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## Overview of Health Foods Regulation in China



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In China, the State Administration for Market Regulation (SAMR) is responsible for health food registration and notification of first-time imported health food that belongs to the vitamin and mineral supplement category. Provincial departments for market regulation are working with the SAMR to perform on-site audits of health foods applying for registration. In contrast, municipality-level and county-level departments supervise market regulation and manage health foods that have achieved registration and notification status within their administrative region.



**A**ny manufacturer interested in developing a health foods business in China must know the Chinese market and regulations. This article provides a comprehensive insight into the management and registration of health foods in China.

Food and dietary supplements, such as beverages, candy, vitamins and minerals, sports nutrition, nutrition supplement beverage, probiotics and prebiotics product, and health functional claim product, are very popular worldwide. According to the "Food Safety Law of P.R.C.,"

### Approved Health Claims for Functional Foods

Enhancing Immune Systems	Eliminating Skin Pigmentation	Assisting Blood Pressure Reduction
Sleep Improvement	Improving Skin Ability to Retain Moisture	Facilitating Milk Secretion
Alleviating Physical Fatigue	Improving Skin Oil Content Function	Assisting Weigh Control
Enhancing Anoxia Endurance	Assisting Blood Lipids Reduction	Improving Child Growth
Irradiation Hazard Protection Function	Assisting Blood Sugar Reduction	Improving Nutritional Anaemia
Increasing Bone Density	Anti-oxidative Function	Regulating Gastrointestinal Flora
Assisting Liver Protection Against Injury	Assisting Memory Improvement	Facilitating Digestion (Regularity)
Alleviating Eye Fatigue	Alleviating Lead Excretion	Facilitating Bowel Movement
Eliminating Acne	Improving Throat Function	Protection of Gastric Mucosa

the food is classified into general food and special food depending on the product format, ingredients and dosage, target population, and product claim. There are thirty-two (32) categories, including twenty-nine (29) categories of general food and three (03) categories of special food. Although there was no category for dietary supplements under China’s food framework, they could be categorised as general foods (especially special dietary food). Especially when there is no claim function, no special target population, no special format, and use of general food ingredients. Also, dietary supplements could be categorised as health foods for the target population, special format, function claim, functional/ special ingredients, and dosage.

#### Definition of Health Foods

Health food is defined as food with specified health functions suitable for the specified group(s) of people, which helps regulate the functional state of the human body and is not used for treating any disease.

They include vitamin and mineral supplements that may not be used for disease treatment.

#### Classification of Health Foods

Health foods in China are divided into the following two (02) categories:

- **Functional Health Food:** Health Foods with specific health functions (27 approved health claims), such as immunity development and memory improvement, must be registered with the SAMR before importing to China. Besides, raw materials present in the health food that are beyond the scope of the permitted raw material catalog must be registered as well.
- **Nutritional Supplement:** Health Foods that supplement vitamins or minerals must be filed with the SAMR. Besides, raw materials present in the health food that are beyond the scope of the permitted raw material catalog must be filed

as well.

Any manufacturer who wishes to sell health food products in the Chinese market must either apply for health food registration or filing/notification. The application dossiers must be submitted to the competent Chinese authority (SAMR) for review.

#### Companies manufacturing/importing the products mentioned below must be filed with the SAMR

- Health food containing raw materials listed in the Health Food Raw Material List
- Mineral and vitamin supplements are imported for the first time. In this case, the nutrients must be listed in the Health Food Raw Material List.

Companies manufacturing/importing health products other than those mentioned above must be registered with the SAMR.

#### Qualification of the Health Food Registration/ Notification Applicant

The applicant for the registration/notification of imported health food shall be an overseas manufacturer of health food, which refers to legal persons or other organisations whose products meet the listing requirements of the country (region) where they are located.

#### Health Food Labels and Specifications

Health food labels and specifications should not involve any statement related to disease prevention and treatment. The phrase - “This product cannot replace a drug” – must be provided on the label.

Health food names must not contain the following:

- Words that express/imply prevention or treatment of diseases
- False, exaggerated, or absolute words
- Vulgar or superstitious words
- Words that describe human tissues and organs

### Current Laws and Regulations Mainly Related to Food and Dietary Supplements

<b>Laws</b>	<ul style="list-style-type: none"> <li>● Food Safety Law of the People's Republic of China Product Quality Law</li> <li>● Advertisement Law</li> <li>● Laws on Import and Export Commodity Inspection</li> </ul>
<b>Administrative Regulations</b>	<ul style="list-style-type: none"> <li>● Regulations on the Implementation of Food Safety Law</li> <li>● Administrative Measures on Safety of Import and Export Food of the People's Republic of China (NO.249 of 2021)</li> <li>● Regulations of the People's Republic of China on Registration Administration of Overseas Production Enterprises of Imported Foods (NO.248 of 2021)</li> <li>● Administrative Measures for Registration and Notification of Health Food</li> <li>● Health Food Labeling Management Regulations (1996 Edition) (current under modification)</li> <li>● Administrative Measures on Health Food Raw Material Directory and Health Function Directory (SAMR 2019 Order No. 13)</li> </ul>
<b>Announcements</b>	<ul style="list-style-type: none"> <li>● Health Food Naming Guidelines (2019 Edition)</li> <li>● Announcement of the General Administration on Regulating the Labeling of Health Food Function Claims (No. 23 of 2018)</li> <li>● Guidelines for Labeling Warning Words for Health Foods (Announcement No 29, 2019)</li> <li>● Announcement of the General Administration on Regulating the Labeling of Health Food Function Claims (No. 23 of 2018)</li> <li>● Technical Guidelines for the Inspection and Evaluation of Physical, Chemical, and Health Indicators of Health Foods (2020 Edition)</li> <li>● Technical Guidelines for Toxicological Testing and Evaluation of Safety of Health Foods and their Raw Materials (2020 Edition)</li> <li>● Catalogue of Health Food Notification Raw Materials (2020 Edition)</li> <li>● Health Food Notification Auxiliary Materials and Usage List (2021 Edition)</li> </ul>
<b>Technical Standards</b>	<ul style="list-style-type: none"> <li>● GB 16740-2014 National Food Safety Standard Health Food</li> <li>● GB 22570-2014 National Food Safety Standard Complementary Food Supplement</li> <li>● GB 24154-2015 National Food Safety Standard for Food Safety General Rules for Sports Nutrition Food</li> <li>● GB 31601-2015 National Food Safety Standard Nutritional Supplements for Pregnant and Lactating Women</li> <li>● GB 7101-2015 National Food Safety Standard Drinks</li> <li>● GB 15266-2009 Sports Beverage</li> <li>● GB 7718-2011 National Food Safety Standard General Rules for the Labeling of Prepackaged Foods (currently under modification)</li> <li>● GB 28050 -2011 National Food Safety Standard for Nutrition Labeling of Prepackaged Foods</li> <li>● GB 13432-2013 National Food Safety Standard Labeling of Prepackaged Foods for Special Dietary Uses</li> <li>● GB 14880-2012 National Food Safety Standard for the Use of Nutritional Fortification Substances in Foods</li> </ul>

- Symbols except for quotation marks (“)
- Other misleading words

In a nutshell, the focus on health and an active lifestyle is on the rise in China, providing numerous opportunities for health food manufacturers. However, the market is fast-moving and complex, with an ever-changing landscape of consumer preferences and

channels. By 2050, it is expected that almost 30 per cent of China's population will be 60 years and older, resulting in the increased consumption of health food products. Therefore, companies willing to expand their footprint in China must understand the implications to align with the health authority regulations to meet the consumer demand and succeed in the market. **NS**