

**GUIDELINES ON FORMULATED SUPPLEMENTARY FOODS
FOR OLDER INFANTS AND YOUNG CHILDREN
CAC/GL 08-1991¹**

1. PURPOSE

To provide guidance on nutritional and technical aspects of the production of formulated supplementary foods for older infants and young children as defined in Section 3.1, including:

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

2. SCOPE

The provisions of these Guidelines apply to Formulated Supplementary Foods for Older Infants and Young Children as defined in Section 3.1 below.

3. DESCRIPTION

3.1 *Formulated Supplementary Foods for Older Infants and Young Children* means foods suitable for use during the infant's weaning period and for feeding young children as a supplement to breastmilk or breastmilk substitutes or other food available in the country where the product is sold. They are not suitable for use for infants before the beginning of the weaning period. These foods provide those nutrients which either are lacking or are present in insufficient quantities in the basic staple foods.

3.2 The term *older infants* means persons from the 6th month and not more than 12 months of age.

3.3 The term *young children* means persons from the age of 12 months up to the age of three years (36 months).

4. SUITABLE RAW MATERIALS AND INGREDIENTS

4.1 Basic Ingredients

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

¹ The Guidelines on Formulated Supplementary Foods for Older Infants and Young Children were adopted by the Codex Alimentarius Commission at its 19th Session in 1991.

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 eliminate tannins or other phenolic materials which can lower the protein digestibility.

4.1.1.2 Besides carbohydrates (mainly consisting of starch) cereals contain a significant quantity of protein (8-12%). Whereas rice has a satisfactory essential amino-acid composition, other cereals are as a rule limiting in lysine.

4.1.2 Pulses

4.1.2.1 Pulses, including chick peas, lentils, peas, cow peas, mungo beans, green gram and kidney beans are a source of appropriate proteins (20-24%).

4.1.2.2 On the whole, pulses have a high content of lysine. They are, however, deficient in methionine. Depending on the nature of the other ingredients in the formulation, the addition of methionine might be desirable in order to improve the nutritional value of the product.

4.1.2.3 Pulses have to be appropriately processed to eliminate, as far as possible, the anti-nutritional factors normally present such as lectins (haemagglutinins) and trypsin and chymotrypsin inhibitors:

- Lectins can be destroyed by heat treatment;
- Trypsin inhibitor activity may be reduced to acceptable levels by heating to high temperatures or by prolonged boiling.

4.1.2.4 Field beans (*Vicia faba L.*) while having a very good nutritional quality and being a high yield crop, should not be used in the formulation of supplementary food for older infants and young children because of the danger of favism. Heat treatment does not inactivate the toxic principles vicin and co-vicin.

4.1.3 Oil Seed Flours and Oil Seed Protein Products

4.1.3.1 Flours, protein concentrates and protein isolates of the following oil seeds are acceptable if manufactured to appropriate specifications²:

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

Groundnuts: defatted flour, isolate

Sesame seed: whole ground and defatted flour

Cottonseed: defatted flour

Sunflower seed: defatted flour

4.1.3.2 Oil seed flours and protein products are a rich source of protein (50-95%). They could provide the main source of proteins in Formulated Supplementary Foods for Older Infants and Young Children.

² The following Guidelines were elaborated by the FAO/WHO/UNICEF Protein and Energy Advisory Group:

PAG Guideline No. 2: **Preparation of Food Quality Groundnut Flour**

PAG Guideline No. 4: **Preparation of Edible Cotton Seed Protein Concentrates**

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

PAG Guideline No. 14: **Preparation of Defatted Edible Sesame Flour**

4.1.4 **Fish Meals and Fish Protein Concentrates**

4.1.4.1 Food quality meals from edible fish species and edible fish protein concentrates are acceptable if produced under appropriate conditions³.

4.1.4.2 Fish protein concentrates have a protein content of 70-80%. The protein is of high quality and high in lysine content.

4.1.5 **Fats and Oils**

4.1.5.1 Fats and oils should be added to the preparation if possible for the purpose of increasing the energy density of the product.

4.1.5.2 The minimum requirements for essential fatty acids should be met.

4.2 **Other Ingredients**

The following ingredients may be used to improve the nutritional quality and/or acceptability of the food provided that they are readily available:

4.2.1 **Milk and/or milk products**

4.2.2 **Digestible carbohydrates including sugars**

Energy density should preferably be increased by the addition of fat and/or digestible carbohydrates. If nutritive sweeteners are used, they should be used in moderation.

4.2.3 **Flavours:** vanilla and/or traditional flavours provided they have been evaluated for their safety-in-use.

4.2.4 **Other ingredients of food quality:** provided they have been proven to be suitable for their intended purpose.

5. **TECHNOLOGIES FOR AND EFFECTS OF PROCESSING**

5.1 **Preliminary Treatment of Raw Materials**

Cereals, pulses and oilseeds should first be treated to obtain wholesome and clean raw materials of good quality. Such treatments include:

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, oilseeds and certain cereals such as oats, barley, sorghum, millet and teff should be dehulled as completely as is feasible to reduce the crude fibre content to acceptable levels and to eliminate tannins and other phenolic materials which can lower the protein digestibility.

³ FAO/WHO/UNICEF Protein and Energy Advisory Group PAG Guideline No. 9: **Fish Protein Concentrates for Human Consumption.**

5.2 Milled Products

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, pulses and/or oilseeds without further processing require prolonged boiling during the preparation of the feed to gelatinize the starch portions and/or eliminate anti-nutritional factors present in pulses. Boiling improves the digestibility and absorption of nutrients and sterilizes the feed.

5.2.4 The bulkiness of feeds 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 feed.

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 destroys micro-organisms and insects and reduces enzyme activity, 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. Soaking results in puffed grains with a light texture.

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

5.4 Sprouting and Malting

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.

5.4.2 During the process, the seedcoat of the grain splits and can be removed by washing. The malted raw material is milled or ground after drying.

5.5 Advanced 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 affect available lysine, sulphur-containing amino acids, arginine and tryptophan. 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 simultaneous reduction of trypsin inhibitor activity;
- a reduction in the quantities of water needed for preparation of the feed.

5.5.2 Enzymatic Predigestion

5.5.2.1 Under this process the milled or ground basic ingredients (cereals, pulses, oilseed flours) are slowly heated under continuous stirring until the mixture acquires the desired fluidity. 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.

5.5.2.2 The predigested product has improved organoleptic characteristics, higher digestibility, good solubility and requires less water for the preparation of the feed.

6. FORMULATION

6.1 Nutritional Aspects (General)

6.1.1 In accordance with the purpose of these guidelines and the definition of "Formulated Supplementary Foods for Older Infants and Young Children", the product is intended to supply additional energy and nutrients to the staple foods used for the feeding of older infants and young children. The following sections might not be applicable under all conditions prevailing in different countries and appropriate modifications might have to be made for adapting them to specific conditions.

6.1.2 One hundred grammes of the product, when prepared according to the instructions, is considered a reasonable quantity which an older infant or young child can ingest easily in two or more feedings.

6.1.3 The selection of ingredients for the formulation of Formulated Supplementary Foods for Older Infants and Young Children should be made having regard to the provisions in Sections 4 through 6.1.2 above and taking into account the following aspects:

- nutrient content of staple food;
- dietary habits;
- other socio-economic aspects as determined by the national authorities dealing with nutrition;
- availability and costs of raw materials and other ingredients.

6.1.4 In cases where older infants and young children are given specific vitamins and/or minerals through maternal and child health centres or other health agencies, the addition of these vitamins and/or minerals to supplementary foods may be unnecessary, provided that distribution of the supplementary foods is carefully limited to those receiving the vitamins and/or minerals.

6.2 Energy

6.2.1 The energy density of a mixture of milled cereals and pulses and defatted oilseed meals and flours is relatively low.

6.2.2 The energy density of the food can be increased by:

- (a) the addition of fats and oils, and/or digestible carbohydrates including, in moderation, sugars;

- and/or,
(b) processing the basic ingredients as indicated in Section 5.

6.2.3 One hundred grammes of the food should provide at least 400 kcal.

6.3 Proteins

6.3.1 Cereals, legumes and/or oilseed flours, alone or preferably mixed, can constitute an appropriate source of proteins, provided they are prepared in such a way that in the finished product the proteins in the mixture satisfy the criteria below.

6.3.2 The amino-acid score⁴ (previously called the chemical score) corrected in accordance with the true digestibility of the crude proteins, should not be less than 70 per cent of that of casein. Higher values should be required if calculation of the score was based not, as is usually the case, on the most limiting amino acid⁵, but on two or more key amino acids such as lysine, methionine, cystine, threonine and tryptophan.

6.3.3 If, for technical reasons, the amino acid score and the digestibility of a protein cannot be determined, the protein quality should be measured by biological assays. Alternatively, the protein quality may be computed 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 (except for DL-methionine, which may be used in foods for children over 12 months of age) 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 protein content should be in the order of 15 g per 100 g of the food on a dry matter basis⁶.

6.4 Fat

6.4.1 Incorporation of adequate quantities of fats and/or oils, as technologically feasible, is recommended in order to increase the energy density of the product. A level of between 20% and 40% of energy derived from fat would be desirable. This corresponds to between about 10 g and 25 g of fats and/or oils in 100 g of the food.

6.4.2 The level of linoleic acid (in the form of glycerides) should not be less than 300 mg per 100 kcal or 1.4 g per 100 g of product.

6.4.3 Where it is not feasible to include all of the desired fats and/or oils in the formulation of the food, the instructions for use on the label should recommend the addition of a specified quantity of fats and oils during the preparation of the feed.

⁴ The amino acid score is the ratio between the quantity of limiting amino acid in the protein tested and the quantity of the same amino acid in the reference protein: $100 \times (\text{mg of the limiting amino acid in 1 g of the protein tested}) / (\text{mg of the same amino acid in 1 g of the protein with the reference amino acid profile})$.

⁵ The limiting amino acid is the essential amino acid present in the lowest proportion as compared with the quantity of this amino acid in the reference protein.

⁶ Joint FAO/WHO/UNU Expert Group (1985), **Energy Requirements and Protein Requirements**, World Health Organization, Tech. Rep. Ser. No. 724.

6.5 Carbohydrates

6.5.1 Starch is likely to be a major constituent of many supplementary foods for older infants and young children. 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.

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 enhances stool bulk. They also may affect the efficiency of absorption of various nutrients of significance in diets with a marginal nutrient content, so the dietary fibre content of the food should be reduced to a level not exceeding 5 g per 100 g.

6.6 Vitamins and Minerals

6.6.1 The addition of vitamins and minerals should take into account local nutrition and health conditions as well as the requirements stipulated by national legislation.

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

6.6.3 Vitamins and/or minerals 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).

6.6.4 The Table in the Annex to these Guidelines contains the reference daily requirements for the vitamins and minerals that are most frequently deficient in the diets of older infants and young children. It is important to keep in mind that the Table is simply a guideline to emphasize the nutrients to be considered in the development of a supplementary food.

7. HYGIENE

It is recommended that Formulated Supplementary Foods for Older Infants and Young Children comply with the following mandatory hygiene requirements:

7.1 To the extent possible in good manufacturing practice, food products shall be free from objectionable matter.

7.2 When tested by appropriate methods of sampling and examination, the product:

- (a) shall be free from pathogenic microorganisms;
- (b) shall not contain any substances originating from microorganisms in amounts which may represent a hazard to health; and
- (c) shall not contain any other poisonous or deleterious substances in amounts which may represent a hazard to health.

7.3 The product shall be prepared, packed and held under sanitary conditions and should comply with the Recommended International Code of Hygienic Practice for Foods for Infants and Children (CAC/RCP 21-1979).

8. PACKAGING

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

8.2 The containers, including packaging material, shall be made only of materials which are safe and suitable for their intended uses.

9. LABELLING

9.1 It is recommended that the labelling of Formulated Supplementary Foods for Older Infants and Young Children be in accordance with the Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985)⁷.

9.2 The following mandatory provisions should apply:

9.2.1 The Name of the Food

9.2.1.1 The name of the food to be declared on the label shall indicate that the food is a formulated supplementary food, as appropriate, for older infants and young children. The appropriate description should be in accordance with national legislation.

9.2.1.2 The following information shall appear in close proximity to the name of the food:

- (a) the major sources of protein;
- (b) a statement that the food may be administered as a food supplement during the weaning period but not before the 6th month of age and when nutritional requirements are not covered by locally available foods.

9.2.2 List of Ingredients

The list of ingredients shall be declared in accordance with Section 4.2 of the General Standard.

9.2.3 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 food as sold as well as per specified quantity of the food as suggested for consumption:

- (a) the amount of energy, 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 in the final product of each vitamin and mineral added in accordance with Section 6.6 expressed in metric units.

⁷ Hereafter referred to as "General Standard".

9.2.4 **Information for Utilization**

9.2.4.1 Directions as to the preparation and use of the food shall be given; preferably accompanied by pictorial presentations.

9.2.4.2 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 cold or warm boiled water, as appropriate.

9.2.4.3 Foods which have been formulated with the intent that fats, sugars or other digestible carbohydrates are added during preparation, shall bear an indication of the amounts which are required to achieve the desired nutrient density of the food.

9.2.4.4 Directions for use shall include a statement that only the amount of food sufficient for one meal should be prepared at one time.

ANNEX

TABLE

The vitamins and minerals listed in the Table include those for which deficiency is most frequently found in older infants and young children and should be considered in the formulation of a supplementary food. Local conditions including the nutrient contribution to the diet from the staple foods of the area and the nutritional status of the target population as well as national legislation should be taken into account in determining the nutrients to be added. When a food is supplemented with one or more of these nutrients, the total amount of the added vitamin(s) and/or mineral(s) contained in 100 g of the food on a dry matter basis should be at least 2/3 of the reference daily requirements.

NUTRIENTS	REFERENCE DAILY REQUIREMENTS
Vitamin A	400 µg retinol equivalents
Vitamin D ⁸	10 µg
Vitamin E	5 mg
Vitamin C	20 mg
Thiamine	0.5 mg
Riboflavin	0.8 mg
Niacin	9 mg
Vitamin B ₆	0.9 mg
Folate	50 µg
Vitamin B ₁₂	1 µg
Calcium	800 mg
Iron ⁹	12 mg
Iodine ¹⁰	---
Zinc	10 mg

References:

- **FAO/WHO Handbook on Human Nutritional Requirements**, FAO, Rome, 1974.
- **Requirements of Vitamin A, Iron, Folate and Vitamin B₁₂**, Report of Joint FAO/WHO Expert Consultation, Rome, 1988.

⁸ Vitamin D should be added if there is inadequate exposure to sunlight.

⁹ Requirement with low bioavailability diet (5%).

¹⁰ No FAO/WHO reference values are available. Recommended intakes are about 50-70 µg per day.