

# Chinese Legislation on Nutrition and Health Products

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# Functional foods in China

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- ❑ Health foods are an important part of the Chinese food industry with several different types of products and health claims.
  - ❑ Functional foods and supplements with vitamins and minerals are in China regulated as **health foods**. The legislation came into force 1996.
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# Health food approvals

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- ❑ China has a **pre-market registration procedure** for health foods.
  - ❑ Health foods are foods claiming to have certain health improving functions **or** to be able to supply vitamins and minerals. A health food is good for a particular group of people and able to adjust body functions.
  - ❑ **A health food is not used to cure diseases.**
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# Health food authorities

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- A Chinese company submits the health food application to provincial health administration authorities, who perform preliminary examination. Upon passing this, the application is submitted to the State Food and Drug Administration (SFDA).
  - For imported foods, the application for health food approval is sent **straight to the SFDA.**
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# Types of health foods

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- ❑ Early health foods were basically foods made of medicinal plants.
  - ❑ Today also other materials such as probiotics are used.
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# The data requirements

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- ❑ Prior to submission of the application, the following reports must be obtained from an authorized laboratory:
  - ❑ - report of toxicological safety assessment,
  - ❑ - report of functionality (efficacy) evaluation,
  - ❑ - analytical report of active ingredient,
  - ❑ - report of product stability study, and
  - ❑ - report of sanitary inspection.
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# The testing authorities

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- ❑ Health foods by Chinese companies are tested by various laboratories across the country.
  - ❑ All **imported health foods** are tested by the Institute of Nutrition and Food Safety, the Chinese Center for Disease Control in Beijing.
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# The allowed raw materials

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- ❑ There are important restrictions to health food **raw materials**. There are three categories of raw materials:
  - ❑ category I: materials that can be either food or medicine,
  - ❑ category II: permitted health food materials,
  - ❑ category III: prohibited health food materials.
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# The allowed raw materials

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- ❑ A health food can contain a maximum of **14** plant and animal raw ingredients.
  - ❑ If you use raw materials outside category I, the number of raw materials is limited to **4**.
  - ❑ If a health food is made of something outside categories I and II, it can only contain **1** raw material.
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# The Chinese novel food regulation

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- ❑ A new regulation on novel foods (issued in March by the Ministry of Health) will come into force **December 2007**.
  - ❑ Novel foods have to undergo a pre-market safety assessment.
  - ❑ Novel foods are defined as **ingredients that have not traditionally formed part of the Chinese diet**.
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# Novel foods in China

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- The old novel food regulation dates from 1990. The new regulation is stricter and makes the process simpler.
  - Currently, there are some 340 novel foods on the market. These may be reviewed to comply with the new rules. The sugar replacer Isomalt was apparently the first non-Chinese novel food approved in China (2006). Martek was granted initial approval for its omega-3 in 2007.
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# Choice of raw materials affects the safety test requirements

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- ❑ **Toxicological testing requirements range from zero to extensive.**
  - ❑ Safety of a simple health food made of common foods and category I materials might not have to be tested at all.
  - ❑ A previously unknown material outside the lists will have to be tested for acute, genetic, sub-chronic, and chronic toxicity.
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## Health claims vs. medicinal claims

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- ❑ **Only health foods are allowed to bear health claims = normal foods cannot bear health claims!**
  - ❑ Health food cannot bear medicinal claims.
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# The allowed claim categories

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- ❑ There are **27 legal claim categories** for health foods.
  - ❑ All of the important functional food functions and claims relating to gastrointestinal flora, blood lipids, blood sugars, overweight etc. are included.
  - ❑ **Other types of health claims are prohibited**, for example claims related to cancer prevention.
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# The list of allowed claim categories

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- Assisting in blood lipids reduction
  - Assisting in blood sugar reduction
  - Assisting in hypertension alleviation
  - Weight reduction
  - Anti-oxidation
  - Increasing bone density
  - Enhancing immune function
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## The list of allowed claims (continued)

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- Regulating gastrointestinal flora
  - Facilitating digestion
  - Alleviating constipation
  - Assisting in protection against gastric mucosa injury
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# The list of allowed claim categories (continued)

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- Enhancing sleep
  - Assisting in memory improvement
  - Reducing eye fatigue
  - Alleviating physical fatigue
  - Enhancing anoxia endurance
  - Facilitating lactation
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## The list of allowed claim categories (continued)

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- Alleviating nutritional anemia
  - Enhancing child growth and development
  - Assisting in protection against liver chemical injury
  - Assisting in protection against irradiation hazard
  - Facilitating lead excretion
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## The list of allowed claims (continued)

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- Alleviating acne
  - Eliminating skin pigmentation
  - Improving skin moisture
  - Improving skin oil content
  
  - Thinning throat mucus
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## The function = claim affects the required tests for efficacy

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- ❑ There are precise regulations on trial design and testing parameters for different functions.
  - ❑ For 22 claims, **animal tests** are required.
  - ❑ For 20 claims, **human trials** are required.
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# Vitamin or mineral supplements

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- ❑ **No clinical tests** on safety or efficacy **are required** of a food supplement consisting of approved vitamins and minerals.
  - ❑ The product still must be authorised as health food.
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# Other food supplements

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- ❑ Other supplements such as those containing dietary fibres, proteins, or amino acids, are considered **common foods** where no pre-market control applies.
  - ❑ For common foods, health claims are not allowed. If health claims are wanted, the supplement must undergo the whole health food process.
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## Further readings

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- Huang, Guangwei – Lapsley, Karen: Chinese Health (Functional) Food Regulations. In: *Regulation of Functional Foods and Nutraceuticals*. Edited by Clare M. Hasler. Blackwell Publishing. 2005. Pages 263-291.
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# Web pages

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- Chinese Food, Drug and Cosmetic Regulations: <http://www.chinafdc-law.com/>.
  - The State Food and Drug Administration: <http://eng.sfda.gov.cn/eng/>.
  - The Ministry of Health: <http://www.moh.gov.cn/2.htm> (in Chinese).
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# My contact information

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  - Thank you!
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# Future of Chinese regulation

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- Chinese health food legislation is at the moment based on **several different pieces** of administrative regulations given by the Ministry of Health and the State Food and Drug Administration.
  - In the future, all health food legislation will hopefully be codified in **one piece** of law.
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# The challenge of post-market control

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- China will also have to focus on post-market control, as there are already thousands of approved health foods on the market competing with the illegal ones.
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