CODEX ALIMENTARIUS COMMISSION





Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codex.alimentarius.org

Agenda Item 7

CX/NFSDU 12/34/10

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

Thirty-fourth Session
Bad Soden am Taunus, Germany
3 – 7 December 2012

PROPOSED DRAFT AMENDMENT OF THE STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN (CODEX STAN 74-1981) TO INCLUDE A NEW PART B FOR UNDERWEIGHT CHILDREN

Report of the electronic Working Group (EWG) chaired by India

The members of Electronic Working Group are Argentina, Belgium, Brazil, Burundi, Cameroon, Canada, Chile, Ecuador, Egypt, European Union, Germany, Jamaica, Japan, Malaysia, Mexico, New Zealand, Mauritius, Poland, Republic of Moldova, Indonesia, Senegal, Sudan, United States of America, Uruguay, and ISDI, ILCA, ESPGHAN and AIDGUM.

RATIONALE FOR PART B

This new work for establishment of part B of CODEXSTAN 074-1981 as discussed in the 32nd session of Codex Committee of Nutrition and Foods For special Dietary Uses (CCNFSDU) focuses on the following three key issues concerning underweight infants and young Children including those at risk:

- a) *Cereal content*: The processed foods for underweight infants and young children are based primarily on cereals, as they are not only an important source of carbohydrates but also provide a good amount of protein and other nutrients like minerals and vitamins. The Committee would consider establishing minimum cereal content for these foods.
- b) *Minimum protein content*: The Committee would consider establishing the minimum protein content and quality in the processed cereal based foods for underweight infants and young children.
- c) Energy Density: The Committee would consider establishing the minimum energy density of processed cereal based foods for underweight infants and young children and if necessary fats and oils may be added to increase the energy density.

Conduct of Electronic Working Group

- 1. An Electronic Working Group chaired by India working in English was established as agreed during the 32nd CCNFSDU to prepare a Draft Standard for Inclusion of New "Part B" for Underweight Children in the Standard for Processed Cereal-Based Foods for Infants and Young Children (Codex Stan 74-1981).
- 2. The 34th Session of CAC approved the work in July 2011 on Inclusion of a New Part B for Underweight Children in the Standard for Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 74-1981) (NO4-2011).
- 3. In August 2011, an invitation to participate in this EWG was extended to the Codex members and observer organizations. Expression of interest in participating were received from Argentina, Belgium, Brazil, Burundi, Cameroon, Canada, Chile, Ecuador, Egypt, European Union, Germany, Jamaica, Japan, Malaysia, Mexico, New Zealand, Mauritius, Poland, Republic of Moldova, Indonesia, Senegal, Sudan, United States of America, Uruguay, and ISDI, ILCA, ESPGHAN and AIDGUM. In September 2011, the Chair circulated a consultation document on the "Proposed draft standard for Processed Cereal-Based Foods for Infants and Young Children" Codex Stan 074-1981, "Part B" for Underweight Infants and Young Children" to EWG members. In addition to this report please refer to CX/NFSDU 10/32/8 and Project document REP/11/NFSDU.
- 4. As per the paras 127-129 of the report of 33rd session of the CCNFSDU (REP12/NFSDU) the revised discussion paper has been shared with the members of the eWG chaired by India in September 2012.

5. Responses have been received from Fourteen members on the consultation document circulated among the members of EWG during August 2011 and subsequently in September 2012. This document presents a brief summary of the EWG responses on the preliminary proposal and issues for the consideration at the current session.

6. Based on the responses received the Proposed Draft standard have been modified, keeping in mind the further discussion during the session. The responses to some of the comments are mentioned in italics.

II. Proposed Draft Standard for PART B of CODEX STAN 074-1981

Following are the summary of the comments and responses on the proposed draft on Appendix V of REP/NFSDU and CX/NFSDU 11/33/9 that form the basis for the revised text in Annex I for consideration by the Committee.

Some of the suggestions received from member countries in relation to the key issues:

The suggestions or comments are given in italics and the response in bold letters

TITLE: PROPOSED DRAFT STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN CODEX STAN 074-1981

PART B FOR UNDERWEIGHT INFANTS AND YOUNG CHILDREN

Comments: The EWG (Canada, ISDI) asked if the title should be revised to "high energy, high protein foods".....

Response: The title needs to be consistent with the title in the project document, hence not revised.

1. SCOPE

This standard covers processed cereal-based complementary foods intended to meet the dietary requirements of underweight infants after the age of six months and young children as well as those at risk of becoming underweight¹

There were views from the members (Mexico, Canada, New Zealand, European Union, Brazil, United States and ISDI) that the term "underweight" needs to be defined; in addition "children at risk" may be included as they are the intended target consumers of these products and this would enable the work to progress effectively.

Suggestions: "This standard covers processed cereal-based complementary foods intended to meet the dietary requirements for feeding underweight infants after the age of six months and those at risk of becoming underweight, taking into account infants' individual nutritional requirements, and for feeding underweight young children and those at risk of becoming underweight as part of a progressively diversified diet, in accordance with the Global Strategy for Infant and Young Child Feeding and World Health Assembly Resolution WHA54.2 (2001)."

Response: The suggestion is accepted excluding the words "<u>taking into account infants</u>' <u>individual nutritional requirements</u>, <u>and for feeding</u> underweight¹ young children and those at risk of becoming underweight"

With respect to the definition of "underweight" stated in footnote 1, we suggest including the source of the definition, i.e. the WHO reference used, in order to ease the reader access to the definition given that the WHO reference could be updated in the future. Moreover, we suggest revising the wording of the definition in footnote 1 in order to improve the understanding.

Response: Foot note is modified as "using WHO growth standards, Children having weight-for-age below -2 standard deviations (SDs) or weight-for-age z-score [WAZ] <-2, are classified as underweight and children at risk of becoming underweight with growth faltering due to inadequate complementary feeding" http://www.who.int/childgrowth/standards/weight_for_age/en/index.html

2. **DESCRIPTION:**

Processed cereal-based foods should contain minimum 50% cereals on a dry weight basis

Comments: Few members (Brazil, European Union, New Zealand, United States, ISDI& Canada) pointed out towards the quantity of cereal content i.e. 50% compared to 25% as in part A.

Response: The product is primarily cereal based and meant for the underweight as well as children at risk. Therefore the need to have 50% cereals since they are not only an important source of carbohydrates but also provide a good amount of protein and other nutrients like minerals and vitamins.

Comment: An EWG member (Mexico) has raised the concern of product presentation, palatability & acceptability by altering the minimum cereal content from 25% to 50%.

Response: The palatability, texture etc. of the final product might be affected if the cereal content is low and pulse constitute more than the cereals (30-40%) to raise the nutritive value of these products and replacing with starch might reduce its nutritive value.

2.1. Product Definitions

Two categories are distinguished:

- 2.1.1 Products consisting of cereals which are or have to be prepared for consumption with milk or other appropriate nutritious liquids;
- 2.1.2 Cereals with an added high protein food which are or have to be prepared for consumption with water or other appropriate protein-free liquid;

Comment: Brazil and EU has raised the issue on inclusion of 2.1.3 and 2.1.4 in Part B.

Response: Only 2.1.1 and 2.1.2 are addressed in this new part B and are appropriately modified in line with part A.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential Composition

3.1.1 The two categories listed in 2.1.1 and 2.1.2 are prepared primarily from one or more milled cereal products, such as wheat, rice, barley, oats, rye, maize, millet, sorghum and buckwheat. They may also contain legumes (pulses), or oil seeds in smaller proportions.

Comment: Some EWG members (Brazil, New Zealand) have raised the issue regarding exclusion of "starchy roots" & starchy stems" from the item 3.1.1.......

Response: As these products do not have any nutritive value other than caloric value & cassava, tapioca etc. Also have certain anti-nutrients, therefore excluded in Part B.

Suggestions: The EWG members (European Union, Mexico, Canada, United States, New Zealand, ISDI and India) have suggested the modifications and edit.

Response: Accordingly the subsets of essential composition and quality factors are modified

3.2 Energy Density

The energy density of cereal-based foods from 2.1.1 and 2.1.2 should <u>not</u> be <u>less than</u> 4.184 kJ/g (1.0 kcal/g) of the reconstituted food.

3.3 Protein

3.3.1 The chemical index of the added protein shall be equal to at least 80% of that of the reference protein casein or the Protein Efficiency Ratio (PER) of the protein in the mixture shall be equal to at least 70% of that of the reference protein casein. In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the protein mixture, and only in the proportions necessary for that purpose. Only natural forms of L-amino acids should be used.

Comment: Brazil suggested that the Committee considers the possibility to update the reference used for protein quality from PER to PDCAAS (Protein Digestibility Corrected Amino Acid Score), as they feel that this criterion is more appropriate, considering the current scientific knowledge. Furthermore, the Draft of the Guidelines on formulated complementary foods for older infants and young children has incorporated this reference, in the item 6.3.2.

Response: This is same as given in CODEX STAN 074 – 1981, Rev. 1 - 2006

3.3.2 For products mentioned in point 2.1.2 the added protein content shall not be less than 0.48 g/100 kJ (2 g/100 kcal).

- 3.3.3. For product mentioned at 2.1.2 the total protein content shall not be less than 0.72 g/100kJ (3g/100 kcal)
- 3.3.4. For products mentioned at 2.1.1 and 2.1.2, the protein content shall not exceed 1.3g/100KJ (5.5g/100Kcal)

Comments: Many member countries have questioned the rationale for increasing the energy density and minimum protein content

Response: Explanation is given in Annexure II

3.4 CARBOHYDRATES²

3.4.1 If sucrose, fructose, glucose, glucose syrup or honey are added to products mentioned in points 2.1.1

3.5 LIPIDS

3.5.2 Product category 2.1.1shall not exceed a maximum lipid content of 0.8 g /100 kJ (3.3 g/100 kcal).

3.6 MINERALS

3.6.1 The sodium content of the products described in Sections 2.1.1 and 2.1.2 of this Standard shall not exceed 24 mg/100 kJ (100 mg/100 kcal) of the ready-to-eat product.

Repositioning of 3.6.2 and 3.6.3 (Interchanging the position)

Comments: The EWG members (Canada, United States, New Zealand, ISDI, Mexico, Brazil, Mauritius, Sudan & Burundi) have provided few suggestions on the sections of 3.7, 3.8, 3.10, 3.12 and Section 5.

Response: The Section 3.7 to Section 5 is retained as Part A (CODEX STAN -074, 1981, Rev I 2006).

6. HYGIENE

It is recommended that the products covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice – General Principle of Hygiene (CAC/RCP 1 1969), Recommended International Codex of Hygienic Practice for Foods for Infants and Children (CAC/RCP 66-2008) and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice.

The product should comply with any microbiological criteria established in accordance with the Principles for the Establishment and application of microbiological Criteria for Foods (CAC/GL 21-1997).

Comments: EWG members (Brazil, United States &New Zealand) have suggested that as the International Codex of Hygiene Practice for Foods for Infants and Children (CAC/RCP 21-1979) has been revised and the scope of the (CAC/RCP 66-2008) has been narrowed to focus on powdered infant formula therefore it is reworded as follows:

Response: The suggestion is incorporated in the draft

7 & 8 PACKAGING & LABELLING

Comments EWG members (Brazil, Uruguay & Mauritius) have suggested certain modifications under Section 7 & 8.

Response: The Section 7 (Packaging) and 8 (Labelling) are retained as Part A (CODEX STAN -074, 1981, Rev I 2006).

Comments: The EWG Members (Brazil, European Union &, Canada) are of the view that those sections which are to be referred to PART A may be mentioned as such rather than repeating those sections as done in CODEX STAN 72-1981 (Standard For Infant Formula and Formulas For Special Medical Purposes Intended For Infants).

Response: Accordingly the Sections from 3.7 to Section 5, and sections 7 to 9 are retained as Part A (CODEX STAN -074, 1981, Rev I 2006) except section 8.6.2 and 8.7

Annex 1

PROPOSED DRAFT STANDARD FOR PROCESSED CEREAL-BASED FOODS FOR INFANTS AND YOUNG CHILDREN (CODEX STAN 074-1981) PART B FOR UNDERWEIGHT INFANTS AND YOUNG CHILDREN

1. SCOPE

"This standard covers processed cereal-based complementary foods intended to meet the dietary requirements of for feeding underweight infants after the age of six months and and young children as well as those at risk of becoming underweight¹, as part of a progressively diversified diet, in accordance with the Global Strategy for Infant and Young Child Feeding and World Health Assembly Resolution WHA54.2 (2001)."

2. DESCRIPTION

Processed cereal-based foods should contain minimum 50% cereals on a dry weight basis

2.1 Product Definitions

Two categories are distinguished:

- 2.1.1 Products consisting of cereals which are or have to be prepared for consumption with milk or other appropriate nutritious liquids;
- 2.1.2 Cereals with an added high protein food which are or have to be prepared for consumption with water or other appropriate protein-free liquid;

2.2 Other Definitions

- 2.2.1 The term infant means a person not more than 12 months of age.
- 2.2.2 The term young children means persons from the age of more than 12 months up to the age of three years (36 months).

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential Composition

- 3.1.1 The two categories listed in 2.1.1 and 2.1.2 are prepared primarily from one or more milled cereal products, such as wheat, rice, barley, oats, rye, maize, millet, sorghum and buckwheat. They may also contain legumes (pulses), or oil seeds in smaller proportions.
- 3.1.2 The requirements concerning energy and nutrients refer to the product ready for use as marketed or prepared according to the instructions of the manufacturer, unless otherwise specified.

3.2 Energy Density

The energy density of cereal-based foods from 2.1.1 and 2.1.2 should not be less than 4.184 kJ/g (1.0 kcal/g) of the reconstituted food.

3.3 Protein

- 3.3.1 The chemical index of the added protein shall be equal to at least 80% of that of the reference protein casein or the Protein Efficiency Ratio (PER) of the protein in the mixture shall be equal to at least 70% of that of the reference protein casein. In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the protein mixture, and only in the proportions necessary for that purpose. Only natural forms of L-amino acids should be used.
- 3.3.2 For product mentioned in point 2.1.2 the added protein content shall not be less than 0.48 g/100 kJ (2 g/100 kcal).

Using WHO growth standards(2006), Children having weight-for-age below -2 standard deviations (SDs) or weight-for-age z-score [WAZ] <-2, are classified as underweight and children at risk of becoming underweight with growth faltering due to inadequate complementary feeding.</p>

http://www.who.int/childgrowth/standards/weight_for_age/en/index.html

3.3.3. For product mentioned at 2.1.2 the total protein content shall not be less than 3g/100 kcal (0.72 g/100kJ)

3.3.4. For products mentioned at 2.1.1 and 2.1.2, the protein content shall not exceed 1.3g/100KJ (5.5g/100Kcal)

3.4 Carbohydrates²

- 3.4.1 If sucrose, fructose, glucose, glucose syrup or honey are added to products mentioned in points 2.1.1:
- the amount of added carbohydrates from these sources shall not exceed 1.8 g/100 kJ (7.5 g/100 kcal);
- the amount of added fructose shall not exceed 0.9 g/100 kJ (3.75g /100 kcal).
- 3.4.2 retained as Part A (CODEX STAN -074, 1981, Rev I 2006).

3.5 Lipids

- 3.5.1 retained as Part A (CODEX STAN -074, 1981, Rev I 2006).
- 3.5.2 Product category 2.1.1 shall not exceed a maximum lipid content of 0.8 g/100 kJ (3.3 g/100 kcal).

3.6 Minerals

- 3.6.1 The sodium content of the products described in Sections 2.1.1 and 2.1.2 of this Standard shall not exceed 24 mg/100 kJ (100 mg/100 kcal) of the ready-to-eat product.
- 3.6.2 The calcium content shall not be less than 12 mg/100 kJ (50 mg/100 kcal) for products mentioned in point 2.1.1 manufactured with the addition of milk and presented as such.
- 3.6.3 The calcium content shall not be less than 20 mg/100 kJ (80 mg/100 kcal) for products mentioned in points 2.1.2.

Sections from 3.7 to Section 5 are retained as Part A (CODEX STAN -074, 1981, Rev I 2006).

6. HYGIENE

"It is recommended that the products covered by the provisions of this standard be prepared and handled in accordance with the appropriate sections of the Code of Practice – General Principle of Hygiene (CAC/RCP 1-1969), Recommended International Codex of Hygienic Practice for Foods for Infants and Children (CAC/RCP 66-2008) and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice.

The product should comply with any microbiological criteria established in accordance with the Principles for the Establishment and application of microbiological Criteria for Foods (CAC/GL 21-1997).

Sections from 7 retained as Part A (CODEX STAN -074, 1981, Rev I 2006).

8. LABELLING

Sections from 8.1.to 8.6 have been retained as Part A (CODEX STAN -074, 1981, Rev I 2006) except 8.6.2, which is as follows:

8.6 Information for Utilization

8.6.2 For products covered by 2.1.1, directions on the label shall state "Milk or other appropriate nutritious liquid but no water shall be used for dilution or mixing" or an equivalent statement.

8.7 Additional Requirements

The products covered by this standard are not breast-milk substitutes and shall not be presented as such <u>and would be covered under National Legislation</u>.

Section 9 is retained as Part A (CODEX STAN -074, 1981, Rev I 2006).

Annexure II

Complementary foods have a composite density ranging from 1.07 to 1.46 kcal/g, (cooked food) (Complementary feeding: family foods for breastfed children, WHO, 2000). This translates into around 4-5 kcal per gram on dry weight basis. Energy density also depends on the number feeds the infant is given. If the baby is taking less number of feeds or fed less quantity than mentioned per feed, the energy density has to be accordingly higher to satisfy the energy and nutrient requirements of the child. Considering that the normal dietary intake of all underweight children is much below the desired level, the energy density needs to be sufficiently high so as to meet the energy and protein needs of the child.

In a paper titled "Update on Technical Issues concerning Complementary Feeding of Young Children in Developing countries and Implications for Intervention Programmes" by Kathryne G. Dewey and Kenneth H. Brown published in Food and Nutrition Bulletin Vol. 24, No.1, 2003, revised summary information for adequately nourished children receiving low (mean –2SD), average, or high (mean +2SD) amounts of breast milk energy has been provided. Extracts concerning minimum dietary energy density (kcal/g) required to attain the level of energy needed from complementary foods in 2 meals/day by children in developing countries with low level of Breast Milk Energy (BME)a intake are as under:

Energy	6-8 months	9 -11 months	12-23 months
	LOW BME	LOW BME	LOW BME
Total energy required +2SD (kcal/day) ^b	769	858	1,118
BME (kcal/day)	217	157	90
Energy required from complementary foods (kcal/day)	552	701	1,028
Minimum energy density (kcal/g) 2 meals/day	1.11	1.23	1.49

a. Assumed functional gastric capacity (30g/kg reference Body Weight) as 249g/meal at 6-8 months, 285 g/meal at 9-11 months, and 345 g/meal at 12-23 months.

The consumption of commercial infant foods constitutes <40% of the total food intake of children in this age group. (Donald Study, from Germany, J ped. Gastroenterology NS nutrition, 1998, 547-52, Food and Nutrition Bulletin, March 2003, Page 11). In most of the developing countries the commercial infant foods form only a part of their regular feeding.

Hence, the calorie density and the protein quantity and quality of cereal based foods for infants and young children are very important since the rest of the home foods in poor households are not energy dense and also lack quality protein.

Minimum protein content at 12% for cereal based foods for infants and young children in the context of developing countries for feeding underweight or children at risk, is for the following reasons:

- Milk intake is low
- Animal Protein as well as total protein intakes are low
- Infection rate is high, and hence
- Prevalence of under nutrition in preschool children is high
- Protein requirements are high and nearly 60% of this has to be met from commercial/complementary infant foods.

b. Total energy requirement is based on new US longitudinal data averages plus 25% (2SD).