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 underweight.

DELETE: “as well as those at risk of becoming underweight.”
If these foods are intended to be used for therapeutic uses then they should not be used as foods to prevent underweight. Support for exclusive breastfeeding for the first six months and the addition of energy dense and nutrient rich local culturally appropriate family foods thereafter and continued breastfeeding to two years and beyond is the WHO recommendation for maintaining optimal nutrient status for infants and young children. Most Member states have included these recommendations in their national IYC feeding policies.

INSERT: The marketing and labeling of these products must be in accordance with the International Code of Marketing of Breast-milk Substitutes\(^1\) and subsequent relevant resolutions of the World Health Assembly.


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 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).

3.3.3 DELETE 2.1.2 and CHANGE TO: 2.1.1

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

3.4 CARBOHYDRATES:
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 (3.75 g/100 kcal).

3.4.2 If sucrose, fructose, glucose, glucose syrup or honey are added to products mentioned in point 2.1.2: - the amount of added carbohydrates from these sources shall not exceed 1.2 g/100 kJ (5 g/100 kcal); - the amount of added fructose shall not exceed 0.6 g/100 kJ (2.5 g/100 kcal).

3.4.1 and 3.4.2
Delete: "honey".

Rationale:

*The addition of honey presents additional risks for microbial contamination of these products which infants should not be exposed to.*

Section 3.4.1 The amounts of added sugars and added fructose should be changed from 7.5 g/100 kcal and 3.75 g/kcal to 3.75 g/100 kcal and 1.9 g/100 kcal respectively, to read:

“3.4.1 If sucrose, fructose, glucose, glucose syrup are added to products mentioned in points 2.1.1 and 2.1.4 - the amount of added carbohydrates from these sources shall not exceed 0.9 g/100 kJ (3.75 g/100 kcal). - the amount of added fructose shall not exceed 0.45 g/100 kJ (1.9 g/100 kcal).”

Section 3.4.2 The amounts of added sugars and added fructose should be changed from 5 g/100 kcal and 2.5 g/kcal to 2.5 g/100 kcal and 1.25 g/100 kcal respectively, to
3.4.2 If sucrose, fructose, glucose, glucose syrup is added to products mentioned in point 2.1.2 kcal),
- the amount of added carbohydrates from these sources shall not exceed 0.6 g/100 kJ (2.5 g/100 kcal).
- the amount of added fructose shall not exceed 0.3 g/100 kJ (1.25 g/100 kcal).
Reduce the amounts of added sugars to not exceed 2.5g/100kcal and fructose to not exceed 2.0g/100kcal.

Rationale:
The sugar content should be lower. In both cases the added sugars should not be as high as 30% of total energy. The WHO Global Strategy on diet, physical activity and health, WHA (57.17) recommends reduced sugar intakes. Its report recommends that intakes of added refined sugars should be less than 10% of total calories consumed. Taste preferences are a learned behaviour and the high levels of 7.5g/100kcal to 5.0/100kcal would encourage the development of preferences for sweetened foods. NOTE the excellent discussion paper presented by Thailand to the CX/CCNFSDU Chiang Mai, 2006, ftp://ftp.fao.org/codex/ccnfsdu28/nf28_10e.pdf

3.5 LIPIDS
3.5.1 For products mentioned in point 2.1.2 the lipid content shall not exceed 1.1g/100 kJ (4.5 g/100 kcal). If the lipid content exceeds 0.8g/100kJ (3.3g/100kcal):
- the amount of linoleic acid (in the form of triglycerides=linoleates) shall not be less than 70 mg/100 kJ (300 mg/100 kcal) and shall not exceed 285 mg/100 kJ (1200 mg/100 kcal);
- the amount of lauric acid shall not exceed 15% of the total lipid content;
- the amount of myristic acid shall not exceed 15% of the total lipid content.
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.

3.6.1. The sodium content should be lower.
CHANGE TO: The sodium content of the products described in Sections 2.1.1 and 2.1.2 of this Standard shall not exceed 15 mg/100 kJ (60mg/100 kcal) of the ready-to-eat product.

Rationale:
The higher sodium levels can negatively impact the systolic pressure of an infant and young child. Children may acquire a preferred taste for foods high in salt. A recent study in the United States showed that almost all 12- to 24-month-old toddlers had salt intake above the “adequate level” of the Dietary Reference Intake established by the Food and Nutrition Board of the Institute of
Medicine, and the mean salt intake was \( 4.1 \text{~g/d} \) (2). There is evidence suggesting that salt intake in early life may have a long-lasting effect on BP.


http://www.sciencedirect.com/science?_ob=MiamiImageURL&_cid=272865&_user=125872&_pii=S0002822305017281&_check=y&_origin=&_coverDate=31-Jan-2006&view=c&wchp=dGLbVlSkzk&md5=f5010b0305915fe6c33098221d4ee9ec/1-s2.0-S0002822305017281-main.pdf

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.

3.7 VITAMINS: 3.7.1 The amount of vitamin B1 (thiamin) shall not be less than \( 12.5 \text{~g/100 kJ} \) (50 \text{~g/100 kcal}).
3.7.2 For products mentioned in 2.1.2, the amount of vitamin A and vitamin D shall be within the following limits:

These limits are also applicable to other processed cereal-based foods when vitamin A or D are added.
3.7.3 Reductions of the maximum amounts for vitamin A and Vitamin D referred to in 3.7.2 and the addition of vitamins and minerals for which specifications are not set above shall be in conformity with the legislation of the country in which the product is sold.

\[
\begin{align*}
\text{vitamin A (g retinol equivalents)} & \\
14-43 & \\
60 & – 180 \\
\text{vitamin D} & \\
0.25-0.75 & \\
1 & – 3
\end{align*}
\]

Similar to the document of CODEX STAN 074-1981, Rev. 1-2006
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3.7.4 Vitamins and/or minerals added should be selected from the Advisory Lists of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979).

3.8 OPTIONAL INGREDIENTS

3.8.1 In addition to the ingredients listed under 3.1, other ingredients suitable for infants who are more than six months of age and for young children can be used.

Change to read

In addition to the ingredients listed under 3.1, other specified ingredients suitable for infants who are more than six months of age or for young children can be added but only if they have first shown to be safe and nutritionally useful for consumption by infants, by an independent systematic review of all research, that must include independently-funded research. Minimum and maximum amounts must be stated for each permitted ingredient. At the earliest opportunity the composition requirements listed in the Codex standard must be updated to keep pace with
such developments.

**Rationale**  Failure to require rigorous pre-authorisation of ingredients before their safety has been properly evaluated will mean that vulnerable infants will effectively take part in a mass uncontrolled trial. Manufacturers justify this practice by referring to a 'history of safe use' or suggesting that problems would come to light in consumer phone lines. There is no evidence to support such claims. (10)

3.8.2 Products containing honey or maple syrup should be processed in such a way as to destroy spores of *Clostridium botulinum*, if present.

**CHANGE TO READ:** If honey or maple syrup is present than the product must be labelled for use after 12 months.

**Rationale:**  
If these ingredients are present, then the food may be contaminated and unfit for consumption by infants and young children. To eliminate any risk of contamination it is preferable to prohibit these ingredients as sweeteners for foods for infants under 12 months of age.

**ADD:** If cocoa is present then the product must be labelled for use after 12 months.

**Rationale:**  
*IBFAN* is very concerned about the addition of cocoa to cereals for infants and young children for a number of reasons, especially for underweight children, who may have compromised capacity to deal with the neurological side effects of cocoa.  
Cereals with added cocoa generally contain high levels of sugar and therefore have the potential to create dietary preferences in favour of chocolate and other sweet foods. The WHO Global Strategy on Diet, Physical Activity and Health recommends that the sugar consumption in an individual’s diet should not exceed 10% of total calories in order to reduce the incidence of obesity, cardiovascular disease and diabetes. These diet-related, chronic diseases are prevalent in industrialized countries and are becoming an emerging nutritional problem in developing countries.  
Cocoa added to cereals for infants and young children may also add to the allergenicity of cereal foods.  
Cocoa and high sugar cereal-based foods for infants and young children have a low nutrient to calorie ratio, yet these products are aggressively marketed for and to young children at a time when nutritional status should be optimal to support the highest attainable standard of growth, development and health.
There is abundant literature on the ingestion of cocoa and its main CNS (central nervous system) active substances methylxanthine theobromine and caffeine for mice, rats, racehorses and racing greyhounds. The following effects were detected:

- Theobromine inhibited body weight gain in rats. Sertoli cells in testes seems to be the primary target for the theobromine toxicity.
- Avoidance reactions were decreased while ambulation was increased in mice.
- Caused vacuolation within the Sertoli cells, abnormally shaped spermatids and alters testis structure.
- Decrease of relative length of limbs and decrease in bone vascular endothelial growth factor in offspring of mice.

Although there are few published papers on the effects of cocoa on humans, evidence raises concerns about exposing infants and young children to these CNS active ingredients. IBFAN could not find a single paper that demonstrates the safety of cocoa use in food products for infants and young children. Statements made in the scientific literature regarding the use of cocoa are as follows:

- The results suggest that a usual dietary portion of chocolate would produce behaviourally discriminable plasma levels.
- A normal portion of chocolate exhibits psychopharmacological activity.
- The paper concluded with a call for caution in the use of caffeine and theobromine pending further and more elaborate investigations.

3.8.3 Only L(+) lactic acid producing cultures may be used. 3.9

**FLAVOURS**

The following flavours may be used:

- Natural fruit extracts and vanilla extract: GMP
- Ethyl vanillin and vanillin: 7 mg/100 g RTU

3.10 QUALITY FACTORS

3.10.1 All ingredients, including optional ingredients, shall be clean, safe, suitable and of good quality. It should be free from preservative and added colours.
3.10.2 All processing and drying should be carried out in a manner that minimizes loss of nutritive value, particularly protein quality.
3.10.3 The moisture content of the products shall be governed by good manufacturing practice for the individual product categories and shall be at such a level that there is a minimum loss of nutritive value and at which microorganisms cannot multiply.

3.11 CONSISTENCY AND PARTICLE SIZE

3.11.1 When prepared according to the label directions for use, processed cereal-based foods should have a texture appropriate for the spoon feeding of infants or young children of the age for which the product is intended.

3.12 SPECIFIC PROHIBITION

The product and its components shall not have been treated by ionizing radiation. The use of partially hydrogenated fats for these products is prohibited.

4. FOOD ADDITIVES

Only the food additives listed in this Section or in the Codex Advisory List
of Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979) may be present in the foods described in Section 2.1 of this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:

a) The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and

b) The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the General Standard for Food Additives (CODEX/STAN 192-1995).

The following additives are permitted in the preparation of processed cereal-based foods for infants and young children, as described in Section 2.1 of this Standard (in 100 g of product, ready for consumption prepared following manufacturer’s instructions unless otherwise indicated).

IBFAN is very concerned about the number of food additives permitted. Undernourished children may be more at risk for side effects of colouring agents, emulsifiers and thickening agents. These are not essential to the product, but are cosmetic only and should therefore not be permitted.

5. CONTAMINANTS

5.1 PESTICIDE RESIDUES:
The product shall be prepared with special care under good manufacturing practices, so that residues of those pesticides which may be required in the production, storage or processing of the raw materials or the finished food ingredient do not remain, or, if technically unavoidable, are reduced to the maximum extent possible.

These measures shall take into account the specific nature of the products concerned and the specific population group for which they are intended.

Reword to read:

The product shall be prepared with special care under good manufacturing practices, so that residues of those pesticides which may be required in the production, storage or processing of the raw materials or the finished food ingredient do not remain, or if technically unavoidable, are reduced to the maximum extent possible do not exceed a maximum level of 0.01 mg/kg for each substance in the product as sold.

Rationale:

Underweight infants and children are at greater risk for negative effects of contaminants. Part B should have a stated maximum level for pesticides and not vague phrases such as the present text, "reduced to the maximum extent possible". There are 200 known pesticides found in baby foods. By not stating the maximum allowable levels for each pesticide the cumulative pesticide load is unclear and may present a health hazard to babies and young children. Children are now exposed to more than 50,000 high-production volume synthetic chemicals. Young children are uniquely vulnerable to pesticide exposure and certain cancers have been linked to their presence in foods.
The maximum values as set in the Commission Directive on processed cereal-based foods and baby foods for infants and young children can be applied here, as this offers an achievable protection of infants and young children from pesticide ingestion.

5.2 OTHER CONTAMINANTS: The product shall be free from residues of hormones, antibiotics as determined by means of agreed methods of analysis and practically free from other contaminants, especially pharmacologically active substances.

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).

Reword to read:
The products covered by the provisions of this standard shall be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice – Recommended International Code of Hygenic Practice for Foods for Infants and Young Children (CAC/RPC 21-1997 (under revision) and other relevant Codex texts such as Codes such as Codes of Hygienic Practice and Codes of Practice.

Rationale:
Underweight infants and young children may be immunocompromised and at greater risk for infections from contaminated food products.

Stating that the product shall be manufactured in accordance with these Codes of practice is stronger than a recommendation that the product be made in accordance with them.

As the pathogen Chronobacter sakazakii has been shown to be present in cereal-based foods supplemented with added powdered infant formula, special hygienic measures should be taken during the manufacturing process and warnings placed on the labels to inform caregivers of the risk of microbial contamination of these products.

7. PACKAGING: 7.1 The product shall be packed in containers which will safeguard the hygienic and other qualities of the food.

7.2 The containers, including packaging material, shall be made only of substances which are safe and

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suitable for their intended use. Where the Codex Alimentarius Commission has established a standard for any such substance used as packaging material, that standard shall apply.

8. LABELLING


8.1.2 Taking into account paragraph 1.4 of the Guidelines for Use of Nutrition and Health Claims, nutrition claims may be permitted under national legislation for the foods that are the subject of the standard provided that they have been demonstrated in rigorous studies with adequate scientific standards.

DELETE 8.1.2 and REPLACE with the following text:

“Nutrition and health claims shall not be permitted for foods covered by the scope of the provisions of this standard. The label shall have no pictures OR TEXT – either on the label or in the Name of the Product which suggests a health advantage, idealizes the product or suggests an inappropriate age of introduction for these products. Terms which suggest that the product is like human milk should not be permitted.

Rationale:

Underweight infants and young children in particular, need protection from needless and inappropriate use of these products.

Health and nutrition claims as text or graphics have the potential to deceive parents, suggesting that these products have a nutritional advantage over safe indigenous family foods. By distorting parents perceptions about the nutritional value of processed foods, and diverting attention from the risks, claims increase the risk of sub-optimal nutrition in this critical period of development of at risk children. Excessive sugar, other low-nutrient food ingredients, food additives and contaminants are characteristic of these products. As well, claims can lead to early complementation of breastmilk and so can seriously compromise an infant’s nutritional and immunological needs.

Claims have the potential outcome of placing infants and young children at risk for nutritional deficiencies related to intakes of excessive sugar, other low-nutrient food ingredients and food additives/contaminants characteristic of many of these products. As well, claims can lead to early complementation of breastmilk and seriously compromise an infant’s nutritional and immunological needs.

Nutrition claims are marketing tools which violate the aims and spirit of the International Code and its subsequent relevant Resolutions. Even though we welcome the safeguards in 3.10.1 regarding particle size and spoon feeding, the promotional impact of claims is still likely to persuade caregivers to use these
products inappropriately and will increase the danger of cereal-based foods being fed through feeding bottles and used as breastmilk substitutes at too early an age, undermining the optimum period of exclusive breastfeeding. The promotion of processed packaged foods for infants with nutrition claims will damage confidence in safe, indigenous family foods, exacerbating family poverty and increasing the risks of malnutrition.

The World Health Assembly supports the use of indigenous foods. It has repeatedly stressed how infant and young-child mortality can be reduced by: “exclusive breastfeeding for the first six months with nutritionally adequate and safe complementary feeding through the introduction of safe and adequate amounts of indigenous foodstuffs and local foods while breastfeeding continues up to the age of two years or beyond” (WHA Resolution 54.2, May 2001).

The Assembly also warns that: “the introduction of micronutrient interventions and the marketing of nutritional supplements do not replace, or undermine support for the sustainable practice of, exclusive breastfeeding and optimal complementary feeding” (WHA Resolution 55.25, May 2002).

Nutrition and health claims are not the same as nutrition information (which is essential) and are intended to create a perceived advantage, or to “idealize” commercial foods for infants and young children over indigenous foods.

The scientific articles used to justify claims are invariably funded and/or authored by product manufacturers. In the case of infant feeding this is far too risky.

The above changes will be in accordance with the Guidelines for Use of Nutrition and Health Claims

8.1.3 Any indication required in the labelling should be made in the appropriate language(s) of the country in which the product is sold.

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8.2 THE NAME OF THE FOOD
The name of the food shall be “Processed Cereal Based Foods for Underweight Infants (and/or Young Children)”, or any appropriate designation indicating the true nature of the food, in accordance with national legislation.

8.3 LIST OF INGREDIENTS
8.3.1 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these may be arranged as separate groups for vitamins and minerals, respectively, and within these groups the vitamins and minerals need not be listed in descending order of proportion.
8.3.2 The specific name shall be declared for ingredients and food additives. In addition, appropriate class names for these ingredients and additives may be included on the label.
8.4 DECLARATION OF NUTRITIVE VALUE:
8.4.1 The declaration of nutrition information shall contain the following information which should be in the following order:
(a) The energy value, expressed in kilocalories (kcal) and kilojoules (kJ), and the amount of protein, carbohydrate and fat expressed in gram (g) per 100 g or 100 ml of the food as sold, and where appropriate, as per specified quantity of the food as suggested for consumption;
(b) The average amount of each vitamin and mineral for which specific levels are defined in section 3.6 and 3.7 expressed in numerical form per 100g or 100 ml of the food as sold; Similar to the document of CODEX STAN 074-1981, Rev. 1-2006 and, where appropriate, as per specified quantity of the food as suggested for consumption;
(c) Any other nutritional information required by national legislation.
8.4.2 The labelling may bear the average amount of the vitamins and minerals when their declaration is not covered by the provisions of section 8.4.1 (b) expressed in numerical form per 100g or 100 ml of the product as sold and, where appropriate, per specified quantity of the food as suggested for consumption.

8.5 DATE MARKING AND STORAGE INSTRUCTIONS:
8.5.1 The date of minimum durability (preceded by the words "best before") shall be declared by the day, month and year in uncoded numerical sequence except that for products with a shelf-life of more than three months, the month and year will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer. In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative.
8.5.2 In addition to the date, any special conditions for the storage of the food shall be indicated if the validity of the date depends thereon.
8.5.3 Where practicable, storage instructions shall be in close proximity to the date marking.

INFORMATION FOR UTILIZATION:
8.6.1 Directions as to the preparation and use of the food, and its storage and keeping before and after the container has been opened, shall appear on the label and may also appear on the accompanying leaflet.
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.
8.6.3 When the product is composed of gluten-free ingredients and food additives, the label may show the statement †“gluten-free”.
8.6.4 The label shall indicate clearly from which age the product is recommended for use. This age shall not be less than six months for any product. In addition, the label shall include a statement indicating that the decision when precisely to begin complementary feeding, including any exception to six months of age, should be made in consultation with a health worker, INSERT: independent of commercial influence based on the individual infant’s specific growth and development needs. Additional requirements in this respect may be made in accordance with the legislation of the country in which the product is sold.

8.6.5 Add 8.6.5 to read:
“The label shall contain the following statement: 'Important notice: For optimal child nutrition and health, breastfeeding should continue along with the feeding of complementary foods’.”
Rationale:

*Parents should be notified that the introduction of complementary foods does not signal a need to stop breastfeeding. Sustained breastfeeding is critical for underweight infants and young children. Breastmilk continues to be the most important source of nutrition after six months of age. WHO and UNICEF policy encourage mothers to breastfeed for 2 years and beyond.*

8.7 ADDITIONAL REQUIREMENTS

The products covered by this standard are not breast-milk substitutes and shall not be presented as such and would be covered under National legislation.

METHODS OF ANALYSIS AND SAMPLING