

INTRODUCTION

The General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses was adopted by the 16th Session of the Codex Alimentarius Commission in 1985. This standard has been submitted to all Member Nations and Associate Members of FAO and WHO for acceptance in accordance with the General Principles of the Codex Alimentarius.

GENERAL STANDARD FOR THE LABELLING OF AND CLAIMS FOR PREPACKAGED FOODS FOR SPECIAL DIETARY USES CODEX STAN 146-1985

1. SCOPE

This standard applies to the labelling of all prepackaged foods for special dietary uses as defined in Section 2.1 to be offered as such to the consumer or for catering purposes and to certain aspects relating to the presentation thereof; and to claims made for such foods.

2. DESCRIPTION

2.1 *Foods for Special Dietary Uses* are those foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such ¹. The composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist.

2.2 The definitions laid down in the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985 (Rev. 1-1991), Codex Alimentarius Volume 1) ² apply.

3. GENERAL PRINCIPLES

3.1 Prepackaged Foods for Special Dietary Uses shall not be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding their character in any respect ³.

3.2 Nothing in the labelling and advertising of foods to which this standard applies shall imply that advice from a qualified person is not needed.

4. MANDATORY LABELLING OF PREPACKAGED FOODS FOR SPECIAL DIETARY USES

The label of all prepackaged Foods for Special Dietary Uses shall bear the information required by

¹ This includes foods for infants and young children.

² Hereafter referred to as "General Standard".

³ Examples of descriptions or presentations to which these General Principles refer, are given in the Codex General Guidelines on Claims (CAC/GL 1-1979 (Rev. 1-1991), Codex Alimentarius Volume 1).

Sections 4.1 to 4.8 of this standard as applicable to the food being labelled, except to the extent otherwise expressly provided in a specific Codex standard.

4.1 The Name of the Food

In addition to the declaration of the name of the food in accordance with Section 4.1 of the General Standard, the following provisions apply:

4.1.1 The designation "special dietary", "special dietetic" or an appropriate equivalent term, may be used in conjunction with the name only where the product corresponds to the definition in Section 2.1.

4.1.2 The characterizing essential feature, but not the condition for which the food is intended, shall be stated in appropriate descriptive terms in close proximity to the name of the food.

4.2 List of Ingredients

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

4.3 Nutrition Labelling

4.3.1 The declaration of nutrition information on the label shall include the following:

- (a) The amount of energy per 100 grammes or 100 ml of the food as sold and where appropriate per specified quantity of the food as suggested for consumption, expressed in kilocalories (kcal) and kilojoules (kJ).
- (b) The number of grammes of protein, available carbohydrate and fat per 100 grammes or 100 ml of the food as sold and where appropriate per specified quantity of the food as suggested for consumption.
- (c) The total quantity of those specific nutrients or other components which provide the characterizing essential feature for the special dietary use for which the food is intended per 100 grammes or 100 ml of the food as sold and, where appropriate, per specified quantity of the food as suggested for consumption.

4.4 Net Contents and Drained Weight

The declaration of net contents and drained weight shall be in accordance with Section 4.3 of the General Standard.

4.5 Name and Address

The name and address shall be declared in accordance with Section 4.4 of the General Standard.

4.6 Country of Origin

The country of origin shall be declared in accordance with Section 4.5 of the General Standard.

4.7 Lot Identification

The lot identification shall be declared in accordance with Section 4.6 of the General Standard.

4.8 Date Marking and Storage Instructions

In addition to the declaration of date marking and storage instructions in accordance with Section 4.7

of the General Standard, the following provisions apply:

4.8.1 Storage of Opened Food

Storage instructions of opened packages of a food for special dietary uses shall be included on the label if necessary to ensure that the opened product 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.

5. ADDITIONAL MANDATORY REQUIREMENTS FOR SPECIFIC FOODS

5.1 Quantitative Labelling of Ingredients

The quantitative labelling of ingredients shall be in accordance with Section 5.1 of the General Standard.

5.2 Claims

5.2.1 Any claims made for the foods covered by this standard shall be in accordance with the General Guidelines on Claims elaborated by the Codex Alimentarius Commission (CAC/GL 1-1979 (Rev. 1 -1991), Codex Alimentarius Volume 1).

5.2.2 Where a claim is made that the food is suitable for "special dietary use" that food shall comply with all provisions of this standard except as otherwise provided in a specific Codex Standard for Foods for Special Dietary Uses.

5.2.3 A food which has not been modified in accordance with Section 2.1 but is suitable for use in a particular dietary regimen because of its natural composition, shall not be designated "special dietary" or "special dietetic" or any other equivalent term. However, such a food may bear a statement on the label that "this food is by its nature "X"" ("X" refers to the essential distinguishing characteristic), provided that such statement does not mislead the consumer.

5.2.4 Claims as to the suitability of a food defined in Section 2.1 for use in the prevention, alleviation, treatment or cure of a disease, disorder or particular physiological condition are prohibited unless they are:

- (a) in accordance with the provisions of Codex standards or guidelines for foods for special dietary uses, and follow the principles set forth in such standards or guidelines; or
- (b) in the absence of an applicable Codex standard or guideline, permitted under the laws of the country in which the food is distributed.

5.3 Irradiated Foods

Irradiated foods for special dietary uses shall be labelled in accordance with Section 5.2 of the General Standard.

5.4 Nothing in this standard shall preclude the adoption of additional or different provisions in a Codex standard for a food for special dietary use, in respect of labelling, where the circumstances of a particular food would justify their incorporation in that standard.

6. EXEMPTIONS FROM MANDATORY LABELLING REQUIREMENTS

Exemptions from mandatory labelling requirements shall be in accordance with Section 6 of the General Standard.

7. OPTIONAL LABELLING

Optional labelling of foods for special dietary uses shall be in accordance with Section 7 of the General Standard.

8. PRESENTATION OF MANDATORY INFORMATION

The presentation of the mandatory information shall be in accordance with Section 8 of the General Standard.