CODEX STANDARD FOR THE LABELLING OF AND CLAIMS FOR FOODS FOR SPECIAL MEDICAL PURPOSES CODEX STAN 180-1991

1. SCOPE

This standard applies to the labelling of and claims for foods for special medical purposes as defined in Section 2 below, and presented as such.

2. DESCRIPTION

Foods for special medical purposes are a category of foods for special dietary uses which are specially processed or formulated and presented for the dietary management of patients and may be used only under medical supervision. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary foodstuffs or certain nutrients contained therein, or who have other special medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary uses, or by a combination of the two.

3. GENERAL PRINCIPLES

The formulation of foods for special medical purposes should be based on sound medical and nutritional principles. Their use should have been demonstrated, by scientific evidence, to be safe and beneficial in meeting the nutritional requirements of the persons for whom they are intended. The labels, accompanying leaflets and/or other labelling and advertising of all types of foods for special medical purposes should provide sufficient information on the nature and purpose of the food as well as detailed instructions and precautions for their use. The advertising of these products to the general public should be prohibited. The format of the information given should be appropriate for the person for whom it is intended.

4. LABELLING

4.1 Foods for Special Medical Purposes shall be labelled in accordance with the Codex General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses (CODEX STAN 146-1985)[1] except that:

(a) Sections 4.3, 5.1, 5.2.2, 5.2.3 and 6 of the General Standard do not apply to the Labelling of Foods for Special Medical Purposes; and

(b) the following specific provisions apply:

4.2 Nutrition Labelling

Foods for special medical purposes shall be labelled with complete nutrition labelling as follows:

4.2.1 The declaration of nutrient content shall be numerical. However the use of additional means of

[1] Hereafter referred to as "General Standard".

presentation should not be excluded.

4.2.2 Information on energy value shall be expressed in kJ and kcal per 100 g or per 100 ml as sold as well as per specified quantity of the food as suggested for consumption.

4.2.3 Information on the amounts of protein, carbohydrate and fat in the food shall be expressed in g per 100 g or per 100 ml as sold, as well as per specified quantity of the food suggested for consumption. Information on the amounts of essential and non-essential amino acids and/or essential fatty acids may be expressed similarly in metric units as appropriate.

4.2.4 Information on the amounts of vitamins and essential minerals shall be expressed in metric units per 100 g or per 100 ml as sold as well as per specified quantity of the foods as suggested for consumption.

4.2.5 In addition, where it is appropriate the quantity of nutrients may be expressed in terms of percentages of the relevant internationally recognized recommended daily allowances.

4.2.6 Information on osmolality or osmolarity and/or on acid-base balance shall be given when appropriate.

4.2.7 In countries where serving sizes are normally used, the information described in Sections 4.2.2 to 4.2.4 may be given only per serving as quantified on the label or per portion provided that the number of servings or portions contained in the package is stated.

4.2.8 In addition, information on the nature of the animal or plant proteins or protein hydrolysates should be provided.

4.2.9 Foods for special medical purposes in which the essential characteristic involves a specific modification of the content or the nature of the proteins, fats or carbohydrates shall bear a description of this modification and information on the amino acid, fatty acid or carbohydrate profile, when necessary.

4.3 Date Marking

The date of minimum durability as provided for in Section 4.7 of the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) shall be declared.

4.4 Additional Information

4.4.1 A prominent statement "**USE UNDER MEDICAL SUPERVISION**" shall appear on the label in bold letters in an area separated from other written, printed, or graphic information.

4.4.2 Adequate directions for the preparation including the requirement to add other ingredients, for the use of the food and for its storage and keeping after the container has been opened, shall be included on the label.

4.4.3 An additional prominent warning statement consisting of an explanatory statement shall appear on the label in bold letters in an area separated from other written, printed or graphic information if the food for special medical purpose poses a health hazard when consumed by individuals who do not have the disease(s), disorder(s) or medical condition(s) for which the food is intended.

4.4.4 A statement that the product is not to be used for parenteral administration shall appear on the label.

4.4.5 A prominent statement indicating whether the product is or is not intended as the sole source of nutrition

shall appear on the label.

4.5 Information to be Included in the Labelling [2]

4.5.1 The statement "For the dietary management of ....." with the blank to be filled in with the specific disease(s), disorder(s) or medical condition(s) for which the product is intended, and for which it has been shown to be effective.

4.5.2 A complete statement concerning adequate precautions, known side effects, contraindications, and product-drug interactions, as applicable.

4.5.3 A statement of the rationale for the use of the product and a description of the properties or characteristics that make it useful.

4.5.4 If the product has been formulated for a specific age group, it should carry a prominent statement to this effect.

4.5.5 A statement specifying the nutrient(s) which have been reduced, deleted, increased or otherwise modified, relative to normal requirements, and the rationale for the reduction, deletion, increase or other modification.

4.5.6 Feeding instructions, including the method of administration and serving size, if applicable.

[2] This information may be provided separately from the package.