

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 VERY LOW ENERGY DIETS FOR WEIGHT REDUCTION

CXS 203-1995

Adopted in 1995. 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 very low energy diets for weight reduction as defined in Section 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 pre-packaged 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 qualityⁱ equivalent to a protein-digestibility-corrected amino acid 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 percent of the recommended daily intakes for vitamins and minerals. Other essential nutrients not specified below may also be included.

Vitaminsⁱⁱ

Vitamin A	600 μ g
Vitamin D	2.5 μ g
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 μ g
Folic Acid (as monoglutamate)	200 μ g

Minerals

Calcium	500 mg
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ⁱ Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation, Bethesda, MD USA, 4–8 December 1989, FAO Food and Nutrition Paper No. 51, 1991, Rome, p. 23.

ⁱⁱ These lists should be reviewed when new FAO/WHO recommendations become available.

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 g

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 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 pesticides, which may be required in the production, storage or processing of the raw materials or the finished food ingredient, do not remain in the product, or, if technically unavoidable, are reduced to the maximum extent possible, and shall comply with those maximum residue limits established by the Codex Committee on Pesticide Residues for this commodity.

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.

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 the 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 of 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, and the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991),³ the following specific provisions apply:

9.1 The name of the food shall be "Formula food for use in very low energy diets".

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 grams 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 grams;
- (c) the amounts of vitamins and minerals in Section 3.2.4 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 should be done in accordance with the *Guidelines on Nutrition Labelling* (CXG 2-1985).⁴

9.3.3 In addition, the quantity of nutrients may be expressed in terms of percentages of internationally acceptable recommended daily nutrient standards.

9.4 Date marking

The date of minimum durability shall be declared in accordance with Section 4.7.1 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. 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

In addition to the appropriate sections of the *Standard on the Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991),³ the following directions should be provided:

- 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; and
- 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 Sections 9.1 and 9.6 shall appear on the label of the package and/or sachet for use by the consumer. Other statements, as required under Section 9.6 above and Section 4.5 of the *Standard for the Labelling of and Claims for Foods for Special Medical Purposes* (CXS 180-1991),³ may appear on an accompanying leaflet in which case reference shall be made to this fact on the label of the package and/or sachet.

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. 1991. *Standard for the Labelling of and Claims for Foods for Special Medical Purposes*. Codex Alimentarius Standard, No. CXS 180-1991. Codex Alimentarius Commission. Rome.

⁴ FAO and WHO. 1985. *Guidelines on Nutrition Labelling*. Codex Alimentarius Guideline, No. CXG 2-1985. Codex Alimentarius Commission. Rome.