Asia Pacific Food Law Guide - China

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**Last updated: 2018**

# Food product and safety regulation

## Overview

In China, food quality and integrity is governed by the PRC Food Safety Law (2015) and its implementing regulations. The PRC Food Safety Law sets out comprehensive statutory requirements governing the production, circulation, recall and import/export of food products in China.

Additional regulatory requirements apply to different stages of food safety.

Food production is governed by the Administrative Measures for Food Product Permits (2017), issued by the China Food and Drug Administration (CFDA).1

Food trading is governed by the Administrative Measures for Food Trading Permits (2017), issued by the CFDA. The general measures apply to online food trading. In addition, the CFDA has further elaborated on certain aspects of internet-based food-related conducts in its Measures of the Investigation and Punishment of Illegal Conducts Concerning Online Food Safety (2016).

Food import/export is governed by the Administrative Measures for Food Safety in Importation and Exportation (2011), issued by the PRC General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ).

Food products, including imported food products, must also comply with compulsory national standards on food safety. There are currently more than 200 compulsory standards covering a variety of subject matters concerning food safety, such as additives, hygiene, labeling, examination, packaging, etc. For example, the use of additives and processing aids is governed by the compulsory national standards on food additives (GB 2760-2014). The use of vitamins, minerals and other nutritive substances is governed by the compulsory national standards on food nutritional additives (GB 14880-2012). These standards provide comprehensive requirements on food additives and nutritional additives allowed in China, including the type, maximum amount and source of the additives allowed in various food products.

Novel foods are additionally subject to the Administrative Measures for the Safety Review of New Food Materials (2013, revised in 2017), issued by the PRC National Health and Family Planning Commission (NHFPC).2 New food materials are defined as materials that are not traditionally consumed in China, including (i) animals, plants and microorganisms; (ii) extracts from animals, plants and microorganisms; (iii) food materials obtained by changing the structure of food materials; and (iv) other newly developed food materials. New food materials must be approved by the NHFPC before they can be used in food products in China. If an imported food product contains food materials that are new in China, the materials must be approved as new food materials before the food product can be imported. Similar requirements also apply to the use of novel food additives and are set out in the Administrative Measures for New Food Additives (2010, revised in 2017).  
  
In China, food products are regulated separately from drugs and biological products. As mentioned above, the statutory basis for food regulation is the PRC Food Safety Law (2015). In comparison, the statutory basis for drug and biological product regulation is the PRC Drug Administration Law (2015). Although both product types are administered by the same agency, ie, the China Food and Drug Administration (CFDA), food products are regulated by different CFDA departments from drugs and biological products.

The PRC Food Safety Law generally applies to different categories of food products. Additional regulations can apply depending on the specific food type:

The revised PRC Food Safety Law (2015) provides additional requirements for special food products including health food, formula food for special medical use and infant formula. For example, the product formula of infant formula dairy products should be registered with the CFDA. Pursuant to this requirement, the CFDA has enacted the Administrative Measures for Formula Registration of Infant Formula Dairy Products (2016).

Detailed implementing regulations may apply. For example, dairy products are governed by the Regulations on the Supervision and Administration of Quality and Safety of Dairy Products (2008). Imported dairy products are additionally governed by the Administrative Measures on the Supervision of Inspection and Quarantine of Imported and Exported Dairy Products (2013), issued by the AQSIQ.

Food products should also comply with product-specific compulsory national safety standards, for example, GB 7101-2015 is applicable to all types of beverages.

1. Due to a recent structural change, CFDA is now part of the State Administration for Market Regulation (SAMR)

2. NHFPC has now become the National Health Commission of China pursuant to recent structural change.

## Basic labeling requirements

In China, food labeling is governed by the *Administrative Measures of Food Labeling*. Pre-packaged food must also meet the compulsory national standards on pre-packaged food labeling (**GB 7718-2011**) and pre-packaged food nutrition labeling (**GB 28050-2011**).

In summary, food labels should include the name of the food, the name, address and contact information of the manufacturer, the production date and the expiration date and the ingredient list. Specifically:

(a) product name - the name must identify the true nature of the food product and comply with the prescribed naming convention;

(b) the name and contact information of the manufacturer (which must be an entity able to take up full legal responsibility for the product); and

(c) ingredients identified in descending order by volume/amount, except for ingredients comprising less than 2% of all the ingredients. Food additives are further regulated by the compulsory national standards on food additives (**GB 2760-2011**) and need to be identified on labels by their commonly used names as indicated in GB 2760-2011, or by their functions with names or INS codes. If the product labels emphasize the addition or lack of a particular food additive, the amount of this food additive should be stated in the ingredient list.

For pre-packaged food products, the following requirements also apply:

production date and expiration date;

applicable food standards for producing the product;

specification, net value of the food (e.g., if the food package contains multiple pre-packaged food products, the food product labels on the external package should state the specification of the smaller units, including the net value of each pre-packaged unit and the number of units);

storage conditions;

production license number; and

other mandatory labeling contents required by laws, regulations or food safety standards.

All information on product labels should comply with the general requirement of being true and not misleading.

## Nutrition information panel

Nutrition labeling for pre-packaged food should generally comply with the national standard for pre-packaged food nutritional labeling (**GB 28050-2011**). The nutrition labels should adopt one of the six types of box charts provided under GB 28050-2011 and indicate at least the amount of energy and key nutrients (protein, fat, carbohydrate and sodium), as well as the nutrition reference value (NRV).   
   
Pre-packaged food products for specific groups of consumers, such as babies and people with medical needs, are subject to separate nutrition labeling requirements under the national standard for pre-packaged food products for specific use labeling (**GB 13432-2013**). In addition to energy and key nutrients, the nutrition labels for these food products should also indicate the amount of required nutritive ingredients as set out in the respective product-specific national standard.  
   
  
 

## Language and legibility requirements

Food labels should be prominent and clear, with contrast colors in the background to facilitate identification.

When the food package has a surface area larger than 20 square centimeters, compulsory labeling contents should be at least 1.8 millimeters in height.

Simplified Chinese characters should be used on product labels. Foreign languages are allowed on food labels, provided that the contents in a foreign language match the Chinese contents and are not larger in font size than the corresponding Chinese contents. The above requirements do not apply to registered foreign language trademarks.

## Country of origin labeling

Food labels should state the country of origin.

## Genetically modified (GM) foods

Safety of GM Food

Genetically modified food products are regulated by the Ministry of Agriculture (**MOA**). A "Safety Certificate for Genetically Modified Agricultural Organisms" is required when importing food products that are genetically modified.

A foreign manufacturer must apply to the relevant agricultural department, meet the following requirements, and pass a safety evaluation, in order obtain a Safety Certificate:

The country of origin has allowed the genetically modified materials for the same use in the market.

The genetically modified materials have been demonstrated in the country of origin as not harmful to humans, animals and plants, microorganisms, or the ecological environment.

The genetically modified materials have been tested in China by institutions entrusted by the MOA and it has been verified that no harm will result.

There are suitable safety regulations and control measures in place.

When importing the food products, the foreign manufacturer or its import agent must declare the food products as genetically modified, provide the safety certificate to the local Quality and Technical Supervision Bureau (QTS, the local department of PRC General Administration of Quality Supervision, Inspection and Quarantine), and pass the compliance test conducted by the local QTS.

Labeling of GM Food

Genetically modified foods should be clearly labeled if the products fall under the MOA's *Catalog of Agricultural Genetically Modified Organisms Subject to Labeling Requirements*:

If a food product is genetically modified or contains genetically modified materials, the food label should state "Produced/processed from Genetically Modified (animal, plant, microorganism)" in Chinese.

If a food product is processed from genetically modified materials but contains no genetically modified materials in the final product, it should state "Produced from Genetically Modified (animal, plant, microorganism), but the product no longer contains genetically modified ingredients" in Chinese.

## Nutrition content claims and health claims

Claims about nutritional content for pre-packaged food products are regulated by compulsory national standard GB 28050-2011. This standard sets forth the content limits for claiming the presence, richness or absence of particular nutritional contents. For example, the reference value for protein is 60 g; a food product must contain at least 12 g protein/100 g in order to claim that the food product is "high/rich in protein."

In China, health foods are regulated separately from regular food products. Health food products must be registered or recorded with the CFDA or provincial-level FDA before entering the market. Whether registration or recordal is needed depends primarily on the ingredients and functional claims of the health food products, and for imported health food products, whether the products are first-time import.

Regular food products are not allowed to make health claims other than the claims allowed under GB 28050-2011. GB 28050-2011 provides an exclusive list of general health claims that are allowed for regular food products, for example "Calcium helps to make bones and teeth stronger."

Specific types of food products, e.g., food products for infants, may be subject to additional limitations on permitted claims.

## Mandatory warnings and advisory statements

Food labels should contain cautionary statements in Chinese if the food products are known to be harmful to specific groups of consumers. For example, pre-packaged food products must identify the following ingredients in the ingredient list:

wheat products containing gluten;

shellfish and products containing it;

fish products;

egg products;

peanut products;

soy bean and products containing it;

dairy products (including lactose); and

nuts and products containing them.

If the production process may introduce the above ingredients into food products, it is preferable that the cautionary statement is included in close vicinity to the ingredient list.

## Trade measurement markings

Food product labels must state the net value of the food products. If the food package contains multiple pre-packaged food products, the food product labels on the external package should state the specification of the smaller units, including the net value of each pre-packaged unit and the number of units.

In addition, pre-packaged food products must comply with the trade measurement requirements, which are compulsory national standards set out in GB 7718-2011. For example, the net values of food products in liquid form should be expressed by volume in "L; mL" or by quality in "g; kg".

## Product recalls

In China, food product recalls are governed by the relevant provisions of the *PRC Food Safety Law* and the *Administrative Measures for Food Recall* (2015), issued by the CFDA. Food recalls can be conducted voluntarily by the food manufacturer or ordered by the local FDA.

Upon learning that its food products have potential safety risks, food manufacturers should carry out a safety investigation and assessment. If the food products are confirmed to be unsafe, food manufacturers shall immediately cease production, recall food products already on the market, notify relevant business associates and consumers, and keep records of the recall and notifications. Manufacturers must handle the recalled food products appropriately to remove the harm (e.g., through destruction or remedial treatment) and report the recall and subsequent handling of the recalled food products to the local FDA. The recall process and subsequent effects are subject to ongoing monitoring and examination by the local FDA. A food manufacturer's failure to comply with the foregoing can result in reprimand or suspension of business.

Upon discovering instances of non-compliance with the food safety standards, food distributors and providers, including online traders, must immediately cease providing the food products, notify the relevant manufacturer, other business associates and consumers, and keep records of cessation of supply and notifications.

## Food safety

To ensure the safety of food products, the *PRC Food Safety Law* imposes the following obligations on food businesses:

to ensure that the production, processing, packaging and storage facilities are clean and suitable for the type and amount of food products;

to have food safety specialists, administrative staff members and internal rules in place to ensure food safety. Food manufacturers are obliged to verify that the raw materials, additives and related products used in food production meet relevant food standards. Food manufacturers must keep records of the examination of raw materials, additives and food-related products. In addition, food manufacturers must also establish product quality measures by testing and verifying the safety of food products sold. Food distributors are obliged to require and keep records of documents showing that the food manufacturers from whom they purchase the food products have a proper production license and that the food products meet relevant national standards;

to avoid cross-contamination between food products and raw materials;

to ensure the hygiene of food containers and packages;

to ensure that the water used in food production meets the hygienic standards of drinking water; and

to ensure the personal hygiene of production and circulation staff. In addition, employees in the food business must pass an annual physical examination.

Business operators in the food industry, including distributors, retailers or catering service providers, should establish and execute a recall system for problematic food products. When a food operator discovers that a food product fails to meet the relevant standards, it should immediately cease providing the product, seal the problematic products, inform the relevant trade partners and its consumers, keep records of the cessation of supply and any notification, and report the incident to the local administrative agency.

For online sales, providers of third-party platforms for online food trading shall examine the permits of food traders as required by relevant laws and report illegal activities to local authorities. Detailed food safety responsibilities for online food trading are set out in the CFDA's *Measures of the Investigation and Punishment of Illegal Conducts Concerning Online Food Safety* (2016).

Manufacturers of specific types of food products, e.g., baby formula, may be subject to additional food safety responsibilities.

## Advertising claims (general)

In China, advertisements (including food advertising) are generally governed by the *PRC Advertising Law*. Under the *PRC Advertising Law*, advertisements cannot contain false information or deceive or mislead consumers. Advertisements cannot use superior or absolute descriptors, such as "the best," "No. 1," etc.

Specific types of food products, e.g., food products for infants, alcohol, etc. may be subject to additional prohibitions on advertising claims.

Food advertising is also governed by the *PRC Food Safety Law*. Food advertising cannot contain false or exaggerated claims. Nor can food advertising refer to the preventative or therapeutic effects of food products. Health food is regulated separately from regular food products and permitted claims are explicitly provided for under applicable regulations. Health foods are subject to product registration/recordal with the CFDA or local FDA, and health food advertising must be approved by local FDAs.

Food administrative agencies (including local FDAs) and food industry associations are prohibited from recommending any food products to consumers. Consumer associations are prohibited from recommending any food products for profit. If an individual (such as a celebrity), social group or any other organization recommends any food product to consumers in a false advertisement, the individual, social group or organization will be held jointly liable for damages suffered by consumers.

Endorsement is prohibited for health food and drugs.

## Credence claims (e.g., organic, natural, fresh)

Organic claims are governed by the *Administrative Measures for Organic Product Certification* (2015) issued by the PRC General Administration of Quality Supervision, Inspection and Quarantine (**AQSIQ**). Under the measures, a food product cannot bear the word "ORGANIC," its Chinese translation "You Ji in Chinese," or any other words or logos that may mislead the public into believing that the food products are organic, *unless* an organic product certificate has been obtained. This requirement also applies to imported food products and the certificate must be obtained prior to the import.

An organic product certificate can be obtained by submitting an application and supporting materials to a certification institution approved by the PRC Certification and Accreditation Administration. A basic requirement is that the amount of organic ingredients in the food product should be no less than 95%.

China has another certification called "Green Food," which certifies that the ecological environment, production and processing of the food products meet relevant requirements. The Green Food certification is a certification trademark, and its issuance is governed by the *Administrative Measures for Green Food Labeling* (2012) issued by the MOA.

## Health rating schemes

China does not have a voluntary or mandatory labeling scheme with respect to health ratings. Claims about nutritional contents of pre-packaged food products are regulated by compulsory national standard (**GB 28050-2011**), which sets forth the content limits for claiming the presence, richness or absence of particular nutritional contents, and provides an exclusive list of permissible health claims.

While there is no explicit statutory prohibition against including foreign health rating scheme logos on products imported into China, this labeling may be risky in practice due to potential misleading effects, as consumers may believe that these products are more beneficial to health compared to local products without such logos.

# Licensing and approvals requirements to import/export food

## Customs registration

Food import and export is generally governed by the *PRC Food Safety Law*, its implementing regulations, and relevant PRC General Administration of Quality Supervision, Inspection and Quarantine (**AQSIQ**)\* regulations. Foreign food manufacturers that import food products into China must be **registered** with the AQSIQ. In comparison, domestic food manufacturers that export food products from China only need to be **recorded** with the AQSIQ.

Besides foreign food manufacturers, import agents must be recorded with the AQSIQ. In other words, foreign food manufacturers should select recorded agents when importing food products into China.

For certain products, such as meat, seafood and dairy products, additional requirements may be applicable for import.

\*AQSIQ is currently being restructured, with its divisions for domestic quality supervision being incorporated into the newly established State Market Supervision Administration and its divisions for cross-border quality supervision being merged into the General Administration for Customs.

## Import permit

An import permit is generally not required for food products, with the following exceptions:

For food products that are within the *Merchandise Directory of Automatic Import Permit*, an automatic import permit is required before the food product can be imported into China. The Merchandise Directory is issued jointly by the Ministry of Commerce (**MOFCOM**) and the General Administration of Customs, and is updated annually. In 2017, food products for which automatic import permits are required include, for example, (i) beef, pork, lamb, chicken and related meat products; (ii) milk and milk powder products; (iii) soy bean and bean products; and (iv) canola seed products. Additional permits are required for importing state-operated food products, e.g., vegetable oil, sugar and grains.

An import permit is required if no existing national standards apply to the food products to be imported. In order to obtain such a permit, the importer should apply to the national food standard technical examination institution and submit materials demonstrating the safety of the food product in question.

## Inspection and testing of imported foods

Imported food products are subject to compulsory inspection by local Entry-Exit Inspection and Quarantine Bureau (**CIQ**) at the port of entry. If the imported goods are qualified, the CIQ will issue a Certificate of Inspection for Goods Inward upon which Customs will release the imported foods.

If the food products are being imported into China for the first time, the importer should also provide relevant materials for label examination to ensure that the product labels comply with labeling standards in China.

## Export permits/clearances

An export permit is generally not required for food products, with the following exception:

For food products that are within the *Merchandise Directory of Export Permit*, an export permit is required before the food products can be exported from China. The Merchandise Directory is issued jointly by the Ministry of Commerce (**MOFCOM**) and the General Administration of Customs, and is updated annually. In 2017, food products for which export permits are required include, for example, (i) corn and corn powder; (ii) wheat and wheat powder; (iii) rice and rice powder; and (iv) livestock (live or frozen meat products).

## Other notifications/approvals/licenses

License is required for the production, trading and catering of food products, except for the sale of edible agricultural products. Online traders of food products should be recorded with the local FDA.

# Enforcement

## Enforcement authorities and key responsibilities

The main bodies/agencies responsible for enforcement of food-related laws in PRC are outlined below:

**1. State Market Supervision Administration and its local bureaus**

Responsible for monitoring and enforcing food safety at all levels across the supply chain in the domestic market, including food advertising.

**2. General Administration of Customs and its local bureaus**

Responsible for enforcing food-related laws and regulations at ports.

**3. National Health Commission (NHFPC)**

Responsible for evaluating food safety risks at the national level and issuing food safety standards.

## Penalties for non-compliance

**PRC Food Safety Law (2015)**

**Article 122**: engage in food production/sale or food additive production activities without proper license.

*Penalty:*

confiscate the tools, equipment and raw materials used in production;

forfeit illegal profits; and

fine of up to 20 times the value of the products.

Provide a party with a producing or selling facility or other facilitating conditions with the knowledge that the party is engaged in the above prohibited activities.

*Penalty:*

forfeit illegal profits;

fine of up to RMB 100,000; and

hold jointly liable for damages caused to consumers.

**Article 123:** use materials or additives not approved in food products and sale of such food products; produce and sell food products for specific groups, the nutritional contents of which fail to meet the relevant food standards; produce or sell meat products that are not examined or which fail the examination; or produce and sell food products containing medicines.

*Penalty:*

confiscate the tools, equipment and raw materials used in the production;

forfeit illegal profits;

fine of up to 30 times the value of the products;

revoke food license; and

detain the personnel and supervisor directly responsible for up to 15 days.

Provide a party with a production or selling facility or other facilitating conditions with the knowledge that the party is engaged in the above prohibited activities.

*Penalty:*

forfeit illegal profits;

fine of up to RMB 200,000; and

hold jointly liable for damages caused to consumers.

**Articles 124 and 129:** refuse to recall food products after being ordered to do so; sell expired or unhygienic food products; produce food products that contain excessive ingredients harmful to human health, non-food materials, excessive food additives or chemical ingredients other than food additives; produce or sell unregistered health food and food products for specific groups; use expired raw materials and food additives in production and sale of such food products; import food products, food additives and food-related products that fail to meet the relevant food standards in China; or export food products inconsistent with relevant regulations.

*Penalty:*

confiscate the tools, equipment and raw materials used in the production;

forfeit illegal profits;

fine of up to 20 times the value of the products; and

revoke food license.

**Article 125:** produce and sell food products and food additives contaminated by the package, the container or in transportation; produce and sell pre-packaged food products without proper labels; produce and sell genetically modified food products without proper labeling; or purchase and use raw food materials and food additives that fail to meet food safety standards.

*Penalty:*

confiscate the tools, equipment and raw materials used in the production;

forfeit illegal profits;

fine of up to 10 times the value of the products;

suspend operation; and

revoke food license.

**Articles 126 and 129:** fail to examine raw materials and food additives purchased from third parties; fail to establish and comply with food safety management systems; fail to establish and comply with record-keeping systems; fail to verify permits and relevant documents when purchasing from third parties; fail to establish a food incident response strategy; arrange for staff members with diseases or conditions that may contaminate food products to be in direct contact with food products; or fail to meet recordal requirements for health food and food products for specific groups.

*Penalty:*

rectification and warning;

forfeit illegal profits;

fine of up to RMB 50,000;

suspend operation; and

revoke food license.

**Article 128**: fail to report and properly handle food safety incidents.

*Penalty:*

rectification and warning;

fine of up to RMB 500,000;

suspend operation; and

revoke food license.

**Articles 130 and 131**: providers of third-party platforms for offline and online food trading fail to comply with relevant requirements.

*Penalty:*

rectification and warning;

forfeit of illegal profits;

fine of up to RMB 200,000;

suspend operation; and

revoke license.

Providers of third-party platforms for online food trading shall be jointly liable for damages caused to consumers.

**PRC Advertising Law (2015)**

**Article 55:** use false information in advertisements and deceive or mislead consumers.

*Penalty:*

mandate corrective advertisements; and

fine of up to five times the advertising expense.

**Article 58:** include a health claim in an advertisement for general food products or fail to comply with relevant requirements for health food advertisements.

*Penalty:*

order suspension of illegal advertisements;

mandate corrective advertisements;

fine of up to five times the advertising expense; and

revoke business license.

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