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Report Name: National Food Safety Standard for Nutritionally Complete Foods for Cancer Patients Notified to WTO

Country: China - People's Republic of

Post: Beijing

Report Category: FAIRS Subject Report, Sanitary/Phytosanitary/Food Safety, WTO Notifications

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Report Highlights:

On October 25, 2023, China notified the National Food Safety Standard for Nutritionally Complete Foods for Cancer Patients to the World Trade Organization (WTO) under G/SPS/N/CHN/1284. The proposed date of entry into force is to be determined. Comments may be submitted to China's SPS National Notification and Enquiry Center at sps@customs.gov.cn until December 24, 2023. This report provides an unofficial translation of the draft standard.

Report Summary:

On October 25, 2023, China notified the National Food Safety Standard for Nutritionally Complete Foods for Cancer Patients to the World Trade Organization (WTO) under G/SPS/N/CHN/1284. The proposed date of entry into force is to be determined. Comments may be submitted to China's SPS National Notification and Enquiry Center at sps@customs.gov.cn until December 24, 2023.

This is the first national food safety standard for complete nutrition formula foods targeted to cancer patients. The standard includes a definition of nutritionally complete foods for cancer patients, specifies technical requirements and testing methods, and clarified labels, instructions, and packaging requirements. The report provides an unofficial translation of the draft standard notified to WTO.

BEGIN TRANSLATION

National Food Safety Standard
Nutritionally Complete Foods for Cancer Patients
GB xxxx-xxxx

1. Scope

This standard applies to formula foods of special medical purposes for cancer patients over the age of 10.

2. Terms and Definitions

2.1 Nutritionally complete formula foods for cancer patients

The formula foods of special medical purposes to be used as a single nutrition source, able to meet nutrition needs, and cope with metabolic characteristics for cancer patients.

3. Technical Requirements

3.1 Basic requirements

Formulas of nutritionally complete formula foods of special medical purposes for cancer patients should be developed based on the results in medical and (or) nutritional studies, and the safety and clinical applications (effects) need to be scientifically proved.

Production conditions for nutritionally complete formula foods of special medical purposes for cancer patients should comply with provisions of relevant national regulations.

3.2 Ingredients requirements

Ingredients used in nutritionally complete formula foods of special medical purposes for cancer patients should comply with corresponding standards and (or) relevant regulations. The use of any substances harmful to the health of consumers is prohibited.

3.3 Sensory requirements

The color, taste, flavor, texture, and usage of nutritionally complete formula foods of special medical purposes for cancer patients should comply with the properties of relevant products. It should not contain any visible foreign subjects.

3.4 Nutrition components

3.4.1 The energy contained in every 100 mL (liquid product or product consumed in liquid form) or every 100 g (product directly consumed in non-liquid form) should be no less than 502 kJ (120 kcal). The energy is calculated according to the content of protein, fat, and carbohydrate in every 100 mL or 100 g of a product, multiplied by its energy factors of 17 kJ/g, 37 kJ/g, and 17 kJ/g respectively (the energy factor of dietary fiber is 8 kJ/g). The sum as a result is the value in kJ/100mL or kJ/100g, then it is divided by 4.184 to get the value in kcal/100mL or kcal/100g.

3.4.2 The protein content should be no less than 0.96g/100kJ (4.0g/100kcal), and all are from high-quality proteins such as complete protein, hydrolyzed protein, and protein in peptides category. The testing methods for protein should comply with GB5009.5.

3.4.3 The supply to energy ratio of fat is 25%-50%, supply to energy ratio of n-3 fatty acid (calculated based on EPA and DHA) should be 1%-6%, where the EPA content is no less than 50%. The supply to energy ratio of linolic acid should be no less than 2.0%, while the supply to energy ratio of a-linolenic acid should be no less than 0.5%. The testing methods for fat should comply with GB 5009.6 and testing methods for fatty acid should comply with GB 5009.168.

3.4.4 The supply to energy ratio of carbohydrate is in the range of 30%-50%.

3.4.5 Content of vitamins and minerals that apply to nutritionally complete formula foods of special medical purposes for cancer patients should comply with Table 1.

Table 1: Vitamin and Mineral Indicators

Nutrients	Every 100kJ		Every 100kcal		Testing Methods
	Minimum	Maximum	Minimum	Maximum	
Vitamin A/(μgRE) [a]	9.3	53.8	39.0	225.0	GB 5009.82
Vitamin D/(μg) [b]	0.19	0.75	0.80	3.14	GB 5009.82
Vitamin E/(mg α-TE)[c]	0.19	9.3	0.80	38.9	GB 5009.82
Vitamin K_1/(μg)	1.05	N.S.[e]	4.40	N.S.[e]	GB 5009.158
Vitamin B_1/(mg)	0.02	N.S.[e]	0.07	N.S.[e]	GB 5009.84
Vitamin B_2/(mg)	0.02	N.S.[e]	0.07	N.S.[e]	GB 5009.85
Vitamin B_6/(mg)	0.02	N.S.[e]	0.07	N.S.[e]	GB 5009.154

Vitamin B_{12}/(μg)	0.03	N.S.[e]	0.13	N.S.[e]	GB 5009.285-2022
Nicotinic acid (nicotinamide)/(mg) [d]	0.05	N.S.[e]	0.20	N.S.[e]	GB 5009.89
Folic acid/(μg)	5.3	13.3	22.2	55.6	GB 5009.211
Pantothenic acid/(mg)	0.07	N.S.[e]	0.29	N.S.[e]	GB 5009.210
Vitamin C/(mg)	1.3	26.6	5.6	111.1	GB 5413.18
Biotin/(μg)	0.5	N.S.[e]	2.2	N.S.[e]	GB 5009.259
Sodium/(mg)	20	N.S.[e]	83	N.S.[e]	GB 5009.91 or GB 5009.268
Potassium/(mg)	27	N.S.[e]	111	N.S.[e]	GB 5009.91 or GB 5009.268
Copper/(μg)	11	120	44	500	GB 5009.13 or GB 5009.268
Magnesium/(mg)	4.4	N.S.[e]	18.3	N.S.[e]	GB 5009.241 or GB 5009.268
Ferrum/(mg)	0.20	0.55	0.83	2.30	GB 5009.90 or GB 5009.268
Zinc/(mg)	0.1	0.5	0.4	2.2	GB 5009.14 or GB 5009.268
Manganese/(μg)	6.0	146.0	25.0	611.0	GB 5009.242 or GB 5009.268
Calcium/(mg)	13	26.6	56	111.1	GB 5009.92 or GB 5009.268
Phosphorus/(mg)	9.6	46.5	40.0	194.4	GB5009.87 or GB 5009.268
Iodine/(μg)	1.6	8	6.7	33.3	GB 5009.267
Chlorine/(mg)	N.S.[e]	52	N.S.[e]	218	GB 5009.44
Selenium/(μg)	0.8	5.3	3.3	22.2	GB 5009.93 or GB 5009.268

[a] RE is the retinol equivalent. 1 μg RE =3.33 IU and Vitamin A=1μg all-trans-retinol (Vitamin A). Vitamin A only includes pre-formed retinol, and no carotenoid ingredient is included when the activity of vitamin A is calculated and stated.
[b] Calciferol, 1μg Vitamin D = 40 IU Vitamin D.
[c] 1 mg α-TE (α-Tocopherol equivalent) = 1 mg d-α-Tocopherol. 1 mg dl-α-Tocopherol = 0.74 mg α-TE (α-Tocopherol equivalent).
[d] Niacin doesn't include any form of precursors.
[e] N.S. stands for not specified.

3.4.6 Optional components

3.4.6.1 If one or more components in Table 2 are added to a product or shown in its label, the content should comply with Table 2.

3.4.6.2 If any other substance not included in Table 2 is added to a product, relevant national

regulations should be followed.

Table 2: Indicators of Optional Components

Optional Components [a]	Every 100 kJ		Every 100 kcal		Testing Methods
	Minimum	Maximum	Minimum	Maximum	
Chromium/(μg)	0.4	13.3	1.8	55.6	GB 5009.123 or GB 5009.268
Molybdenum/(μg)	1.3	12.0	5.6	50.0	GB 5009.268
Fluorine/(mg)	N.S.[b]	0.05	N.S.[b]	0.20	GB/T 5009.18
Choline /(mg)	5.3	39.8	22.2	166.7	GB 5413.20
Inositol/(mg)	1.0	33.5	4.2	140.0	GB 5009.270
Taurine/(mg)	4.7	19.8	20	83	GB 5009.169
L-Carnitine/(mg)	6.6	27.8	26.5	111	GB 29989
Nucleotide/(mg)	15.5	30.6	65	128	GB 5413.40
Dietary fiber/(g)	0.18	0.42	0.75	1.74	GB 5009.88 or GB 5009.255 or the second method in GB/T 22224-2008 or GB 5413.6
Arginine/(g)	0.12	N.S.[b]	0.5	N.S.[b]	GB 5009.124
Glutamine/(g)	0.04	0.53	0.15	2.22	-
Leucine/(g)	0.03	N.S.[b]	0.13	N.S.[b]	GB 5009.124
Calcium β-hydroxy-β-methylbutyrate /(g)	0.03	0.11	0.04	0.17	-

[a] Fluorine compounds are from sodium fluoride and potassium fluoride. Refer to Table C.2 in GB 14880 for the sources of nucleotide and dietary fibers that are allowed to be used. Refer to GB 14880 for sources of compounds containing other ingredients.

[b] N.S. stands for not specified.

3.5 Limits for contaminants and mycotoxins

3.5.1 Limits for contaminants shall comply with GB 2762.

3.5.2 Limits for mycotoxin shall comply with GB 2761.

3.6 Microbial limits

3.6.1 Limits on pathogenic bacteria of solid products should comply with GB 29921, while indicators of other microorganisms should comply with Table 3.

3.6.2 Solid and semi-solid products should meet commercial sterility requirements and be tested using the methods specified in GB 4789.26.

Table 3: Microbial Limits

Items	Sampling [a] and Limits (expressed in CFU/g or CFU/mL unless specified)				Testing Methods
	n	c	m	M	
Total bacteria plate count [b]	5	2	1 000	10 000	GB 4789.2
Coliform group	5	2	10	100	Plate counting method in GB 4789.3

[a] Analysis and processing of samples are carried out in accordance with GB 4789.1 and GB 4789.18.
[b] Not applicable to products with added active bacteria (aerobic bacteria and facultative anaerobe) [The count of active bacteria in a product should be $\geq 10^6$ CFU/g(mL)].

3.7 Food additives and nutrition fortifiers

3.7.1 The use of food additives and nutrition fortifiers should comply with GB 2760, GB 14880, and relevant provisions in public announcements.

3.7.2 The quality specifications of food additives and nutrition fortifiers should meet with requirements of corresponding standards and relevant regulations.

3.7.3 According to the special nutrition needs of cancer patients, one or several types of amino acids can be added to nutritionally complete formula foods of special medical purposes for cancer patients, and sources of amino acids used should comply with Appendix B in GB 29922, and (or) the provisions in GB 14880, and relevant public announcements.

4. Others

4.1 Labels

4.1.1 Product labels should comply with GB 13432. Labels should contain indication of content of nutrients and optional components in “Every 100kJ”.

4.1.2 Labels should describe formula features or nutritional characteristics for the products and indicate the sources and proportions of proteins. The product should also be marked with product categories and target population. Language of “not suitable for non-target population to use” should be included on the labels.

4.1.3 Product labels should contain descriptions of preparation instructions, corresponding permeation pressure, and shelf life.

4.1.4 Language of “please use it under the guidance of a doctor or a clinical nutritionist” should be displayed in a noticeable place on the labels.

4.1.5 Language of “the product is prohibited to use for parenteral nutritional support and

intravenous injection" and "nutrition status should be routinely monitored for any nutrients deficiencies" should be marked on the labels.

4.2 Instructions for use

4.2.1 Labels should bear explicit information about usages, guiding instructions, and illustrations for preparations, and storage conditions. When the maximum surface area of the packaging is less than 100 cm^2 or mass of the product is less than 100 g, illustrations are not required on the labels.

4.2.2 Guiding instructions should provide warnings about the possible health hazards caused by improper preparations and incorrect usages of the product.

4.3 Packaging

The carbon dioxide and/or nitrogen that meet with national food safety standards can be used as packaging media.

END TRANSLATION

Attachments:

No Attachments.