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Report Highlights:

The Regulations on the Registration and Administration of Overseas Producers of Imported Food (Degree 248) will enter into force on January 1, 2022. Once implemented, the measure will require that all overseas food manufacturers, processors, and storage facilities be registered with the Chinese authorities to export product to China. The measure covers all food products except food additives. Depending on the product category, food producers must register with the General Administration of Customs of China either a) through the competent authority of the exporting country or b) directly and/or through a private agent. This report provides an unofficial translation of Decree 248.

Executive Summary:

On April 12, 2021, the General Administration of Customs of China (GACC) announced the Regulations on the Registration and Administration of Overseas Producers of Imported Food as GACC Decree 248. The regulation will enter into force on January 1, 2022 and will replace the Administrative Measures for Registration of Overseas Producers of Imported Food (Decree 145). The main regulatory changes enacted by Decree 248 as compared to Decree 145 include the following:

1. Product Scope

Notably, Decree 248 expands the scope of overseas facilities subject to a registration requirement to include all food manufacturers, processors, and storage facilities. The product scope includes all food products except food additives and does not include "food-related products" (which is not defined in the regulation).

2. Method of Registration

a) Exporting Country Competent Authority

Under Decree 248, manufacturers, processors, and storage facilities of the following product groups must be recommended by their country's competent authority for registration with GACC: meat and meat products, sausage casings, aquatic products, dairy products, bird nest products, bee products, eggs and egg products, edible oils and fats, oilseeds, stuffed wheaten products, edible grains, milled grain industry products and malt, fresh and dehydrated vegetables, dried beans, condiments, nuts and seeds, dried fruits, unroasted coffee and cocoa beans, foods for special dietary purposes, and health foods. Note: Under Decree 145, only overseas facilities for meat and meat products, dairy products, seafood products, and bird nest products are required to register with GACC (through recommendation by their country's competent authority).

b) Self-Registration or Private Agent

Under Decree 248, manufacturers, processors, and storage facilities of foods other than those product groups listed in part a above are required to register directly with GACC, either on their own behalf or via a private agent.

3. Registration Conditions and Procedures

Decree 248 modifies and expands the conditions and procedures for registration (Chapter II), including the addition of a requirement that the food safety management system of the exporting country has passed GACC's equivalence assessment or review.

4. Verification Methods

Decree 248 specifies that evaluations must be conducted via document review, video inspection, and/or on-site inspection.

5. Period of Validity

Decree 248 provides that registration is valid for five years versus four years under Decree 145.

6. Product Labeling

Under Decree 248, registered overseas facilities are required to include the Chinese registration number or the registration number approved by the exporting country competent authority on both the inner and outer packaging of food products exported to China.

Note: In November of 2019, GACC issued the first revised draft of the Regulations on the Registration and Administration of Overseas Manufacturers of Imported Food for domestic comments. In November 2020, GACC notified the second revised draft of the Regulations to the WTO TBT Committee as G/TBT/N/CHN/1522. The full Chinese language text of Decree 248 is available on the GACC website.

BEGIN TRANSLATION

Regulations of the People's Republic of China on the Registration and Administration of Overseas Producers of Imported Food Chapter I General Provisions

Article 1) To strengthen the registration management of overseas producers 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, 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, processors, and storage facilities (hereinafter referred to as "overseas producers of imported foods") that export foods to China.

The overseas producers of imported foods mentioned in the above paragraph do not include facilities 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 producers of imported foods.

Article 4) Overseas producers of imported foods shall obtain registration with GACC. Chapter II Conditions and Procedures for Registration

Article 5) The registration conditions for overseas producers of imported foods are as follows: (1.) The food safety management system of the country/region where the producer is located ("country/region") has passed GACC's equivalence assessment or review;

(2.) (The producer was) established with approval by the competent authority of the country/region, and (the producer is) under effective oversight by the competent authority;

(3.) (The producer) has an established, effective food safety and sanitation management system and food defense 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.) (Foods export to China) conform with relevant inspection and quarantine that have been agreed upon after discussion by GACC and the competent authorities of the country/region.

Article 6) Registration of overseas producers of imported foods include: 1) recommendation for registration by competent authority of the country/region, and 2) application for registration by a producer.

GACC, based on analysis of various factors, including sources of raw materials, production and processing techniques, historical data about food safety, consumer groups, consumption methods of food, and in consideration of international practices, determines the method for registration of overseas producers 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 producers of the corresponding food.

Article 7) Overseas producers of the following foods shall be recommended by the competent authorities of their countries/regions to GACC for registration: meat and meat products, sausage casings, aquatic products, dairy products, bird nests and bird nest products, bee products, eggs and egg products, edible oils and fats, oilseeds, stuffed wheaten 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 health foods.

Article 8) The competent authority of the country/region shall examine and inspect the facility to be recommended for registration; after confirming that the facilities conform with the registration requirements, (the competent authority of the country/region) recommends the producers to GACC for registration, and submit the following application materials:

(1.) Letter of recommendation by the competent authority of the country/region;

(2.) List of (recommended) producers and the producers' application for registration;

(3.) Documents certifying identification of the producer, 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 producers.

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

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

(1.) Producer's application for facility registration;

(2.) Documents certifying the identification of the facility, such as business license issued by the competent authority of the country/region;

(3.) Statement by the producer that it conforms with requirements of these Regulations.

Article 10) The application for facility registration shall contain the following information: name of the producer, country/region where the producer 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 facility registration shall be submitted in Chinese or English. If relevant countries (regions) 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 producers of imported foods shall be held accountable for truthfulness, completeness, and legality of the submitted materials.

Article 13) GACC or GACC entrusted institutions set up review teams to conduct evaluations and reviews of the overseas producers 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 producers of imported foods and the competent authorities of the country (region) shall assist (GACC) in carrying out the aforementioned evaluation and review.

Article 14) GACC shall, based on the evaluation and review, register the overseas producers that meet the requirements, and grants them China registration numbers; (GACC) notifies the competent authority of the country/region or the overseas producers in writing (of the registration). GACC denies registration of overseas producers that do not meet the requirements and notifies the competent authority of the country/region or the overseas producers in writing (of the denial).

Article 15) A registered producer 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 producers of imported foods will be valid for five years. GACC determines the starting and the ending dates of the validity period of registration when it registers an overseas producer of imported foods.

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

Chapter III Registration Management

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

Article 19) If an overseas producer's registration information changes while the registration is valid, it shall submit application for change to 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

GACC changes the registration information if it deems (such information) can be changed.

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

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

Application materials for registration renewal should includes:

(1.) Application for renewal of registration;

(2.) Statement promising to continuously conform with the registration requirements.

GACC renews registration of producers that conform with the registration requirements and extends the valid period of registration for five years.

Article 21) If a registered overseas producer of imported foods falls under any of the following circumstances, GACC will revoke its registration, notify the competent authority of the country/region or the registered facility, and issue a public announcement thereof:

- (1.) (The producer) fails to apply for registration renewal following relevant provisions;
- (2.) The competent authority or the overseas producer apply to revoke the registration;
- (3.) The producer no longer conforms with provisions in Article 5.2 of these Regulations.

Article 22) The competent authorities of the countries (regions) shall have effective oversight of the registered producers, urge them to continuously conform to the registration requirements. Finding incompliance to the registration requirements, the competent authorities shall take control measures immediately, suspend food export by relevant producer to China, until (the producer) conforms to registration requirements after taking rectification measures.

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

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

If imports by a foreign competent authority-recommended producer are suspended, the competent authority shall urge the producer to complete rectification within the given time period and shall submit to GACC a written rectification report and a written statement confirming (the producer) conforms with the registration requirements.

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

GACC reviews the rectification by the producers; passing GACC review, food imports from relevant producers are resumed.

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

(1.) Severe food safety incidents of imported foods caused by the producer;

(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 producer's food safety and sanitation management, which cannot ensure its food export to China conforms with safety and sanitation requirements;

(4.) The producer fails to meet the registration requirements after taking rectification measures;

(5.) (The producer) provides false materials or conceals relevant facts;

(6.) (The producer) refuse to cooperate with GACC in reviews and incident investigations;

(7.) (The producer) leases, lends, transfers, or resells its registration number, or claims another producer'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 (GACC) detects a serious disease/epidemic outbreak or public health incident in its

inspection and quarantine, GACC will issue a public announcement suspending food imports from the country/region. During the import suspension, GACC will not accept applications for registration by food producers 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 oversight of food producing facilities in the country/region.

Article 27) 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 Producers of Imported Foods, released as 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.

END TRANSLATION Attachments: No Attachments.