

CODEX ALIMENTARIUS

INTERNATIONAL FOOD STANDARDS



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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STANDARD FOR FORMULA FOODS FOR USE IN WEIGHT-CONTROL DIETS

CXS 181-1991

Adopted in 1991. Amended in 2023.

Amendments 2023

Following decisions taken at the Forty-sixth Session of the Codex Alimentarius Commission in December 2023, the food additives provisions were amended in this standard and have been included in the *General Standard for Food Additives* (GSFA) (CXS 192-1995)¹ in line with the process of alignment of all food additive provisions with the GSFA. Amendments were also made in Section 7 Packaging.

1. SCOPE

This standard applies to formula foods for use in weight-control diets, as defined in Section 2.

It does not apply to pre-packaged meals controlled in energy and presented in the form of conventional foods.

2. DESCRIPTION

Formula foods for use in weight-control diets are foods which, when presented as "ready-to-serve" or when prepared in conformity with the directions for use, are presented as a replacement for all or part of the total daily diet.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Energy content

3.1.1 A formula food presented as a replacement for all meals of the daily diet shall provide not less than 800 kcal (3350 kJ) and not more than 1200 kcal (5020 kJ). The individual portions or servings contained in these products shall provide approximately one third or one fourth of the total energy of the product depending on whether the recommended number of portions or servings per day is three or four, respectively.

3.1.2 A formula food presented as a replacement for one or more meals of the daily diet shall provide not less than 200 kcal (835 kJ) and not more than 400 kcal (1670 kJ) per meal. When such products are presented as a replacement for the major part of the diet, the total energy intake shall not exceed 1200 kcal (5020 kJ).

3.2 Nutrient content

3.2.1 Protein

3.2.1.1 A minimum of 25 percent and a maximum of 50 percent of the energy available from the food, when ready-to-serve, shall be derived from its protein content. The total amount of protein shall not exceed 125 g per day.

3.2.1.2 The protein shall be:

- (i) of a nutritional quality equivalent to egg or milk protein (the reference protein);
- (ii) where the protein quality is less than the reference protein, the minimum levels should be increased to compensate for the lower protein quality. No protein with a quality of less than 80 percent of that of the reference protein shall be used in a formula food for use in a weight-control diet.

3.2.1.3 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 Fat and linoleate

Not more than 30 percent of the energy available from the food shall be derived from fat including not less than 3 percent of the energy available derived from linoleic acid (in the form of a glyceride).

3.2.3 Vitamins and minerals

3.2.3.1 For a formula food represented as a replacement for all meals per day, at least 100 percent of the amounts of vitamins and minerals specified below shall be present in the daily intake. Other essential nutrients not specified below may also be included.

Vitamin A	600 µg retinol equivalents
Vitamin D	2.5 µg
Vitamin E	10 mg
Vitamin C	30 mg
Thiamine	0.8 mg
Riboflavin	1.2 mg
Niacin	11 mg
Vitamin B ₆	2 mg
Vitamin B ₁₂	1 µg
Folate	200 µg
Calcium	500 mg
Phosphorus	500 mg
Iron	16 mg
Iodine	140 µg
Magnesium	350 mg
Copper	1.5 mg
Zinc	6 mg
Potassium	1.6 g
Sodium	1.0 g

3.2.3.2 For a formula food represented as a replacement for a single meal, the amounts of vitamins and minerals shall be reduced below the amounts specified in Section 3.2.3.1 to provide a minimum of 33 percent or 25 percent of these amounts, depending on whether the recommended number of servings per day is three or four, respectively.

3.3 Ingredients

Formula foods for weight control shall be prepared from protein constituents of animals and/or plants 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 Sections 3.1 and 3.2 above.

4. FOOD ADDITIVES

Food additives used in accordance with Table 1 and Table 2 of the *General Standard for Food Additives* (CXS 192-1995)¹ in food category 13.4 (Dietetic formulae for slimming purposes and weight reduction) or listed in Table 3, are acceptable for use in foods conforming to this standard.

5. CONTAMINANTS

5.1 Pesticide residues

The product shall 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 ingredient do not remain, 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 practice, 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 food. When in liquid form, the product shall be thermally processed and packed in hermetically sealed containers to ensure sterility.

7.2 The containers, including packaging materials, shall be made only of substances which are safe and suitable for their intended uses. Where the Codex Alimentarius Commission 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 container shall be:

- (a) not less than 80 percent v/v for products weighing less than 150 g (5 oz);
- (b) not less than 85 percent v/v for products in the weight range 150-250 g (5-8 oz); and
- (c) not less than 90 percent 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

In addition to the appropriate sections of the *General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses* (CXS 146-1985),² hereinafter referred to as General Standard, the following specific provisions apply:

9.1 The name of the food

The name of the food shall be "Meal replacement for weight control".

9.2 List of ingredients

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

9.3 Declaration of nutritive value

9.3.1 The nutritive value shall be declared on the label per 100 grammes or 100 ml of the food as sold and, where appropriate, per 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 grams;
- (c) the amounts of vitamins and minerals in Section 3.2.3 expressed in metric units;
- (d) the amounts of other nutrients may also be declared.

9.3.2 If the fatty acid composition is declared on the label, it shall be done in accordance with the *Guidelines on Nutrition Labelling* (CXG 2-1985).³

9.3.3 In addition, the quantities of vitamins and minerals may be expressed as a percentage of the reference recommended daily allowance in accordance with the *Guidelines on Nutrition Labelling* (CXG 2-1985).³

9.3.4 In countries where serving sizes are normally used, the information described in Sections 9.3.1 to 9.3.3 may be given per serving only as quantified on the label or per portion provided that the number of servings or portions contained in the package is stated.

9.3.5 If the directions for use indicate that the food should be combined with other ingredient(s), the nutritive value of the final combination may be provided on the label in addition to the declaration required in Section 9.3.1.

9.4 Date marking

The date of minimum durability shall be declared in accordance with Section 4.8 of the General Standard.

9.5 Storage instructions

9.5.1 Unopened food

Any special conditions for the storage of the food shall be declared on the label if the validity of the date depends thereon.

9.5.2 Opened food

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 Additional provisions

9.6.1 The label and labelling shall not make any reference to the rate or amount of weight loss which may result from the use of the food or to a reduction in the sense of hunger or an increase in the sense of satiety.

9.6.2 The label or labelling should make reference to the importance of maintaining an adequate daily fluid intake when formula foods for weight control are used.

9.6.3 If the food provides a daily intake of sugar alcohols in excess of 20 g per day, there shall be a statement on the label to the effect that the food may have a laxative effect.

9.6.4 The label and labelling shall carry a statement to the effect that the food may be useful in weight control only as part of an energy-controlled diet.

9.6.5 For those products presented as replacements of the total daily diet, the label shall contain a prominent statement recommending that, if the food is used for more than six weeks, medical advice should be sought.

NOTES

¹ FAO and WHO. 1995. *General Standard for Food Additives*. Codex Alimentarius Standard, No. CXS 192-1995. Codex Alimentarius Commission. Rome.

² FAO and WHO. 1985. *General Standard for the Labelling of and Claims for Pre-packaged Foods for Special Dietary Uses*. Codex Alimentarius Standard, No. CXS 146-1985. Codex Alimentarius Commission. Rome.

³ FAO and WHO. 1985. *Guidelines on Nutrition Labelling*. Codex Alimentarius Guideline, No. CXG 2-1985. Codex Alimentarius Commission. Rome.