Specialized Products Sectional Committee, FAD 24

FOREWORD

(Adoption clause will be added later).

1. SCOPE

This standard applies to formula foods for use in very low energy diets for weight reduction as defined in clause 2. These foods are defined as foods for special medical purposes and must be used under medical supervision by individuals with moderate or severe obesity. The matter of sale on prescription should be a decision made at national level. It does not apply to prepackaged meals presented in the form of conventional foods.

2. DEFINITION

A formula food for use in very low energy diets is a food specially prepared to supply a minimum amount of carbohydrates and the daily requirements of the essential nutrients in 450-800 kcal which represents the sole source of energy intake.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

The product as sold should comply with the following composition and quality factors:

3.1 Energy Content

A formula food for very low energy diets shall provide when prepared according to instructions a daily energy intake of 450-800 kcal as the only source of energy.
3.2 Nutrients Contents

3.2.1 Protein

- Not less than 50 g protein with a nutritional quality equivalent to a protein-digestibility-corrected aminoacid score of 1 shall be present in the recommended daily intake of energy.

- Essential amino acids may be added to improve protein quality only in amounts necessary for this purpose. Only L-forms of amino acids shall be used, except that DL-methionine may be used.

3.2.2 Fats

Very low energy diets shall provide not less than 3 g of linoleic acid and less than 0.5 g α-linolenic acid in the recommended daily intake with the linoleic acid/α-linolenic acid ratio between 5 and 15.

3.2.3 Carbohydrates

Very low energy diets shall provide not less than 50 g of available carbohydrates in the recommended daily intake of energy.

3.2.4 Vitamins and Minerals

Very low energy diets shall provide 100% of the recommended daily intakes for vitamins and minerals. Other essential nutrients not specified below may also be included.

<table>
<thead>
<tr>
<th>Vitamin</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A</td>
<td>600 µg</td>
</tr>
<tr>
<td>Vitamin D</td>
<td>2.5 µg</td>
</tr>
<tr>
<td>Vitamin E</td>
<td>10 mg</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>30 mg</td>
</tr>
<tr>
<td>Thiamin</td>
<td>0.8 mg</td>
</tr>
<tr>
<td>Riboflavin</td>
<td>1.2 mg</td>
</tr>
<tr>
<td>Niacin</td>
<td>11 mg</td>
</tr>
<tr>
<td>Folic Acid (as monoglutamate)</td>
<td>B6 2 mg</td>
</tr>
<tr>
<td>Vitamin B12</td>
<td>B12 1 µg</td>
</tr>
<tr>
<td>Vitamin</td>
<td>200 µg</td>
</tr>
<tr>
<td>Calcium</td>
<td>500 mg</td>
</tr>
<tr>
<td>Phosphorus</td>
<td>500 mg</td>
</tr>
<tr>
<td>Iron</td>
<td>16 mg</td>
</tr>
<tr>
<td>Iodine</td>
<td>140 µg</td>
</tr>
<tr>
<td>Magnesium</td>
<td>350 mg</td>
</tr>
<tr>
<td>Copper</td>
<td>1.5 mg</td>
</tr>
<tr>
<td>Zinc</td>
<td>6 mg</td>
</tr>
<tr>
<td>Potassium</td>
<td>1.6 g</td>
</tr>
</tbody>
</table>
3.3 Ingredients

Very low energy diets shall be prepared from protein constituents of animal and/or plant which have been proved suitable for human consumption and from other suitable ingredients necessary to achieve the essential composition of the product as set out in clauses 3.1 and 3.2 above.

4. FOOD ADDITIVES

Food additives cleared by the PFA shall be permitted at levels endorsed by the Indian Standards for the same.

5. CONTAMINANTS

5.1 Pesticide Residues

The product shall be prepared with special care under good manufacturing practices, so that no residues of pesticides, which may be required in the production, storage or processing of the raw materials or the finished food ingredient, remain in the product, or, if technically unavoidable, are reduced to the maximum extent possible.

5.2 Other Contaminants

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

6. HYGIENE

6.1 To the extent possible in good manufacturing practices, the product shall be free from objectionable matter.

6.2 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. PACKAGING

7.1 The product shall be packed in containers which will safeguard hygienic and other qualities of the foods. When in liquid form, the product shall be thermally processed and
packed in hermetically sealed containers to ensure sterility; nitrogen and carbon dioxide may be used as packing media.

7.2 The containers, including packaging materials, shall be made only of substances which are safe and suitable for their intended uses. Where the Bureau of Indian Standards has established a standard for any such substances used as packaging materials, that standard shall apply.

8. FILL OF CONTAINER

In the case of products in ready-to-eat form, the fill of the container shall be:

(a) Not less than 80% v/v for products weighing less than 150 g (5 oz);
(b) not less than 85% v/v for products in the weight range of 150-250 g (5-8 oz); and
(c) not less than 90% v/v for products weighing more than 250 g (8 oz) of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20°C, which the sealed container will hold when completely filled.

9. LABELLING

9.1 The name of the food shall be "Formula Food for Use in Very Low Energy Diets".

9.2 List of Ingredients

9.2.1 Except for single ingredient foods, a list of ingredients shall be declared on the label.

9.2.1.1 The list of ingredients shall be headed or preceded by an appropriate title which consists of or includes the term ‘ingredient’.

9.2.1.2 All ingredients shall be listed in descending order of ingoing weight (m/m) at the time of the manufacture of the food.

9.2.1.3 Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient constitutes less than 5% of the food, the ingredients, other than food additives which serve a technological function in the finished product, need not be declared.

9.2.1.4 The following foods and ingredients are known to cause hypersensitivity and shall always be declared.

- Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these;
- Crustacea and products of these;
- Eggs and egg products;
- Fish and fish products;
- Peanuts, soybeans and products of these;
- Milk and milk products (lactose included);
- Tree nuts and nut products; and
- Sulphite in concentrations of 10 mg/kg or more.

**9.2.1.5** Added water shall be declared in the list of ingredients except when the water forms part of an ingredient such as brine, syrup or broth used in a compound food and declared as such in the list of ingredients. Water or other volatile ingredients evaporated in the course of manufacture need not be declared.

**9.2.1.6** As an alternative to the general provisions of this section, dehydrated or condensed foods which are intended to be reconstituted by the addition of water only, the ingredients may be listed in order of proportion (m/m) in the reconstituted product provided that a statement such as “ingredients of the product when prepared in accordance with the directions on the label” is included.

**9.2.2** The presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in clause 9.2.1.4 shall be declared. When it is not possible to provide adequate information on the presence of an allergen through labelling, the food containing the allergen should not be marketed.

**9.2.3** A specific name shall be used for ingredients in the list of ingredients.

**9.2.3.1** The name shall indicate the true nature of the food and normally be specific and not generic:

**9.2.3.1.1** Where a name or names have been established for a food in an Indian Standard, at least one of these names shall be used.

**9.2.3.1.2** In other cases, the name prescribed by national legislation shall be used.

**9.2.3.1.3** In the absence of any such name, either a common or usual name existing by common usage as an appropriate descriptive term which was not misleading or confusing to the consumer shall be used.

**9.2.3.1.4** A “coined”, “fanciful”, “brand” name, or “trade mark” may be used provided it accompanies one of the names provided in Subsections 9.2.3.1.1 to 9.2.3.1.3.

**9.2.3.2** There shall appear on the label either in conjunction with, or in close proximity to, the name of the food, such additional words or phrases as necessary to avoid misleading or confusing the consumer in regard to the true nature and physical condition of the food including but not limited to the type of packing medium, style, and the condition or type of treatment it has undergone; for example: dried, concentrated, reconstituted, smoked.
9.2.3.1 Except for those ingredients listed in section 9.2.1.4, and unless a general class name would be more informative, the following class names may be used:

<table>
<thead>
<tr>
<th>NAME OF CLASSES</th>
<th>CLASS NAMES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refined oils other than olive</td>
<td>‘Oil’ together with either the term ‘vegetable’ or ‘animal’, qualified by the term ‘hydrogenated’ or ‘partially-hydrogenated’, as appropriate</td>
</tr>
<tr>
<td>Refined fats</td>
<td>‘Fat’ together with either, the term ‘vegetable’ or ‘animal’, as appropriate</td>
</tr>
<tr>
<td>Starches, other than chemically modified starches</td>
<td>‘Starch’</td>
</tr>
<tr>
<td>All species of fish where the fish constitutes an ingredient of another food and provided that the labelling and presentation of such food does not refer to a specific species of fish</td>
<td>‘Fish’</td>
</tr>
<tr>
<td>All types of poultry meat where such meat constitutes an ingredient of another food and provided that the labelling and presentation of such a food does not refer to a specific type of poultry meat</td>
<td>‘Poultrymeat’</td>
</tr>
<tr>
<td>All types of cheese where the cheese or mixture of cheeses constitutes an ingredient of another food and provided that the labelling and presentation of such food does not refer to a specific type of cheese</td>
<td>‘Cheese’</td>
</tr>
<tr>
<td>All spices and spice extracts not exceeding 2% by weight either singly or in combination in the</td>
<td>‘Spice’, ‘spices’, or ‘mixed spices’, as appropriate</td>
</tr>
<tr>
<td>Ingredient</td>
<td>Description</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>All herbs or parts of herbs not exceeding 2% by weight either singly or</td>
<td>‘Herbs’ or ‘mixed herbs’, as appropriate</td>
</tr>
<tr>
<td>in combination in the food</td>
<td></td>
</tr>
<tr>
<td>All types of gum preparations used in the manufacture of gum base for</td>
<td>‘Gum base’</td>
</tr>
<tr>
<td>chewing gum</td>
<td></td>
</tr>
<tr>
<td>All types of sucrose</td>
<td>‘Sugar’</td>
</tr>
<tr>
<td>Anhydrous dextrose and dextrose monohydrate</td>
<td>‘Dextrose’ or ‘glucose’</td>
</tr>
<tr>
<td>All types of caseinates</td>
<td>‘Caseinates’</td>
</tr>
<tr>
<td>Milk Protein</td>
<td>Milk products containing a minimum of 50% of milk protein (m/m) in dry matter</td>
</tr>
<tr>
<td>Press, expeller or refined cocoa butter</td>
<td>‘Cocoa butter’</td>
</tr>
<tr>
<td>All crystallized fruit not exceeding 10% of the weight of the food</td>
<td>‘Crystallized fruit’</td>
</tr>
</tbody>
</table>

* Calculation of milk protein content: Kjeldahl nitrogen x 6.38

**9.2.3.2** Notwithstanding the provision set out in clause 9.2.3.1, pork fat, lard and beef fat shall always be declared by their specific names.

**9.2.3.3** For food additives falling in the respective classes and appearing in lists of food additives permitted for use in foods generally, the following class titles shall be used together with the specific name or recognized numerical identification as required by national legislation.

- Acidity Regulator
- Acids
- Anticaking Agent
- Antifoaming Agent
- Antioxidant
- Bulking Agent
- Colour
- Colour Retention Agent
- Emulsifier
- Emulsifying Salt
- Firming Agent
9.2.3.4 The following class titles may be used for food additives falling in the respective classes and appearing in lists of food additives permitted generally for use in foods:

• Flavour(s) and Flavouring(s)

Modified Starch(es) The expression “flavours” may be qualified by “natural”, “nature identical”, “artificial” or a combination of these words as appropriate.

9.2.4 Processing Aids and Carry-Over of Food Additives

9.2.4.1 A food additive carried over into a food in a significant quantity or in an amount sufficient to perform a technological function in that food as a result of the use of raw materials or other ingredients in which the additive was used shall be included in the list of ingredients. The exemption does not apply to food additive and processing aids listed in clause 9.2.1.4.

9.2.4.2 A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. The exemption does not apply to food additives and processing aids listed in clause 9.2.1.4.

9.3 Declaration of Nutritive Value

9.3.1 The nutritive value shall be declared on the label per 100 g or 100 ml of the food as sold and, where appropriate, for a specified quantity of the food as suggested for consumption:

(a) The amount of energy expressed in kilocalories (kcal) and kiloJoules (kJ);
(b) the amounts of protein, available carbohydrates and fat expressed in grammes;
(c) the amounts of vitamins and minerals in clause 3.2.4 expressed in metric units;
(d) the amounts of other nutrients may also be declared.
9.3.2 In addition, the quantity of nutrients may be expressed in terms of percentages of internationally acceptable recommended daily nutrient standards.

9.4 Date Marking

If not otherwise determined in an individual Indian Standard, the following date marking shall apply:

(i) The “date of minimum durability” shall be declared.
(ii) This shall consist at least of:

- the day and the month for products with a minimum durability of not more than three months;
- the month and the year for products with a minimum durability of more than three months. If the month is December, it is sufficient to indicate the year.

(iii) The date shall be declared by the words:

- “Best before ...” where the day is indicated;
- “Best before end ...” in other cases.

(iv) The words referred to in paragraph (iii) shall be accompanied by:

- either the date itself; or
- a reference to where the date is given.

(v) The day, month and year shall be declared in uncoded numerical sequence except that the month may be indicated by letters in those countries where such use will not confuse the consumer.

(vi) Notwithstanding 9.4 (i) an indication of the date of minimum durability shall not be required for:

- fresh fruits and vegetables, including potatoes which have not been peeled, cut or similarly treated;
- wines, liqueur wines, sparkling wines, aromatized wines, fruit wines and sparkling fruit wines;
- beverages containing 10% or more by volume of alcohol;
- bakers’ or pastry-cooks’ wares which, given the nature of their content, are normally consumed within 24 hours of their manufacture;
- vinegar;
- food grade salt;
- solid sugars;
- confectionery products consisting of flavoured and/or coloured sugars;
- chewing gum.
9.5 Storage Instructions

9.5.1 Un-opened Food

Any special conditions for the storage of the food shall be declared on the label if the validity of the date depends thereon. Storage instructions of opened packages of the food shall be included on the label to ensure that the opened food maintains its wholesomeness and nutritive value. A warning should be included on the label if the food is not capable of being stored after opening or is not capable of being stored in the container after opening.

9.6 Information for Utilization

- The statement "for the dietary management of obesity" shall be declared on the label, in close proximity to the name of the food.

- Reference to the importance of maintaining adequate daily fluid intake.

- A statement that the product should not be used by pregnant, nursing and lactating women or by infants, children, adolescents and elderly, except when medically indicated.

9.7 Additional Provisions

A statement that the product may not be recommended for use for purposes other than the dietary management of obesity. The statements with respect to the name of the food and the indications for use as given in clauses 9.1 and 9.6 shall appear on the label of the package and/or sachet for use by the consumer.