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China, People's Republic of

Food and Agricultural Import Regulations and Standards

Health Food Standard

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Report Highlights:
This is an UNOFFICIAL English translation of the People's Republic of China *Health Food Standard* and should be used as a guide only. Exporters should carefully discuss regulations and their application with Chinese importers to ensure that their interpretation of the regulations is accurate.

Includes PSD changes: No
Includes Trade Matrix: No
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This report was prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in Beijing, People's Republic of China for U.S. exporters of domestic food and agricultural products. While every possible care was taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

Summary
This Standard provides guidelines for the manufacturing, labeling, and hygiene of the health (functional) food industry in China. Chapter Eight provides some specific requirements for imported health (functional) foods for the Chinese domestic market. The Department of Hygiene under the State Council (also known as the Ministry of Health) is the statutory authority responsible for this regulation.

Health Food Standard (GB 16740-1997)

Foreword

Chinese health (functional) food can be traced back to remote antiquity. Traditional Chinese diet and medicinal foods have been used over a period of several thousand years. In recent years, many health (functional) foods have entered the market or been developed. The purpose of this standard is to improve and formalize the manufacture of health (functional) foods, to provide guidelines for governing the market, to defend the right of manufacturers, and to safeguard consumers' interest.

This standard provides the hygiene requirements (Clause 6.5) to the "Hygiene Requirements for Health Foods" issued by the Department of Hygiene Administration of the State Council.

This standard provides the requirements for labeling according to GB7718-94 "General Food Labeling Standard" and GB13432-92 "Labeling Special Nutritional Food" in reference to "Health Foods Labeling & Labeling Contents and Requirements of Product Description" issued by the Department of Hygiene Administration of the State Council. In view of the special features of health (functional) foods, additional labeling requirements are included.

Upon implementation, the enterprise standards established by health (functional) food manufacturers and filed with the Local Bureau of Technical Supervision shall comply with this standard. This standard proposed by the China National Food Industry Standardization Committee of Techniques. This standard appointed to the China National Food Industry Standardization Committee of Techniques. This standard prepared by the drafting group of the China National Bee Product Quality Supervision Testing Center, China Agriculture University, China National Research Institute of Food and Fermentation Industries, Technique Committee of China National Health Foods Association, and China National Food Industry Standardization Committee of Technique. The principal authors of this standard are Hao Yu, Li Zijian, Cai Tongyi, Chen Xiangkui; and co-authors are Lin Linan, Yang Xiaoming.

Chapter One: Main Contents and Application

This standard stipulates the definitions, general principals, technical requirements, testing methods, and labeling

requirements for health (functional) foods. This standard applies to health (functional) foods manufactured and/or sold within the People's Republic of China.

Chapter Two: Referenced Standards

The following standards contain provisions that, through reference in this text, constitute provisions of this standard. At the time of implementation, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent version of the standards listed below.

GB 2760-1996	Hygiene Standard for Food Additive Use
GB 4789.2-94	Microbiological Examination of Food Hygiene - Detection of Aerobic Bacterial Count
GB 4789.3-94	Microbiological Examination of Food Hygiene - Detection of Coliform Bacteria
GB 4789.4-94	Microbiological Examination of Food Hygiene - Examination of Salmonella
GB 4789.5-94	Microbiological Examination of Food Hygiene - Examination of Shigella
GB 44789.10-94	Microbiological Examination of Food Hygiene - Examination of Staphylococcus Aureus
GB 4789.11-94	Microbiological Examination of Food Hygiene - Examination of Streptococcus Hemolyticus
GB 4789.15-94	Microbiological Examination of Food Hygiene - Enumeration of Molds and Yeasts
GB/T 5009.11-1996	Method for Total Arsenic Determination in Foods
GB/T 5009.12-1996	Method for Lead Determination in Foods
GB/T 5009.17-1996	Method for Total Mercury Determination in Foods
GB 7718-94	General Standard for Food Labeling
GB 13432-92	Labeling of Special Nutrient Food
GB 14880-94	Hygiene Standard for Nutritional Fortification Substances Used in Food
GB 14881-94	General Hygiene Regulation for Food Enterprises
GB 14882-94	Limited Concentration of Radioactive Materials in Foods
GB 15266-94	Sport Drinks

Chapter Three: Definition of terms

For the purpose of this standard:

3.1 Health (functional) food

Any food possessing the general characteristics of food that is able to regulate human body functions and is suitable for specific consumer groups, but without any intention for therapeutic purposes.

3.2 Functional component

Any substance able to regulate human body functions by initiating enzyme activities or by other means. Currently, the following substances are included:

- Polysaccharide; such as dietary fiber, and lentinan;
- Functional sweeteners; such as mono-saccharide, oligose, and poly-glycitol;
- Functional fats (fatty acid); such as poly-unsaturated fatty acid, phospholipids, and choline;
- Free radical seekers; such as super oxide dismutase (SOD), and glutathione peroxidase;
- Vitamins; such as vitamin A, vitamin E, and vitamin C;
- Peptides and proteins; such as glutathione, and immunoglobulin;

- Active bacteria; such as lactobacillus, and bifid bacterium;
- Trace-elements; such as selenium, and zinc;
- Others; such as octacosyl alcohol, phytosterol, and saponin.

Chapter Four: Product Classification

Health (functional) foods are classified according to their regulating functions of the human body; as follows: regulating the immune system, delaying senility, memory enhancement, growth enhancement, anti-fatigue, weight control, improvement of oxygen-deficiency tolerance, radiation resistance enhancement, anti-mutation and tumor inhibition, blood lipid regulation, libido enhancement, blood sugar regulation, etc.

Chapter Five: General principles

5.1 Health (functional) foods shall not cause any acute, sub-acute, or chronic harm to the human body.

5.2 Health (functional) foods shall be evaluated scientifically through qualitative and quantitative composition analysis and functional testing on animal or human groups, and proven to contain effective functional components that have stable and noticeable body function regulation. Alternatively health (functional) foods shall pass animal or human group tests and demonstrate a stable and noticeable role in body function regulation.

5.3 The ingredient formula and manufacturing method of health (functional) foods shall be scientifically sound.

5.4 Manufacturers of health (functional) foods shall conform to GB 14881-94 and establish and improve their quality assurance system.

Chapter Six: Technical requirements

6.1 Raw materials and supplementary ingredients

6.1.1 Raw materials and supplementary ingredients shall comply with corresponding national standards, trade standards, or relevant regulations.

6.1.2 Food additives shall comply with corresponding national standards or trade standards.

6.1.3 Pesticide, veterinary drug, and biological toxin residue limits shall comply with corresponding national standards.

6.1.4 Radioactive substances residue limits shall comply with GB 14882-94.

6.2 Appearance and sensory properties

Health (functional) food shall have suitable appearance, color, odor, taste, and texture; without any unpleasant nor unacceptable odor and taste.

6.3 Functional requirement

Health (functional) food shall have at least one function regulating the human body.

6.4 Physical-chemical requirements

6.4.1 Net content

The difference between the unit package net contents and the labeled mass or volume shall not exceed the negative deviation (Table 1).

Table 1: Negative deviation for unit package net contents

Net content	Negative deviation	
Q	Percentage of Q	g or mL
5g ~ 50g 5mL ~ 50mL	9	-
50g ~ 100g 50mL ~ 100mL	-	4.5
100g ~ 200g 100mL ~ 200mL	4.5	-
200g ~ 300g 200mL ~ 300mL	-	9
300g ~ 500g 300mL ~ 500mL	3	-
500g ~ 1kg 500mL ~ 1L	-	15
1kg ~ 10kg 1L ~ 10L	1.5	-

6.4.2 Functional ingredient

Health (functional) food shall contain the corresponding functional ingredient with the minimum effective dosage. If necessary, the effective ingredient shall be controlled within the maximum range limit.

6.4.3 Nutrients

Health (functional) food shall contain the characteristic nutrients; in addition to complying with Clause 6.4.2.

6.4.4 Added quantities of food additives or nutritional fortification substances

Health (functional) food shall comply with the dosage requirements for food additives and nutritional fortification substances in GB 2760 and GB 14880.

Health (functional) food for infants and pregnant (lactating) women shall not contain any stimulant nor hormone. Health (functional) food for athletes shall not contain any prohibited drug as designated in GB 15266.

6.5 Hygiene requirements

6.5.1 Harmful metals and harmful substances limits

Health (functional) food shall comply with the limits established in the requirements for the national hygiene standards. Any health (functional) food that does not have a limit in the national standard, shall comply with the limits of lead, arsenic, and mercury in Table 2.

Table 2: The limits of lead, arsenic and mercury

Item	Allowable Limits	
	General product	Specific product
Lead, mg/kg #	0.5	1.5 for capsules; 2.0 for solid beverages and capsules containing algae or tea.
Arsenic, mg/kg #	0.3	1.0 for solid beverages containing algae or tea and all capsules.
Mercury, mg/kg #	-	0.3 for solid beverages containing algae or tea and all the capsule.

6.5.2 Microbial load limit

Health (functional) food shall comply with the limits established in the requirements for the national hygiene standards. Any health (functional) food that does not have a limit in the national standard, shall comply with the microbial load limits in Table 3 as determined by physical properties of the product.

Table 3: Microbe limits

		Limits		
Item	Liquid		Solid or semi -	solid
	Protein $1.0%	Protein < 1.0%	Protein $4.0%	Protein < 4.0%
Total bacterial count, cfu/g or mL #	1,000	100	30,000	1,000
Coliform, MPN/100g or 100mL #	40	6	90	40

Mold, cfu/g or mL #	10	10	25	25
Yeast, cfu/g or mL #	10	10	25	25
Pathogen (enteropath-ogenic bacteria and pathogenic coccus)		No detectable		

Chapter Seven: Testing and analysis method

7.1 Nutrient and functional component
Nutrient and functional component testing and analysis shall be conducted according to the methods provided in the corresponding national standards, trade standards, or the methods approved by the authorized organization.

7.2 Stimulant and hormone
Stimulant and hormone testing and analysis shall be conducted according to the methods provided in the corresponding national standards, trade standards, or the methods approved by the authorized organization.

7.3 Lead
According to GB/T 5009.12.

7.4 Arsenic
According to GB/T 5009.11.

7.5 Mercury
According to GB/T 5009.17.

7.6 Total bacteria count
According to GB 4789.2.

7.7 Coliform
According to GB 4789.3

7.8 Mold and yeast
According to GB 4789.15.

7.9 Pathogens
According to GB 4789.4, GB 4789.5, and GB 4789.11.

Chapter Eight: Labeling

The following information shall be declared on any label of ready to eat prepackaged health (functional) food that is manufactured locally or imported:

8.1 Name of health (functional) food

8.1.1 The name shall indicate the true nature of the food and comply to Clauses 5.1 and 8.4 in GB 7718-94. A "coined", "fanciful", "brand", or "trade mark" name may be used if it accompanies the specific name that indicates the true nature of such food or the approved functional name; such as delaying senility, weight control, and anti-fatigue foods.

8.1.2 The product shall not be named as a pharmaceutical nor resemble a pharmaceutical name, nor the abbreviation of a foreign name, nor Chinese Phonetic Alphabet name.

8.2 Ingredient list (Ingredients)
The ingredients shall be listed in compliance with Clause 5.2 in GB 7718. Food additives and nutritional fortification substances shall be listed with their specific name according to GB 2760 and GB 14880.

8.3 Table of active and nutritional ingredients

8.3.1 The quantity of the main and supplemental active ingredients shall be counted as per 100g or 100mg (in g, mg, Fg or IU unit).

8.3.2 The quantity of live microorganisms (e.g. live lactobacillus) contained in health (functional) food shall be counted in cfu/100g or 100mL.

8.3.3 The name and the quantity of the main and supplemental ingredients shall be labeled for products when active ingredients cannot be identified by current scientific methods.

8.3.4 The nutrient content shall be labeled in compliance with Appendix A in GB13432.

8.4 Health function
The declared health function shall be consistent with the approved function; no description, introduction, or allusion to the "therapeutic effect" of the product shall be declared.

8.5 Net content and solid content
Net content and solid content shall be labeled according Clause 5.3 in GB 7718-94.

8.6 Name and address of the manufacturer

8.6.1 The legally registered name and address of the manufacturer, packaging operation, or retail goods packaging operation of health (functional) food shall be declared.

8.6.2 Imported health (functional) food may be exempted from Clause8.6.1. However, the country or region (like Hong Kong, Macao, Taiwan) of origin, and the name and address of the exclusive distributor or agency in China shall be declared.

8.7 Manufacturing date, date of minimum durability and/or the expiration date

8.7.1 The health (functional) food manufacturing date shall follow the sequence of year, month, and day.

8.7.2 The health (functional) food date of minimum durability and/or the expiration date shall be in compliance with Clause 5.4.1.2 in GB 7718.

8.8 Storage instruction (conditions)

If the date of minimum durability and/or the use by date depends on storage conditions, any special storage conditions for the health (functional) food shall be written on the label.

8.9 Instructions for consumption

8.9.1 The target consumers (i.e. the specific consumer group) for the health (functional) food shall be declared.

8.9.2 The instructions for consumption shall be declared according to Clause 7.2 in GB 7718. The recommended dietary allowance or intake for each different consumer group shall be declared.

8.10 Product standard code and approval number

The code and order number of the national standard, trade standard or enterprise standard and the approval number for such food shall be declared.

Imported health (functional) food may be exempted from the product standard code.

8.11 Special labeling

The scientific name and content of each stimulant or hormone contained in health (functional) food shall be declared.