



CIRS

# Guideline on Health Food Exportation to China

2018 Version

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## Foreword

Chinese consumer's consumption of health food was far below that of developed countries in the past. However, presently the demand is increasing rapidly because of the aging aggravation, government encouragement, accelerated urbanization and other drivers. China is recognized as the largest and fastest growing health food market which has huge potential. What's more, Chinese consumers' preferences for imported health food and Chinese government's favorable policies on imported products have brought great opportunity to foreign health food companies. Therefore, 2018 is the good time for foreign health food companies to enter the Chinese market. However, it is obvious that the different cultures and regulations will cause exportation barriers for oversea health food companies.

Under this circumstance, CIRS Food Technical Team decides to prepare a guideline on health food exportation to China. This Guideline focuses on the updates of health food regulations in China, the supervisory mechanisms as well as the future trends and gives an in-depth interpretation to the health food policies, the supervision on health food in China as well as the impacts on enterprises. CIRS aims to deliver information concerning the health food regulations in China to enterprises both at home and abroad, so that these enterprises can better understand the management trends of food regulations in China.

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## Chapter 1: Introduction of Health Food

### 1.1 Definition of Health Food in China and in the World

The definitions of health food are different all around the world. In general, food products in below names are regarded as health food in China:

**Table 1-1 Different Names of Health Food in the World**

Country Name	Product Name
European Union (EU)	Food Supplement
The United States (USA)	Dietary Supplement
Canada	Natural Health Product
Australia	Complementary Medicines
South Korea	Health Functional Food
Japan	Food with Health Claims (FHC)

According to “*Food Safety Law of the People’s Republic of China (2015 version)*”, health food refers to food products which claim the health function based on scientific basis, and have no acute, sub-acute or chronic hazards to human body.

### 1.2 Categories of Health Food in China

In Chinese industry, health food is usually divided into two categories as following:

**(i) Nutrition supplement:**

Health food that provides vitamins and/or minerals but without providing energy or other active ingredients.

**(ii) Functional health food:**

Health food that is claimed with health function and has physiological effects on the human body.

### 1.3 Approved Health Functions for Health Food in China

In accordance with current Chinese health food regulations, there are 27 health functions for functional health food and 1 health function for nutrition supplement.

**Table 1-2 Approved 28 Health Functions for Health Food**

1	2	3	4
Enhancing immune	Assisting blood lipids reduction	Assisting blood sugar reduction	Antioxidative
5	6	7	8
Assisting memory improvement	Alleviating eye fatigue	Alleviating lead excretion	Clear the throat
9	10	11	12
Assisting blood pressure reduction	Sleep Improvement	Facilitating milk secretion	Alleviating physical fatigue

## Chapter 2: Development Status and Analysis of Health Food

### 2.1 Analysis of Health Food Registration from 1996 to 2017

Since the "Administrative Measures for Health Food" was implemented in June 1996, China has approved 17,279 health food products in total by the end of 2017. The number of domestic and imported approved health foods are 16,494 and 785 respectively. Changes of policy have important influence on the approval of health food.

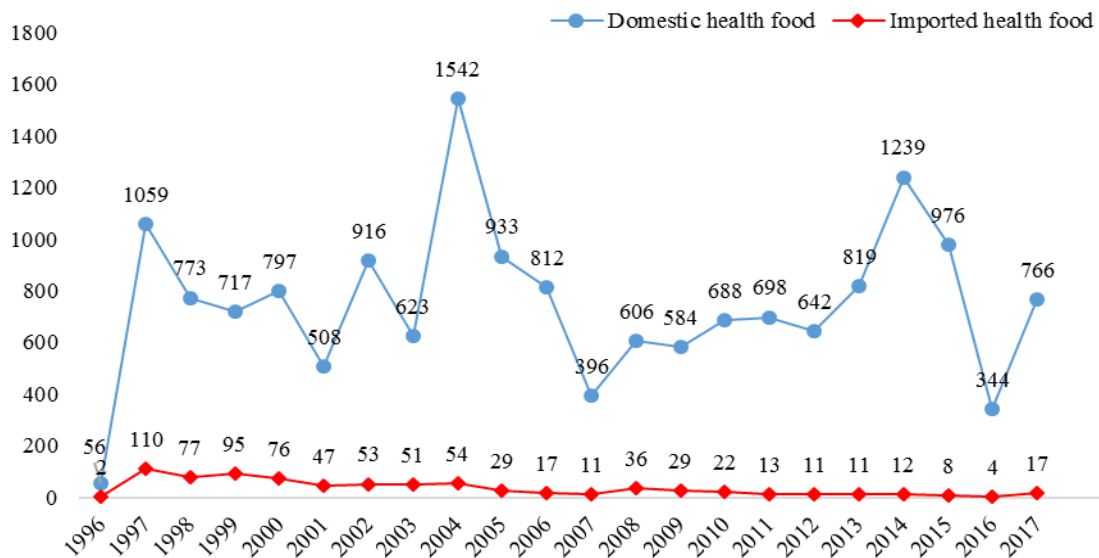


Fig.2-1 Number of Approved Health Food Registration from 1996 to 2017

Table 2-1 The Influence of Policy Changes on Registration of Health Food

Year	Policy Changes	Influence
1996	"Administrative Measures for Health Food" was implemented on June 1, 1996. The legal status of health food was recognized for the first time in the law, and a unified approval standard was established.	The implementation of this measure played a role in helping the superior products and eliminating the unqualified products. Initially, the approval process was slow. After a year of familiarization, a large number of products were registered in 1997.
2005	"Administrative Measures for Health Food Registration (Trial)" was implemented on July 1, 2005, it emphasized that the health food need to be registered before putting in market, and the management of health food was more comprehensive and stricter.	Enterprises generally receive news of policy changes 1-2 years in advance. In order to avoid adverse effects of policy changes on products, they would accelerate the submission of registration application before July 1, 2005. As a result, the number of registration had soared in 2004.
2015	The new "Food Safety Law of the People's Republic of China" was implemented on October 1, 2015, and a new health food management policy was put	Enterprises generally receive news of policy changes 1-2 years in advance. In order to avoid adverse effects of policy changes on products, they would accelerate the submission of registration

## Chapter 3: The Present and Future of Health Food Regulation

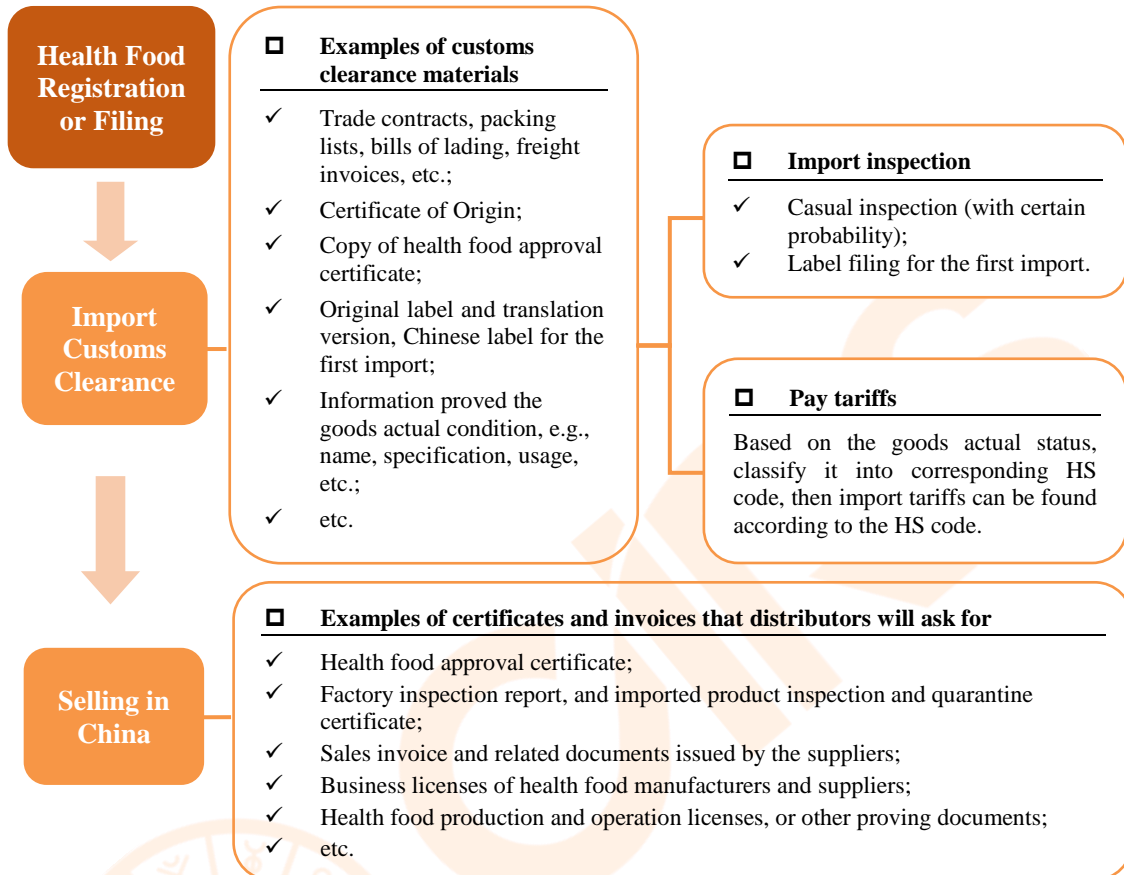
### 3.1 Regulation Framework for China Health Food

**Table 3-1 Current Major Laws and Regulations of Chinese Health Food**

Categories	Major laws and regulations	
Relevant laws	The Food Safety Law of China (2015 version)	
	The Advertising Law of China (2015 version)	
Relevant regulations for health food approval	Administrative Measures on Health Food Registration and Filing	
	Registration	Health Food Registration Review Rules (2016 version)
		Health Food Registration Application Service Guideline (2016 version)
	Filing	Health Food Raw Materials Directory (the first batch) – Nutrition Supplement Raw Materials
		Directory of Health Function Available to Claim for Health Food (the first batch)
		Health Food Filing Guideline (Trail)
		Available Excipients for Health Food Filing and Their Usage Rules (Trail)
Main Production Processes of Health Food Filing Products (Trail)		
Relevant regulations for import & export	Administrative Measures on Import and Export Food Safety	
	Provisions on Imported Food Importer and Exporter Filing	
	Provisions on Food Import Record and Sales Record Management	
	Administrative Measures on the Taxation of Import and Export Goods of China Customs	
Relevant regulations for production and operation	Administrative Measure of Food Production License	
	General Rules for Food Production Licensing Review	
	Rules for Health Food Production Licensing	
	Administrative Measure of Food Operation License	
	General Rules for Food Operation Licensing (Trail)	
Relevant regulations and national standards for tests	Technical Standards for Testing & Assessment of Health Food (Green Book) (2003 version)	
	Administrative Measures on Health Food Registration Re-check Test	
	Guideline on Health Food Stability Test	
	GB 16740-2014 Health Food	
	GB 2760-2014 The Usage of Food Additives	
	GB 2761-2017 Limit of Mycotoxins in Food	
	GB 2762-2017 Limit of Contaminants in Food	
GB 29921-2013 Limit of Pathogens in Food		

## Chapter 4: Compliance Procedures of Health Food Exportation

### 4.1 Compliance Procedures for Health Food Access to the Chinese Market



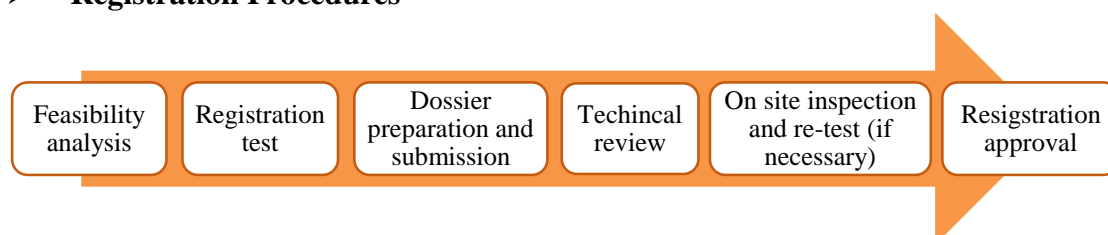
### 4.2 Imported Health Food Registration and Filing

#### 4.2.1 Imported Health Food Registration

##### ➤ Registration Background

<b>Application scope</b>	All imported health food (excluding nutrition supplement that only provides vitamin and/or mineral)
<b>Applicant qualification</b>	Oversea manufacturers (refer to the legal person and other organization)
<b>Authority</b>	SAMR

##### ➤ Registration Procedures



## Chapter 5: Health Food Supervision Status and Case Analysis

### 5.1 Supervision Regulations of Health Food

With the aim of maintaining the health food market order, SAMR (former CFDA) adopts “Double Random, One Publicity” supervision method, and strictly implements “Four Harshes” requirements. SAMR carries out supervision of health food by casual inspection, problem-addressing action, case investigation and disposal, and so on. Once any violation of laws is discovered, SAMR will recall, confiscate products and may give punishment to the involved companies. The results of casual inspection and case investigation and disposal will be disclosed to the public in time.

**Table 5-1 Main Health Food Supervision Regulations**

Main Supervision Regulations of Health Food	Implementation Date
The Proposal on Specific Casual Inspection Work of Food and Health Food	2018.04.02
Announcement on Regulating the Labeling of Function Claim for Health Food	2018.02.13
Implementation Rules on Food Safety Supervision and Casual Inspection (2018 version)	2018.01.24
Plan on Food Safety Casual Inspection of 2018	2018.01.08
Implementation Rules on Disclosure of Cases of Food and Drug Administrative Punishment	2017.12.28
Inspection Key Points on Health food Labelling	2017.11.08
Notice on Further Strengthen the Advertising Supervision of Drug, Medical Device and Health Food	2017.07.31
Proposal on Addressing Food and Health Food Fraud and False Advertising	2017.07.13
Notice on Management of “Double Random, One Publicity”	2017.06.27
Administrative Measures on Daily Supervision and Inspection of Food Production and Operation	2016.05.01
Administrative Measures on Complaints about Food and Medicine	2016.03.01
Advertising Law of People's Republic of China (2015 version)	2015.09.01
Administrative Measures on Food Recall	2015.09.01
Administrative Measures Food Safety Sampling Inspection	2015.02.01
Special Rules on Strengthening the Safety Supervision of Food and Other Products	2007.07.26
Health Food Labeling Rules	1996.07.18

*PS: “Four Harshes” requirements refer to the most rigorous standard, the strictest supervision,*



## Chapter 6: Compliance Procedures of Health Food Exportation through CBEC

### 6.1 Introduction of CBEC

#### 6.1.1 Definition

- **CBEC (Cross-border e-commerce):** It refers to an international business activity between trading entities that belong to different Custom Territories. In order to achieve transactions, payment, and commodities delivery, the international business activity will be completed through the e-commerce platform and cross-border logistics. In a narrow sense, CBEC mostly refers to CBEC retail.
- **CBEC retail:** It refers to a transaction between trading entities that belong to different Custom Territories. In order to achieve transactions and payment, the transaction will be completed through the computer networks. And the commodities will be delivered to consumers through cross-border logistics such as express mail, parcels and other postal methods. It generally refers to B2C (business-to-customer) mode which is for individuals.

#### 6.1.2 Classification

CBEC (B2C) can be divided into two modes of operation:

- **Bonded Import:** stocking in bonded warehouse – orders from consumers – sending products from bonded warehouse.
- **Direct Purchase Import:** orders from consumers - sending products from overseas.

### 6.2 The Development of CBEC Policy

The Chinese government hasn't established a complete CBEC supervision system currently. At present, the CBEC retail import commodities are temporarily supervised as personal items in China. Although necessary quarantine has been conducted, the Chinese standards or inspection requirements are not required for CBEC retail import commodities. The establishment of CBEC management system is still in perfecting period.

#### 6.2.1 Regulations of CBEC Retail

**Table 6-1 Major CBEC Regulations**

S.N.	Name	Implementation time
1	Negative List of Animals and Plants and their Products from Carrying or Mailing into China	2012.03.02
2	Notice on Strengthen the Role of Inspection and Quarantine to Promote the Development of CBEC	2015.05.14