

China Focus

Health Food Regulation

Overview & Updates

ZMUni Compliance Centre



Overview of China Health Food Regulation

1. Definition of Health Food in China

According to the "National Food Safety Standard for Health Food" (GB 16740), health food in China is defined as food that claims to have specific health functions or is intended to supplement vitamins and minerals. It is suitable for specific groups of people, has a regulatory function on the body, is not intended to treat diseases, and does not cause acute, subacute, or chronic harm to the human body. The most important symbol distinguishing health food from other food is the "blue hat" logo.

2. Regulatory Approach for Health Food in China

Before being marketed, all imported health food in China must obtain a registration or filing certificate for health food.

- Filing of health food applies to first-time imported health food that belongs to **nutritional substances such as vitamins and minerals**. The product filing process may take 5–12 months or longer and requires product testing such as for hygiene, stability, composition, etc by approved Chinese laboratories. The filing certificate for health food has no expiration date and cannot be transferred. Changes or cancellations of the filing can be made, but the corresponding application procedures must be completed.
- Registration of health food applies to first-time imported functional health food. The registration certificate for health food is valid for 5 years. The product registration process may take 1–5 years or longer and requires product testing such as for toxicology, efficacy, composition, hygiene, etc by approved Chinese laboratories. Changes, transfers, or cancellations are allowed, but the corresponding application procedures must be completed. If the registration certificate for health food that has been produced and sold is about to expire and needs to be extended, the registrant should apply for an extension six months before the expiration date.

For imported health food filing and registration, the applicant should be a foreign manufacturer of health food that is already on the market (foreign manufacturers refer to legal persons or other organizations whose products meet the market requirements of the country or region they are located in).

3. Related National Standards and Supporting Documents for Health Food in China (including but not limited to the following):

- Food Safety Law of the People's Republic of China
- Measures for the Registration and Filing Administration of Health Food
- GB 16740-2014 National Food Safety Standard for Health Food
- Guidelines for Health Food Filing (Trial)
- Guidelines for Health Food Registration Application Services (2016 version)
- Detailed Rules for the Evaluation and Approval of Health Food Registration (2016 version)
- Catalogue of Permitted Health Functions for Health Food (Nutritional Supplements, 2023 version)
- Catalogue of Permitted Health Functions for Health Food (Non-nutritional Supplements, 2023 version)
- Regulations on the Use of Auxiliary Materials in Filing Products of Health Food (2021 version)
- Technical Requirements for Dosage Forms of Filing Products of Health Food (2021 version)
- Technical Guidelines for Toxicology Evaluation and Assessment of Health Food and Its Ingredients (2020 version)
- Technical Guidelines for Safety Evaluation and Assessment of Microorganisms Used in Health Food Ingredients (2020 version)
- Technical Guidelines for Physicochemical and Hygienic Index Testing and Evaluation of Health Food (2020 version)
- Methods for Function Evaluation and Assessment of Health Food (2023 version)
- Technical Guidelines for Function Evaluation and Assessment of Health Food (2023 version)

China Health Food Regulatory Updates in 2023 & 2024 Q1

1. A total of eight ingredients were newly approved as health food ingredients in 2023 and 2024 Q1. They are Docosahexaenoic acid (DHA), Casein Phosphopeptide + Calcium, Hemoglobin Iron Chloride, Soy Protein Isolate, Whey Protein, Ginseng, American Ginseng and Lingzhi. Domestic-produced products falling under these categories can apply for filing/notification.
2. Updates to the Health Food Claims Catalog for Non-Nutrient Supplements have been made, including adjustments to the allowed claims, revision of terminology, and the removal of claims related to "promoting lactation," "improving growth and development," and "improving skin oil balance."
3. The release of the "Methods for Inspection and Evaluation of Health Food Functions (2023 Edition)" in August 2023 has facilitated the smooth progression of health food registrations. Moreover, the long-awaited policy for reissuing registration certificates with "no expiration date and no product technical requirements" has been officially implemented.
4. Clear guidelines have been established for declaring new functions of health food: "The Detailed Rules on the Implementation for Technical Evaluation of New Functions and Health Food with New Functions (Trial) " were released in August 2023, with the aim of encouraging industries to engage in functional innovation and product research and development. The Rules include "Material Requirements and Technical Evaluation Points for New Function Applications" to provide further guidance to the industry when applying for new functions.
5. On December 22, 2023, the State Administration for Market Regulation of China issued the "Guidelines for the Standardized Labeling of Health Food Symbols." Before the release of the "Guidelines," the existing regulations on health food symbols did not provide detailed requirements for specific aspects such as graphic proportions and color standards.
6. China simplified the registration and filing of applications for imported health food, implementing more relaxed requirements on several documents, including the qualification certification documents, marketing and sales certification documents, quality management system certification documents of production enterprises, power of attorney (agreement), etc. For the above documents issued by contracting parties of the Convention of 5 October 1961 Abolishing the Requirement of Legalisation for Foreign Public Documents, only an Apostille of that country is required. Consular authentication from the government and the Chinese embassy or consulate in the local area is no longer necessary.

Compliance Guide for DHA Algae Oil Products in China



Compliance Guide for Weight Loss Food Products in China





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