



# Regulatory Insights

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**Agency**

National Health and Family Planning  
Commission

**National Food Safety GB Standards**

**Health Food**

**食品安全国家标准 保健食品**



**The Peoples Republic of China National GB Standards**

GB 16740-2014

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**National Food Safety GB Standards**

**Health Food**

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Issued by

**National Health and Family Planning Commission of  
the People 's Republic of China**

**Preambles**

The GB 16740-1997 National Health Functional Food General Standards has been repealed by this regulation.

Compared with GB 16740-1997, this regulation includes changes as follow:

- The title has been changed into 'National Food Safety GB Standards: Health Food' ;
- Change of Scope;
- Change of Terms and Definitions;
- Deletion of Product Category;
- Deletion of Basic Principles;
- Change of Technical Requirements;
- Deletion of Test Method;
- Change of Labeling Method.

## National Food Safety GB Standards Health Food

### 1 Scope

This GB standards regulate all kinds of health food.

### 2 Terms and Definitions

#### 2.1 Health Food

Health food is food which claims to have specific healthcare functions or to be a supplement of vitamins and minerals for human body. Health food is designed for specific group of people, aiming to benefit the functioning of human body whilst not to treat or cure any disease. Health food shall not bring acute or subacute or chronic harm to human body.

### 3 Technical Requirement

#### 3.1 Ingredients and Excipients

Ingredients and excipients shall comply with other relevant regulations

#### 3.2 Sensory Requirements

Sensory requirements shall comply with the regulations in Table 1.

**Table 1 Sensory Requirements**

<b>Items</b>	<b>Requirements</b>	<b>Test Method</b>
Color	Content, coating or capsule shall have reasonable color.	Put an appropriate amount of the sample into a 50ml beaker or

Taste/Smell	The product shall have reasonable taste and smell.	a white porcelain cup, then observe its color and condition, smell it, and rinse the mouth with warm water then taste the sample.
Condition	The content shall have reasonable conditions and no foreign materials shall be found by naked eyes.	

### 3.3 Physicochemical Indexes

Physicochemical indexes shall comply with the national GB standards on relevant categories of food products.

### 3.4 Contamination limits

Contamination limits shall comply with GB 2762 on relevant categories of food. If there is no relevant category for one product, it shall comply with the regulations in Table 2.

**Table 2 Contamination Indexes**

Items	Indexes	Test Method
Lead <sup>a</sup> (Pb)/(mg/kg)	2.0	GB 5009.12
Total Arsenic <sup>b</sup> (As)/(mg/kg)	1.0	GB/T 5009.11
Total Mercury <sup>c</sup> (Hg)/(mg/kg)	0.3	GB/T 5009.17
<sup>a</sup> Lead in Teabags shall $\leq 5.0$ mg/kg; Plumbum in liquid products shall $\leq 0.5$ mg/kg; Plumbum in infant health food solid or semisolid product shall $\leq 0.3$ mg/kg; Plumbum in Infant health food liquid product shall $\leq 0.02$ mg/kg. <sup>b</sup> Total arsenic in liquid products shall $\leq 0.3$ mg/kg; Total arsenic in Infant health product shall $\leq 0.3$ mg/kg. <sup>c</sup> Liquid products (except for infant health food) do not require mercury test. Total mercury in infant health food shall $\leq 0.02$ mg/kg.		

### 3.5 Fungaltoxin Limits

Fungaltoxin indexes shall comply with relevant category of food standards in GB 2761 and(or) other relevant standards.

### 3.6 Microbiological Limits

Microbiological indexes shall comply with relevant category of food standards in GB 29921 and other relevant category of national food standards. If there is no relevant category for one product, it shall comply with the regulations in Table 3.

**Table 3 Microbiological Indexes**

Items	Sampling <sup>a</sup> and Indexes		Test Method
	Liquid	Solid or Semi-solid	
Total Bacterium <sup>b</sup> / (CFU/g OR mL) ≤	10 <sup>3</sup>	3×10 <sup>4</sup>	GB 4789.2
Total Coliform Group (MPN/g OR mL) ≤	0.43	0.92	GB 4789.3 MPN Counting Method
Molds and Yeasts (CFU/g 或 mL) ≤	50		GB 4789.15
Staphylococcus Aureus ≤	0/25g(mL)		GB 4789.10
Salmonella Typhimurium ≤	0/25g(mL)		GB 4789.4
<sup>a</sup> Sampling and sample treatment shall comply with GB 4789.1. <sup>b</sup> This index shall not apply to products which contain active bacteria (aerobic and facultative anaerobic probiotics).			

### 3.7 Food Additives and Nutrition Enhancers

3.7.1 The use of food additives shall comply with GB 2760.

3.7.2 The use of nutrition enhancers shall comply with GB 14880 and(or) relevant regulations.

## 4 Other Requirement

Labeling shall comply with relevant regulations.

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# 中华人民共和国国家标准

GB 16740—2014

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食品安全国家标准

保健食品

## 前 言

本标准代替 GB 16740—1997《保健(功能)食品通用标准》。

本标准与 GB 16740—1997 相比,主要变化如下:

- 标准名称修改为“食品安全国家标准 保健食品”;
- 修改了范围;
- 修改了术语和定义;
- 删除了产品分类;
- 删除了基本原则;
- 修改了技术要求;
- 删除了试验方法;
- 修改了标签标识的要求。

# 食品安全国家标准

## 保健食品

### 1 范围

本标准适用于各类保健食品。

### 2 术语和定义

#### 2.1 保健食品

声称并具有特定保健功能或者以补充维生素、矿物质为目的的食品。即适用于特定人群食用,具有调节机体功能,不以治疗疾病为目的,并且对人体不产生任何急性、亚急性或慢性危害的食品。

### 3 技术要求

#### 3.1 原料和辅料

原料和辅料应符合相应食品标准和有关规定。

#### 3.2 感官要求

感官要求应符合表 1 的规定。

表 1 感官要求

项目	要求	检验方法
色泽	内容物、包衣或囊皮具有该产品应有的色泽	取适量试样置于 50 mL 烧杯或白色瓷盘中,在自然光下观察色泽和状态。嗅其气味,用温开水漱口,品其滋味
滋味、气味	具有产品应有的滋味和气味,无异味	
状态	内容物具有产品应有的状态,无正常视力可见外来异物	

#### 3.3 理化指标

理化指标应符合相应类属食品的食品安全国家标准的规定。

#### 3.4 污染物限量

污染物限量应符合 GB 2762 中相应类属食品的规定,无相应类属食品的应符合表 2 的规定。

表 2 污染物限量

项 目	指 标	检 验 方 法
铅 <sup>a</sup> (Pb)/(mg/kg)	2.0	GB 5009.12
总砷 <sup>b</sup> (As)/(mg/kg)	1.0	GB/T 5009.11
总汞 <sup>c</sup> (Hg)/(mg/kg)	0.3	GB/T 5009.17
<sup>a</sup> 袋泡茶剂的铅≤5.0 mg/kg;液态产品的铅≤0.5 mg/kg;婴幼儿固态或半固态保健食品的铅≤0.3 mg/kg;婴幼儿液态保健食品的铅≤0.02 mg/kg。 <sup>b</sup> 液态产品的总砷≤0.3 mg/kg;婴幼儿保健食品的总砷≤0.3 mg/kg。 <sup>c</sup> 液态产品(婴幼儿保健食品除外)不测总汞;婴幼儿保健食品的总汞≤0.02 mg/kg。		

### 3.5 真菌毒素限量

真菌毒素限量应符合 GB 2761 中相应类属食品的规定和(或)有关规定。

### 3.6 微生物限量

微生物限量应符合 GB 29921 中相应类属食品和相应类属食品的食品安全国家标准的规定,无相应类属食品规定的应符合表 3 的规定。

表 3 微生物限量

项 目	采样方案 <sup>a</sup> 及限量		检 验 方 法	
	液态产品	固态或半固态产品		
菌落总数 <sup>b</sup> /(CFU/g 或 mL)	≤	10 <sup>3</sup>	3×10 <sup>4</sup>	GB 4789.2
大肠菌群(MPN/g 或 mL)	≤	0.43	0.92	GB 4789.3 MPN 计数法
霉菌和酵母(CFU/g 或 mL)	≤	50		GB 4789.15
金黄色葡萄球菌	≤	0/25 g(mL)		GB 4789.10
沙门氏菌	≤	0/25 g(mL)		GB 4789.4
<sup>a</sup> 样品的采样及处理按 GB 4789.1 执行。 <sup>b</sup> 不适用于终产品含有活性菌种(好氧和兼性厌氧益生菌)的产品。				

### 3.7 食品添加剂和营养强化剂

3.7.1 食品添加剂的使用应符合 GB 2760 的规定。

3.7.2 营养强化剂的使用应符合 GB 14880 和(或)有关规定。

## 4 其他