NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

GB 31662-2025

National food safety standard - Total nutrient formula food for tumour patients

食品安全国家标准 肿瘤全营养配方食品

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Table of Contents

1 Scope

The standard applies to formula food for special medical purposes intended for tumour patients over 10 years of age.

2 Terms and definitions

Total nutrient formula food for tumour patients: a formula food for special medical purposes that can serve as the sole source of nutrition to meet the nutritional needs of tumour patients and that suits their metabolic characteristics. The clause carries this single definition and gives it no subclause number.

3 Technical requirements

3.1 Basic requirements. The formula shall be based on the results of medical or nutritional research, and its safety and its clinical application effect shall be scientifically demonstrated. The production conditions shall comply with the relevant national provisions.

3.2 Raw material requirements. The raw materials used shall comply with the relevant standards or provisions, and substances harmful to the health of the consumer are prohibited.

3.3 Sensory requirements. The colour, taste, odour, texture and reconstitution behaviour of the product shall suit the characteristics of the product concerned, and there shall be no foreign matter visible to normal eyesight. The clause fixes no numerical limit.

3.4.1 Energy. Each 100 mL of a liquid product, or of a product that can be reconstituted into a liquid, in the ready-to-eat state, or each 100 g of a non-liquid product eaten directly, shall contain not less than 502 kJ (120 kcal). Energy is calculated by multiplying the protein, fat and carbohydrate content of 100 mL or 100 g of product by their respective energy factors of 17 kJ/g, 37 kJ/g and 17 kJ/g, the energy factor for dietary fibre being 8 kJ/g; the sum is the value in kJ per 100 mL or kJ per 100 g, which divided by 4.184 gives the value in kcal per 100 mL or kcal per 100 g.

3.4.2 Protein. The protein content shall be not less than 0.96 g/100 kJ (4.0 g/100 kcal). The protein shall come entirely from high quality protein and may be intact protein, hydrolysed protein or peptides. The test method refers to GB 5009.5.

3.4.3 Fat. The energy contribution of fat shall be 25 % to 50 %. The energy contribution of n-3 fatty acids, expressed as EPA plus DHA, shall be 1 % to 6 %, of which the EPA content shall be not less than 50 %. The energy contribution of linoleic acid shall be not less than 1.0 % and that of alpha-linolenic acid not less than 0.15 %. The test method for fat refers to GB 5009.6 and that for fatty acids to GB 5009.168.

3.4.4 Carbohydrate. The energy contribution of carbohydrate shall be in the range 30 % to 50 %.

3.4.5 Vitamins and minerals. The vitamin and mineral content shall comply with Table 1. The table has six columns: the nutrient with its unit, the minimum and maximum per 100 kJ, the minimum and maximum per 100 kcal, and the test method. It covers vitamin A, vitamin D, vitamin E, vitamin K1, vitamin B1, vitamin B2, vitamin B6, vitamin B12, niacin (nicotinamide), folic acid, pantothenic acid, vitamin C, biotin, sodium, potassium, copper, magnesium, iron, zinc, manganese, calcium, phosphorus, iodine, chlorine and selenium, each with the GB 5009 series test method or methods to be used. The entry N.S. in a cell means that no value is specified. The footnotes state that RE means retinol equivalent, that 1 μgRE equals 3.33 IU of vitamin A and 1 μg of all-trans retinol, and that vitamin A covers only preformed retinol, no carotenoid fraction being counted in the calculation or the claim of vitamin A activity; that vitamin D is calciferol and 1 μg of vitamin D equals 40 IU; that 1 mg of alpha-tocopherol equivalent equals 1 mg of d-alpha-tocopherol and that 1 mg of dl-alpha-tocopherol equals 0.74 mg of alpha-tocopherol equivalent; and that niacin does not include precursor forms. The individual limit values of the table are not reproduced here.

3.4.6 Optional ingredients. Where one or more of the ingredients of Table 2 is added to the product or declared on the label, its content shall comply with Table 2; where a substance not listed in Table 2 is added, it shall comply with the relevant national provisions. Table 2 has the same six columns as Table 1 and covers chromium, molybdenum, fluorine, choline,

inositol, taurine, L-carnitine, nucleotides, dietary fibre, arginine, glutamine, leucine and calcium beta-hydroxy-beta-methylbutyrate. A footnote states that the compound sources of fluorine are sodium fluoride and potassium fluoride, that the sources of nucleotides and dietary fibre follow the permitted sources of Table C.2 of GB 14880 and that the compound sources of the other ingredients follow GB 14880; a second footnote states that N.S. means that no value is specified; a third footnote allows a suitable test method to be chosen where soluble dietary fibre is added. The individual limit values of the table are not reproduced here.

3.5 Limits of contaminants and mycotoxins. The limits of contaminants shall comply with GB 2762 and the limits of mycotoxins with GB 2761.

3.6 Microbiological limits. For solid products the limits of pathogenic bacteria shall comply with GB 29921 and the other microbiological indicators with Table 3; liquid and semi-solid products shall meet the requirement of commercial sterility, tested by the method of GB 4789.26. Table 3 has six columns: the item, the sampling plan values n, c, m and M, the limits being expressed in CFU per gram or CFU per millilitre unless otherwise stated, and the test method. It covers the aerobic plate count with n equal to 5, c equal to 2, m equal to 1 000 and M equal to 10 000, tested by GB 4789.23, and coliforms with n equal to 5, c equal to 2, m equal to 10 and M equal to 100, tested by the plate count method of GB 4789.3. A footnote states that samples are analysed and handled in accordance with GB 4789.1 and GB 4789.18; a second footnote states that the aerobic plate count does not apply to products to which live cultures, aerobic or facultatively anaerobic, have been added, the viable count of live bacteria in such products having to be not less than 10 to the power of 6 CFU per gram or per millilitre.

3.7 Food additives and nutritional fortification substances. The use of food additives may follow the kinds and quantities permitted for the same or similar products in GB 2760. The use of nutritional fortification substances shall comply with GB 14880 or the relevant provisions. According to the particular nutritional needs of tumour patients, one or more amino acids may be added to the formula, the sources used complying with GB 29922 or GB 14880 and the relevant announcements.

4 Other

4.1 Labelling. The product label shall comply with GB 13432. The declaration of nutrients and optional ingredients shall additionally state the content per 100 kJ. The label shall describe the formulation characteristics or the nutritional features of the product and shall state the source and proportion of the protein. It shall state the category of the product and the intended population, and shall carry the statement that the product is not suitable for people outside the target population. The label shall describe how the product is reconstituted, the corresponding osmotic pressure and the keeping time. It shall carry, in a conspicuous position, the statement that the product is to be used under the guidance of a

physician or clinical dietitian. It shall also carry statements to the effect that the product must not be used for parenteral nutrition support or intravenous injection, and that periodic monitoring for nutrient deficiency is advised.

4.2 Instructions for use. The instructions on use, preparation and storage conditions shall be stated clearly on the label. The instructions shall give a warning about the health hazards that improper preparation and improper use may cause.

4.3 Packaging. Carbon dioxide or nitrogen complying with the national food safety standards may be used as the packaging medium.