

Translation for reference

Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food

Chapter I General Provisions

Article 1 To strengthen the registration management of overseas manufacturers of imported foods, these Regulations are formulated in accordance with provisions of the Food Safety Law of the People's Republic of China and its implementing regulations, the Law of the People's Republic of China on Import and Export Commodity Inspection and its implementing regulations, the Law of the People's Republic of China on the Entry and Exit Animal and Plant Quarantine and its implementation regulations, the Special Provisions of the State Council on Strengthening the Supervision and Administration of Food and Other Products Safety, as well as relevant administrative regulations.

Article 2 These Regulations apply to the registration management of overseas manufacturers of production, processing, and storage (hereinafter referred to as “overseas manufacturers of imported foods”) that export foods to China.

The overseas manufacturers of imported foods mentioned in the above paragraph do not include manufacturers engaging in the production, processing, and storage of food additives and food-related products.

Article 3 The General Administration of Customs of the People’s Republic of China (GACC) is responsible for the registration management of overseas manufacturers of imported foods.

Article 4 Overseas manufacturers of imported foods shall obtain registration with

the GACC.

Chapter II Conditions and Procedures for Registration

Article 5 The registration conditions for overseas manufacturers of imported foods are as follows:

1. The food safety management system of the country/region where the manufacturer is located has passed GACC's equivalence assessment and/or review;

2. The manufacturer was established with approval by the competent authority of the country/region, and the manufacturer is under effective regulation by the competent authority;

3. The manufacturer has an established, effective food safety and sanitation management system and protection system, legally produces and exports food in the country/region, and ensures that foods exported to China comply with relevant Chinese laws, regulations, and national food safety standards;

4. Food exporting to China conforms with relevant inspection and quarantine requirements that have been agreed upon after discussion by the GACC and the competent authorities of the country/region.

Article 6 Registration of overseas manufacturers of imported foods include recommendation for registration by competent authority of the country/region, and application for registration by a manufacturer.

The GACC, based on analysis of various factors, including sources of raw materials, production and processing technologies, historical data about food safety, consumer groups, consumption methods of food, and in consideration of international practices, determines the method for registration of overseas manufacturers of imported food and the required application materials.

If risk analysis or evidence presents that risks of a certain category of food has changed, GACC may adjust the registration method and required application materials for overseas manufacturers of the corresponding food.

Article 7 Overseas manufacturers of the following foods shall be recommended by the competent authorities of their countries/regions to the GACC for registration: meat and meat products, casings, aquatic products, dairy products, bird's nests and bird's nest products, bee products, eggs and egg products, edible oils and fats, oilseeds, stuffed pastry products, edible grains, milled grain industry products and malt, fresh and dehydrated vegetables and dried beans, condiments, nuts and seeds, dried fruits, unroasted coffee beans and cocoa beans, foods for special dietary purposes, and functional foods.

Article 8 The competent authority of the country/region shall examine and inspect the manufacturer to be recommended for registration; after confirming that the manufacturer conforms with the registration requirements, the competent authority of the country/region recommends the producer to the GACC for registration, and submits the following application materials:

1. Letter of recommendation by the competent authority of the country/region;
2. List of recommended manufacturers and the manufacturers' applications for registration;
3. Documents certifying identification of the manufacturer, such as the business license issued by the competent authority of the country/region;
4. Statement that the producer recommended by the competent authority of the country/region conform with requirements of these Regulations;

5. Reports of examinations/inspections/review conducted by the competent authority of the country/region to relevant manufacturers.

If necessary, the GACC may request documents related to the manufacturer's food safety, sanitation, and protection system, such as floor plans of the factory/workshops/cold storages, and the processing flow chart and others.

Article 9 Overseas manufacturers of foods other than those listed in Article 7 of these Regulations shall, by themselves or by agents, file applications for registration with the GACC and submit the following application materials:

1. Manufacturer's application for registration;
2. Documents certifying the identification of the manufacturer, such as business license issued by the competent authority of the country/region;
3. Statement by the manufacturer that it conforms with requirements of these Regulations.

Article 10 The application for manufacturer registration shall contain the following information: the name of the manufacturer, country/region where the manufacturer is located, address of the production site, legal representative, contact person, contact information, registration number approved by the competent authority of the country/region, the type of food for registration, type of production, and production capacity, etc.

Article 11 The application materials for manufacturer registration shall be submitted in Chinese or English. If relevant country /region and China have separate agreements on registration method and application materials, registration shall be carried out following the agreement.

Article 12 Competent authority of the country /region or overseas manufacturers of

imported foods shall be held accountable for truthfulness, completeness, and legality of the submitted materials.

Article 13 The GACC or GACC entrusted institutions, set up a review team to conduct evaluations and reviews of the overseas manufacturers applying for registration. The evaluation is conducted in forms of document review, video inspection, and/or on-site inspection. A review team is composed of two or more reviewers.

Overseas manufacturers of imported foods and the competent authorities of the country/ region shall assist the GACC in carrying out the aforementioned evaluation and review.

Article 14 The GACC shall, based on the evaluation and review, register the overseas manufacturers that meet the requirements, and grants them Chinese registration numbers; and shall notify the competent authority of the country/region or the overseas manufacturers in writing of the registration. The GACC shall decline the registration of overseas manufacturers that do not meet the requirements and notify the competent authority of the country/region or the overseas manufacturers in writing of the denial.

Article 15 A registered manufacturer shall mark the Chinese registration number or the registration number approved by the competent authority of the country/region on the inner and outer packaging of the foods exported to China.

Article 16 The registration for overseas manufacturers of imported foods is valid for five years.

The GACC shall determine the starting and the ending dates of the validity period of registration when it registers an overseas manufacturer of imported foods.

Article 17 The GACC publishes lists of oversea manufacturers of imported foods that receive registration in a unified way.

Chapter III Registration Management

Article 18 The GACC or its entrusted institutions set up a review team to conduct re-evaluation on whether the overseas manufacturers of imported food continuously meet the registration requirements. A review team is composed of two or more reviewers.

Article 19 If an overseas manufacturer's registration information changes while the registration is valid, it shall submit an application for change to the GACC through the application path, and submit the following materials:

1. A table that exhibits the changed information and the original information;
2. Supporting materials related to the changed information.

The GACC changes the registration information if it deems such information can be changed after review.

In cases of changing production site, legal representative, or registration number in the country/region where the manufacturer is located, the overseas manufacturer shall re-apply for registration, and the original Chinese registration number will automatically become invalid.

Article 20 If an overseas manufacturer of imported foods intends to renew its registration, it shall, within three to six months before the registration expires, apply to the GACC for renewal of registration through the registration application path.

Application materials for registration renewal shall include:

1. An application for renewal of registration;
2. Statement promising to continuously conform with the registration requirements.

The GACC shall renew the registration of manufacturers that conform with the registration requirements and extends the valid period of registration for five years.

Article 21 If a registered overseas manufacturer of imported foods falls under any of

the following circumstances, the GACC will revoke its registration, notify the competent authorities of the country/region or the registered facility, and issue a public announcement thereof:

1. The manufacturer fails to apply for registration renewal following relevant provisions;

2. The competent authority or the overseas manufacturer applies to revoke the registration;

3. The manufacturer no longer conforms with provisions in Article 5.2 of these Regulations.

Article 22 The competent authorities of the countries /regions shall have effective regulation of the registered manufacturers, urge them to continuously conform with the registration requirements. Finding incompliance to the registration requirements, the competent authorities shall take control measures immediately, suspend food export by relevant manufacturer to China, until the manufacturer conforms with registration requirements after taking rectification measures.

Finding itself unable to conform with the registration requirements, an overseas manufacturer of imported foods shall voluntarily suspend its food exports to China, and take immediate rectification measures until it conforms with registration requirements.

Article 23 Finding a registered manufacturer no longer conforms with the registration requirements, the GACC shall instruct the manufacturer to make rectification measures within a given time period and shall suspend imports from the manufacturer during the rectification period.

If imports by a foreign competent authority-recommended manufacturer are suspended, the competent authorities shall urge the manufacturer to complete rectification

within the given time period and shall submit a written rectification report to the GACC and a written statement confirming the manufacturer conforms with the registration requirements.

If imports by a self-registered or agent-registered manufacturer are suspended, the manufacturer shall complete the rectification within the given time period and submit a written rectification report to the GACC and a written statement confirming (it) conforms with the registration requirements.

The GACC shall review the rectification by the manufacturers. Passing the GACC review, food imports from relevant producers are to be resumed.

Article 24 If a registered overseas manufacturer of imported foods falls under any of the following circumstances, the GACC shall revoke its registration and issue a public announcement thereof:

1. Severe food safety incidents of imported foods caused by the manufacturer;
2. Food safety problems detected in foods exported to China in the entry inspection and quarantine, and the circumstance is serious;
3. Significant problems exist in the manufacturer's food safety and sanitation management, which cannot ensure its food export to China conforms with safety and sanitation requirements;
4. The manufacturer fails to meet the registration requirements after taking rectification measures;
5. The manufacturer provides false materials or conceals relevant facts;
6. The manufacturer refuse to cooperate with the GACC in reviews and incident investigations;
7. The manufacturer leases, lends, transfers, or resells its registration number, or

claims another manufacturer's registration number.

Chapter IV Supplementary Provisions

Article 25 When an international organization or a foreign competent authority issues a notification of a disease/epidemic, or the GACC detects a serious disease/epidemic outbreak or public health incident in its inspection and quarantine, the GACC will issue a public announcement suspending food imports from the country/region. During the import suspension, the GACC will not accept applications for registration by food manufacturers in the country/region.

Article 26 The competent authority of the country /region in these Regulations refers to government agencies in charge of safety and sanitation regulation of food manufacturers in the country/region.

Article 27 The GACC is responsible for the interpretation of these Regulations.

Article 28 These Regulations come into effect on January 1, 2022. The Administrative Measures for Registration of Overseas Manufacturers of Imported Foods, released as the Decree 145 of the former General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) on March 22, 2012, revised by GACC Decree No. 243 on November 23, 2018, is abolished at the same time.