alpha-linolenic acids, anti-nutrients such as phytate, avoidance of trans-fatty acids, types/forms of dairy products that can be used in FCF, and energy percentage from fat. Because Reference Nutrient Intakes (RNI) for children 7–12 months and 1–3 years of age have been updated, the Guidelines need to reflect these updates as well.

The proposed revision is timely because countries and regions are currently in the process of developing standards for complementary foods and are trying to harmonize their actions with Codex. For example, the Uganda National Bureau of Standards is now working on “Improving the safety and quality of foods for infant and young children in Uganda”, and recommends

- a) Evaluating these types of products, including processing, hygiene, product safety and quality, in line with international recommendations and standards
- b) Formulation of national standards and codes for the products’ specification, hygiene and marketing of products in line with developments at the Codex Alimentarius Commission and WHO and FAO activities.

The East Africa Region (including Burundi, Kenya, Rwanda, Tanzania, and Uganda) is now in the process of harmonizing standards for infant foods based on Codex standards and guidelines.

## 3. Main aspects to be considered

The work is proposed to revise the title and content of the Guidelines to refer to Formulated Complementary Foods as well as revise Sections 4, 5, 6 and 9 and the Annex. Such revisions could include:

- a) Adding a statement regarding the form of milk and/or milk products to use as ingredients in FCFs.
- b) Updating the advice on process technology to reduce or eliminate anti-nutrients, including phytate (Section 5).
- c) Revising downward the daily serving size for 6–36 months of age. Depending on the type of FCF, ten to fifty grams of FCF is considered a reasonable quantity which an older infant (above 6 months) or young child can ingest easily in two or more feedings in a day (Section 6). This suggested daily quantity will be appropriate for a wide range of FCFs for both breastfed and non-breastfed older infants and young children.
- d) Recommending the use of the Protein Digestibility Corrected Amino Acid Score (PDCAAS) to assess protein quality (Section 6).
- e) Revising upward the energy derived from fat to a minimum of at least 30% of energy from fat (Section 6).

f) Specifying a ratio between linoleic acid and alpha-linolenic acid. The participants at the Moderate Malnutrition meeting suggested a ratio between linoleic acid and alpha-linolenic acid between 5:1 and 10:1 (Section 6).

g) Adding a statement that partially hydrogenated (trans) fatty acids should not be added to the product (Section 6).

h) Revising product labeling. For example, to specify type of fat used and amounts of linoleic and alpha-linolenic acid. Also, to include a statement on continued breastfeeding during the complementation period and should exclude any pictorial presentations that might support the idea of FCF replacing or being preferential to breast milk/other milks or local foods, which are equally important during this period (Section 9).

i) Revising fortification levels to contain at least 50% of the reference daily requirements per daily ration, with updated 1–3 year RNIs (Annex) and include fortification level information in the labeling. Because RNIs for children aged 7–12 months are usually less than or equal to RNIs for children aged 1–3 years for most micronutrients (except iron), RNIs for children aged 1–3 years are suggested to be used. It is unlikely that children in areas with existing mass fortification programs might get too much of some nutrients because mass fortification programs target the general population and have little impact on the nutrition status of children in this age group (6–36 mo).

j) Updating references to other Codex standards/guidelines referenced in the Guidelines that have since been revised.

#### **4. Assessment against the criteria for the establishment of work priorities.**

The revision of these Codex Guidelines provides for protection of consumer health, food safety, ensuring fair practices in the international food trade and takes into account the identified needs of moderately malnourished and at-risk children aged 6–36 months.

The revision would assist governments in improving the quality of the foods used in feeding programs as well as those sold for use by older infants and young children, which will directly protect infant and young child health.

This would help ensure fair practices in international food trade so that products which do not meet the specified quality criteria would be accurately positioned and not inappropriately represented as a FCF.

This work also aims to update the contribution of international food standards and related texts to infant and young child health based on work already undertaken by other international organizations in this field, including WHO, UNICEF, FAO, WFP and UNHCR. Revision of the relevant Codex standards and guidelines is recommended by these international intergovernmental bodies.

#### **5. Relevance to the Codex strategic objectives**

The proposed revision is consistent with the Strategic Plan 2008-2013 of the Codex Alimentarius Commission. It will contribute to: Goal 1 – Promoting sound regulatory frameworks, specifically Activity 1.3: “Review and develop Codex standards and related texts for food labeling and nutrition.”



It will also contribute to: Goal 2 - Promoting widest and consistent application of scientific principles. Updated evidence on energy needs from complementary foods, feeding frequency and gastric capacity for breastfed and non-breastfed infants as well as updated RNIs are the basis for this revision.

#### **6. Information on the relation between the proposal and other existing Codex documents**

The Codex Standard for Processed Cereal Based Foods for Infants and Young Children Codex Stan 074-1981, Rev. 1 -2006 includes information on many components of cereal-based foods but includes neither suggested amounts to be consumed daily nor comprehensive micronutrient levels. A draft proposal advocating high-protein content to be incorporated in this Standard was discussed during the 30<sup>th</sup> CCNFSDU in 2008 and further revision was suggested with India as the chair for the EWG for the revision. The key goal of the proposal by India is to improve nutritional status of infants and young children in developing countries by ensuring minimum cereal and protein content and energy density in processed cereal-based foods only.

By contrast, this proposal for a revision of the Guidelines put forth by Ghana proposes changes to serving size, fortification levels, ingredients and processing methods for the wide range of foods that together constitute FCF.

#### **7. Identification of any requirement for and availability of expert scientific advice**

None foreseen.

#### **8. Identification of any need for technical input to the standard from external bodies so that this can be planned for**

None foreseen

#### **9. Proposed time-line for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years.**

<b>Activity</b>	<b>Step/date</b>
The 31 <sup>st</sup> CCNFSDU agrees the work to be undertaken	November 2009
33 <sup>rd</sup> Session of the Commission approves new work	July 2010
Guidelines are circulated for comments for consideration by the 32 <sup>nd</sup> Session of the CCNFSDU, 2010	Step 3/ 2010
Provisional adoption by the 34 <sup>th</sup> Session of the Commission, July 2011	Step 5/ July 2011
Final adoption by the 35 <sup>th</sup> Session of the Commission	Step 8/ 2012