

# CODEX ALIMENTARIUS

INTERNATIONAL FOOD STANDARDS



Food and Agriculture  
Organization of  
the United Nations



World Health  
Organization

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## GUIDELINES ON FORMULATED COMPLEMENTARY FOODS FOR OLDER INFANTS AND YOUNG CHILDREN

CAC/GL 8-1991

Adopted in 1991. Amended in 2017. Revised in 2013.

## 1. PURPOSE

To provide guidance on nutritional and technical aspects of the production of Formulated Complementary Foods for Older Infants and Young Children as defined in Section 3.1, including:

- i. Formulation of such foods, based on the nutritional requirements of older infants and young children;
- ii. Processing techniques;
- iii. Hygienic requirements;
- iv. Provisions for packaging;
- v. Provisions for labelling and instructions for use.

## 2. SCOPE

The provisions of these Guidelines apply to Formulated Complementary Foods for Older Infants and Young Children as defined in Section 3.1 below and include but are not limited to porridges containing cereals, ready-to-use products and food-based home fortificants. Micronutrient supplements, processed cereal based foods<sup>1</sup>, and canned baby foods<sup>2</sup> are not covered by these Guidelines.

These Guidelines should be used in accordance with the Global Strategy for Infants and Young Child Feeding and World Health Assembly Resolution WHA54.2 (2001).

## 3. DESCRIPTION

**3.1 Formulated Complementary Foods for Older Infants and Young Children** means foods that are suitable for use during the complementary feeding period. These foods are specifically formulated with appropriate nutritional quality to provide additional energy and nutrients to complement the family foods derived from the local diet by providing those nutrients which are either lacking or are present in insufficient quantities.

**3.2 Older infants** means persons from the age of 6 months and not more than 12 months of age.

**3.3 Young children** means persons from the age of more than 12 months up to the age of three years (36 months).

**3.4 Complementary feeding period** means the period when older infants and young children transition from exclusive feeding of breastmilk and/or breastmilk substitutes to eating the family diet<sup>3</sup>.

## 4. SUITABLE RAW MATERIALS AND INGREDIENTS

### 4.1 Basic Raw Materials and Ingredients

The following raw materials, most of which are locally available, are suitable ingredients for the production of Formulated Complementary Foods for older infants and young children under the specified conditions given below:

#### 4.1.1 Cereals

**4.1.1.1** All milled cereals suitable for human consumption may be used provided that they are processed in such a way as to reduce the fibre content, when necessary, and to decrease and, if possible, to eliminate anti-nutrients such as phytates, tannins or other phenolic materials, lectins, trypsin, and chymotrypsin inhibitors which can lower the protein quality and digestibility, amino acid bioavailability and mineral absorption. The use of appropriate enzymes may be considered to decrease fibre and anti-nutrients, if needed.

**4.1.1.2** Besides carbohydrates (mainly consisting of starch) cereals contain a significant quantity of protein (8-12%) but are limiting in the amino acid lysine. Combining cereals with legumes and/or pulses, which are higher in lysine, can compensate for the limiting level in cereals.

#### 4.1.2 Legumes and Pulses

**4.1.2.1** Legumes and pulses, such as chick peas, lentils, peas, cowpeas, mungo beans, green gram, kidney beans and soya beans, containing at least 20% protein on a dry weight basis.

<sup>1</sup> *Standard for Processed Cereal-Based Foods for Infants and Young Children* (CODEX STAN 74-1981)

<sup>2</sup> *Standard for Canned Baby Foods* (CODEX STAN 73-1981)

<sup>3</sup> According to the WHO, 2002, Complementary Feeding, Report of the Global Consultation appropriate complementary feedings should start from the age of six months with continued breast feeding up to two years or beyond ; refer also to WHO 2003 Guiding Principles for Complementary feeding of the breastfed child, WHO 2005 Guiding principles for feeding non-breastfed children 6-24 months of age.

- 4.1.2.2** On the whole, legumes and pulses are deficient in L-methionine. Depending on the nature of the other ingredients in the formulation, the addition of L-methionine may be desirable in order to improve the nutritional value of the product.
- 4.1.2.3** Legumes and pulses must be appropriately processed to reduce, as much as possible, the anti-nutritional factors normally present, such as phytate, lectins (haemagglutinins), trypsin and chymotrypsin inhibitors. When phytoestrogen containing legumes and pulses such as soya are added as an ingredient, products with low levels of phytoestrogens should be used.
- Lectins can be reduced by moist heat treatment;
  - Trypsin inhibitor activity may be reduced to acceptable levels by heating to high temperatures or by prolonged boiling.
  - Phytate can be reduced enzymatically or by soaking or fermentation.
  - Phytoestrogens can be reduced by fermentation.
- 4.1.2.4** Field beans or faba beans (*Vicia faba L.*) should not be used in the formulation of Complementary Food for Older Infants and Young Children because of the danger of favism. Heat treatment does not completely inactivate the toxic components (vicine and co-vicine).

#### **4.1.3 Oil Seed Flours and Oil Seed Protein Products**

- 4.1.3.1** Flours, protein concentrates and protein isolates of oil seeds are acceptable if manufactured to appropriate specifications<sup>4,5,6,7</sup> which assure sufficient reduction of anti-nutritional factors and undesirable toxic substances such as trypsin and chymotrypsin inhibitors and gossypol. The decision to add oil seeds flour to a formulated complementary food should take into account local conditions and requirements. Such oil seeds may include

Soya beans: dehulled flour, (full fat and defatted) protein concentrate, protein isolate

Groundnuts: paste, protein isolate

Sesame seed: whole ground and defatted flour

Cottonseed: defatted flour

Sunflower seed: defatted flour, full fat

Low erucic acid rapeseed: full fat flour.

- 4.1.3.2** Defatted oil seed flours and protein isolates, if produced and appropriately processed for human consumption, can be good sources of protein (50-95%).

#### **4.1.4 Animal Source Foods**

Animal source foods such as meat, fish, poultry, eggs, milk and milk products are nutrient dense and good sources of high quality proteins and micronutrients and incorporation of these foods or their derived protein concentrates in Formulated Complementary Foods as technologically feasible is encouraged.

#### **4.1.5 Fats and Oils**

- 4.1.5.1** Fats and oils can be incorporated in adequate quantities as technologically feasible for the purpose of increasing the energy density of the product. Care must be taken to avoid oxidized fat which will adversely affect nutrition, flavour and shelf life. Such care is important for fat-containing ingredients (e.g., oil seed flours and oil seed protein products, fish meals, and fish protein concentrates) as well as fats and oils.
- 4.1.5.2** Partially hydrogenated fats (and oils) should not be used in Formulated Complementary Foods.

#### **4.1.6 Fruits and Vegetables**

Fruits and vegetables may be good sources of micronutrients and can be added to Formulated Complementary Foods, when technologically feasible.

<sup>4</sup> The following Guidelines were elaborated by the FAO/WHO/UNICEF Protein and Energy Advisory Group:

PAG Guidelines No 2: Preparation of Food Quality Ground Flour

PAG Guidelines No 4: Preparation of Edible Cotton Seed Protein Concentrates

PAG Guidelines No 5: Guideline for Heat Processed Soy Grits and Flours

<sup>5</sup> *Standard for Vegetable Protein Products* (CODEX STAN 174-1989)

<sup>6</sup> *Standard for Soy Protein Products* (CODEX STAN 175-1989)

<sup>7</sup> *Standard for wheat protein products including wheat gluten* (CODEX STAN 163-1987)

## 4.2 Other Ingredients

Other ingredients, including those listed below, may be used to improve the nutritional quality and/or acceptability of the Formulated Complementary Foods provided that they are readily available and have been proven to be suitable and safe for their intended purpose.

### 4.2.1 Digestible carbohydrates

Energy density of Formulated Complementary Foods can be increased by the addition of appropriate digestible carbohydrates.

### 4.2.2 Food additives and flavourings

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.

Only the food additives referred to in those Standards may be present in the foods covered by these Guidelines, as a result of carry-over from a raw material or other ingredients (including food additives) 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 material 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).

## 5. TECHNOLOGIES FOR AND EFFECTS OF PROCESSING

### 5.1 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:

- 5.1.1 **Cleaning or washing:** to eliminate dirt, damaged grains, foreign grains and noxious seeds, insects and insect excreta and any adhering material.
- 5.1.2 **Dehulling:** when necessary, pulses, legumes, oilseeds and certain cereals such as oats, barley, sorghum, millet and teff should be dehulled as completely as is feasible to reduce the fibre content to acceptable levels and to decrease, and 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.
- 5.1.3 **Degermination:** where necessary and appropriate, degermination of wheat, corn, soy and other crops should be considered in order to reduce the phytate content.

### 5.2 Milling

- 5.2.1 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.
- 5.2.2 Dry raw materials may be milled together, if technologically feasible, or mixed after milling or grinding.
- 5.2.3 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 legumes and pulses. Boiling improves the digestibility and absorption of nutrients.
- 5.2.4 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.

### 5.3 Toasting

- 5.3.1 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.

**5.3.2** Protein damage due to the Maillard reaction may occur in the presence of reducing carbohydrates. The toasting process should therefore be carefully controlled.

**5.3.3** Pulses as well as oilseeds such as soya beans, groundnuts and sesame seeds can be toasted as whole grains directly or after soaking.

**5.3.4** Toasted raw materials can be milled or ground for use as ingredients.

## **5.4 Sprouting, Malting and Fermentation**

**5.4.1** 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 predigestion 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.

**5.4.2** 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.

## **5.5 Other Processing Technologies**

### **5.5.1 Extrusion Cooking**

**5.5.1.1** The mix of milled or ground basic ingredients (cereals, pulses, oilseed flours) may be further processed by extrusion cooking. Extrusion cooking may decrease available L-lysine, sulphur-containing amino acids, L-arginine, L-tryptophan and vitamins. The process should therefore be carefully controlled. The extruded product, after drying if necessary, is milled or ground to the desired particle size.

**5.5.1.2** The effects of this technology are:

- gelatinization of the starchy portion of the mixture with minimal quantities of water;
- inactivation of lectins and reduction of trypsin inhibitor activity;
- a reduction in the quantities of water needed for preparation of the food;
- flavour development.

### **5.5.2 Enzymatic Predigestion**

**5.5.2.1** With this process the milled or ground basic ingredients (cereals, pulses, and oilseed flours) can be processed in the presence of water and appropriate enzymes under continuous stirring until the mixture acquires the desired fluidity. In the case of the use of amylase, starch molecules are split into dextrans and reducing sugars. After raising the temperature to inactivate the enzyme, the slurry is dried and comminuted to flour or to small flakes to allow for greater nutrient density.

**5.5.2.2** The predigested product may have improved organoleptic characteristics, higher digestibility, good solubility, requires less water for the preparation of the food, and hence higher nutrient density.

## **6. NUTRITIONAL COMPOSITION AND QUALITY FACTORS**

### **6.1 General Aspects**

**6.1.1** The selection of raw materials and ingredients for the formulation of Formulated Complementary Foods for Older Infants and Young Children should be made having regard to the provisions in Sections 4 and 5 and taking into account the following aspects:

- nutrient content of the local diet;
- dietary habits and infant feeding practices;
- other socio-economic aspects as determined by the national authorities dealing with nutrition;
- availability and quality of raw materials and ingredients.

**6.1.2** All processing should be carried out in a manner that maintains protein quality and minimizes loss of micronutrients and maintains overall nutritive value.

**6.1.3** Ten to fifty grammes of the Formulated Complementary Food, when prepared according to the instructions, is considered a reasonable quantity which an older infant or young child during the complementary feeding period can ingest easily in one feeding and who may receive two or more feedings per day, depending on age. The range in amount per feeding allows for the various types of Formulated Complementary Foods. The lower part of the range applies to products with higher energy density (e.g. lipid-based products) whereas the upper part of the range would apply to products with lower energy density (e.g. porridges containing cereals).

## 6.2 Energy

**6.2.1** The energy density of a mixture of milled cereals and pulses and defatted oilseed meals and flours on dry weight basis is relatively low.

**6.2.2** The energy density of the food can be increased during manufacture 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 5.

**6.2.3** The energy density of the Formulated Complementary Food should be at least 4 kcal per gram on dry weight basis.

## 6.3 Proteins

**6.3.1** Mixtures of cereals, legumes, pulses and/or oilseed flours, can constitute an appropriate source of proteins, provided that the proteins in the Formulated Complementary Food satisfy the criteria below. Protein quality can also be improved by the inclusion of fish products, milk and milk products and/or other animal source foods.

**6.3.2** The Protein Digestibility Corrected Amino Acid Score (PDCAAS)<sup>8910</sup> should not be less than 70 per cent of that of the WHO amino acid reference pattern for children from 2 – 5 years .

**6.3.3** If, for technical reasons, the PDCAAS digestibility of a protein cannot be determined, the protein quality should be measured by biological assays. Alternatively, the protein quality may be calculated from published data on essential amino acid patterns of dietary proteins and their digestibility.

**6.3.4** The addition of methionine, lysine, tryptophan or other limiting amino acids, solely in the L-form should be contemplated only when, for economic and technological reasons, no mixture of vegetable and/or animal proteins makes it possible to obtain an adequate protein quality (see 6.3.2).

**6.3.5** Taking into account the preceding considerations, the energy from protein<sup>11</sup> should not be less than 6 % of the total energy from the product and typically should not exceed 15%<sup>12</sup>

## 6.4 Fat

**6.4.1** Incorporation of fats and/or oils in Formulated Complementary Foods serves to increase the energy density and the amount of essential fatty acids as well as reduce total volume of the food consumed. At least 20 % of energy derived from fat<sup>13</sup> is desirable.

**6.4.2** The level of linoleic acid (in the form of glycerides) should not be less than 333 mg per 100 kcal or 1.6 g per 100 g of dry product and the fat or oil when used in the production of Formulated Complementary Foods should ensure a ratio between linoleic acid and alpha-linolenic acid of between 5:1 and 15:1.

**6.4.3** The use of edible oils containing polyunsaturated fatty acids, including omega-3 fatty acids and in particular docosahexaenoic acid, should be considered. The levels in the FAO/WHO recommendations<sup>14</sup> may be considered.

<sup>8</sup> PDCAAS (%) =  $\frac{\text{mg of limiting amino acid in 1 gram of test protein}}{\text{mg of limiting amino acid in 1 gram of reference protein}} \times \text{true digestibility of test protein} \times 100$

<sup>9</sup> The limiting amino acid is the essential amino acid present in the lowest proportion as compared with the quantity of this amino acid reference pattern

<sup>10</sup> Sarwar, G., J. Nutr. 1997, 127:758-764.

<sup>11</sup> Conversion factor based on *Guidelines on Nutrition Labelling* (CAC/GL 2-1985)

<sup>12</sup> Michaelsen KF et al. 2009. Food and Nutr Bull 30:343-404

<sup>13</sup> Conversion factor based on *Guidelines on Nutrition Labelling* (CAC/GL 2-1985)

<sup>14</sup> FAO/WHO Expert Consultation on Fats and Fatty Acids in Human Nutrition. Geneva 2008.

## 6.5 Carbohydrates

**6.5.1** Starch is likely to be a major constituent of many Formulated Complementary Foods. To ensure that its energy value is realized, this starch should be provided in a readily digestible form. Guidance on increasing the digestibility of starches is given in Section 5. Any carbohydrate added for sweetness should be used sparingly.

**6.5.2** Dietary fibres and other non-absorbable carbohydrates are partially fermented by the intestinal flora to produce short-chain fatty acids, lactate and ethanol which may subsequently be absorbed and metabolized.

Increasing the intake of dietary fibres<sup>15</sup> increases stool bulk, may cause flatulence and decrease appetite. Fibre load also can reduce the energy density of Formulated Complementary Foods. They also may affect the efficiency of absorption of important nutrients from diets with marginal nutrient contents. The dietary fibre content of the Formulated Complementary Food should therefore be reduced to a level not exceeding 5 g per 100 g on a dry weight basis.

## 6.6 Vitamins and Minerals

### 6.6.1 *Setting levels for the addition of vitamins and minerals*

**6.6.1.1** The decision to add vitamins and minerals to a Formulated Complementary Food should take into account local conditions including the nutrient contribution to the diet from local foods, vitamins and minerals provided by national programs, food processing technologies applied and the nutritional status of the target population as well as the requirements stipulated by national legislation and the *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 9-1987).

**6.6.1.2** If the dietary intake data for the target population are available, they can be used to determine appropriate levels for the addition of vitamins and/or minerals to ensure a low prevalence of either inadequate or excessive nutrient intakes using available assessment or monitoring tools.

**6.6.1.3** If the dietary intake data for the target population is not available, the vitamins and minerals listed in the Table in the Annex to these Guidelines can be used as a reference for the selection of particular vitamins and minerals and their amounts for addition to a Formulated Complementary Food.

**6.6.2** National authorities should ensure that the total micronutrient intake from the Formulated Complementary Foods, local diet (including breastmilk and/or breastmilk substitutes) and other sources do not regularly exceed recommended upper levels of micronutrient intake for older infants and young children.

### 6.6.3 *Selecting vitamins and/or minerals for nutrient addition*

**6.6.3.1** When establishing the specifications for the premix of vitamin compounds and mineral salts, the vitamin and mineral content and presence of antinutritive substances in the other ingredients used in the formulation of the food should be taken into account.

**6.6.3.2** Vitamins and/or minerals should be selected from the *Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children* (CAC/GL 10-1979) those authorised for cereal-based foods and canned baby foods.

**6.6.3.3** The choice of a vitamin and/or mineral compound should take into account its relative bioavailability within the food vehicle, the effect on the sensory properties of the food vehicle and its stability in the packaged food vehicle under normal storage conditions. The *General Principles for the Addition of Essential Nutrients to Foods* (CAC/GL 9-1987) provides specific guidelines in this area.

## 7. CONTAMINANTS

### 7.1 Pesticides Residues

The products should 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 ingredients do not remain, or, if technically unavoidable, are reduced to the maximum extent possible.

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

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<sup>15</sup> Definition of Dietary Fibre given in the *Guidelines on Nutrition Labelling* (CAC/GL 2- 1985).

## 7.2. Other Contaminants

The product should not contain contaminants or other undesirable substances (e.g. biologically active substances) in amounts which may represent a hazard to the health of older infants and young children. The product covered by the provisions of these Guidelines shall comply with those maximum residue limits and maximum levels established by the Codex Alimentarius Commission.

## 8. HYGIENE

- 8.1 It is recommended that the products covered by the provisions of these Guidelines be prepared and handled in accordance with the appropriate sections of the *General Principles of Food Hygiene* (CAC/RCP 1-1969) 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 and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CAC/GL 21-1997).

- 8.2 The ingredients and final product should be prepared, packed and held under sanitary conditions and should comply with relevant Codex texts<sup>16</sup>.

## 9. PACKAGING

- 9.1 It is recommended that Formulated Complementary Foods for Older Infants and Young Children be packed in containers which will safeguard the hygienic and other qualities of the food.

- 9.2 The containers, including packaging material, shall be made only of materials 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 material, that standard shall apply.

## 10. LABELLING

- 10.1 It is recommended that the labelling of Formulated Complementary Foods for Older Infants and Young Children be in accordance with the *General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses* (CODEX STAN 146-1985), the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997) and the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985).

- 10.2 The following mandatory provisions should apply:

### 10.2.1 The Name of the Food

The name of the food to be declared on the label shall indicate that the food is a Formulated Complementary Food for Older Infants and Young Children. The appropriate designation indicating the true nature of the food should be in accordance with national legislation. The major sources of protein and the age from which the product is recommended for use shall appear in close proximity to the name of the food.

### 10.2.2 List of Ingredients

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

### 10.2.3 Declaration of Nutritive Value

The declaration of energy and nutrients on the label or in labelling shall contain the following information expressed per 100 grammes of the Formulated Complementary-Food as sold or otherwise distributed as well as per feeding of the food ready for consumption:

- (a) energy value, expressed in kilocalories and kilojoules;
- (b) the amounts of protein, carbohydrates and fat, expressed in grammes;
- (c) in addition to any other nutritional information required by national legislation, the total quantity per feeding of the Formulated Complementary Food ready for consumption of each vitamin and mineral added in accordance with Section 6.6, expressed in metric units.

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<sup>16</sup> Examples of relevant Codex texts include *Principles and Guidelines for the Establishment and Application of Microbiological Criteria related to Foods* (CAC/GL 21- 1997); *Code of Hygienic Practice for Milk and Milk Products* (CAC/RCP 57-2004); *Code of Practice for the Reduction of Acrylamide in Foods* (CAC/RCP 67-2009); *Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts* (CAC/RCP 55-2004); *Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals* (CAC/RCP 51-2003)

**10.2.4 Instructions for use**

- 10.2.4.1** 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. In addition, the label shall include a statement indicating that the decision when precisely to introduce formulated complementary feeding, including any exception to six months of age, should be made in consultation with a health worker, 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.
- 10.2.4.2** Directions as to the preparation and use of the food shall be given; preferably accompanied by graphical presentations.
- 10.2.4.3** The suggested number of feedings per day should be indicated.
- 10.2.4.4** In the case that addition of water is needed, the directions for the preparation shall include a precise statement that:
- (a) where the food contains non-heat-processed basic ingredients, the food must be adequately boiled in a prescribed amount of water;
  - (b) where the food contains heat-processed basic ingredients:
    - (i) the food requires boiling, or
    - (ii) can be mixed with boiled water that has been cooled.
- 10.2.4.5** For Formulated Complementary Foods to which fats, sugars or other digestible carbohydrates should be added during preparation, the instructions for use shall identify appropriate sources and indicate the amounts of the ingredients to be added. In such situations, fats and oils with an appropriate essential fatty acid ratio should be recommended.
- 10.2.4.6** Directions for use shall include a statement that only an amount of food sufficient for one feeding occasion should be prepared at one time. Foods not consumed during the feeding occasion should be discarded, unless consumed within a period as recommended by the manufacturer under the instructions for use.
- 10.2.4.7** The label should also include a statement that Formulated Complementary Foods are to be consumed to complement family foods and breastmilk/breastmilk substitutes.

**11. Additional Requirements:**

The products covered by these Guidelines are not breastmilk substitutes and shall not be presented as such.

## ANNEX

## TABLE

The reference INL<sub>98</sub> values listed in the Table provide a guide for selection and amounts of vitamins and minerals to be added to a Formulated Complementary Food. The suggested total quantity of each of these vitamins and/or minerals contained in a daily ration of the Formulated Complementary Food is at least 50% of INL<sub>98</sub>.

VITAMINS AND MINERALS	REFERENCE NUTRIENT INTAKE or Individual Nutrient Levels <sub>98</sub> (INL <sub>98</sub> ) <sup>17</sup>
Vitamin A µg retinol equivalent	400
Vitamin D <sup>18</sup> µg	5
Vitamin E mg (α-Tocopherol)	5
Vitamin C mg	30
Thiamine mg	0.5
Riboflavin mg	0.5
Niacin mg NE	6
Vitamin B <sub>6</sub> mg	0.5
Folate µg DFE	150
Vitamin B <sub>12</sub> µg	0.9
Biotin µg	8
Pantothenic acid mg	2
Vitamin K µg	15
Calcium mg	500
Iron mg <sup>19</sup>	11.6, 5.8, 3.9
Zinc mg <sup>20</sup>	8.3, 4.1, 2.4
Iodine µg	90
Copper mg <sup>21</sup>	0.34
Selenium µg	17
Magnesium mg	60
Manganese mg <sup>21</sup>	1.2
Phosphorus mg <sup>21</sup>	460

<sup>17</sup> Reference nutrient intake or INL<sub>98</sub> from FAO/WHO Vitamins and Mineral requirements in Human Nutrition.2<sup>nd</sup> Edition. FAO/WHO 2004 (for all nutrients except copper, manganese and phosphorus)

<sup>18</sup> Vitamin D should be added if there is inadequate exposure to sunlight

<sup>19</sup> Iron values are given for 5%, 10 % and 15% dietary iron bioavailability

<sup>20</sup> Zinc values are given for low, medium and high dietary zinc bioavailability

<sup>21</sup> Values are Dietary Reference Intakes. Institute of Medicine, 1997/2001 (Source for Copper, Manganese and Phosphorus).