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**Report Highlights:**

This report contains an unofficial English translation of the General Administration of Customs of the People's Republic of China (GACC) Interpretation of Decree 248 as published on the GACC website. The information provided by GACC in this report relates to GACC's rationale for Decree 248 and the registration of overseas facilities that export select food and agricultural products to China.

## **Background:**

On November 5, 2021, the General Administration of Customs of the People's Republic of China (GACC) posted its interpretation of Decree 248 on its website. This report contains an unofficial English translation of the interpretation.

Please refer to the reports below for additional information on Decrees 248 and 249. FAS China will provide information on the implementation of both decrees as it becomes available.

- [Decree 248 Foreign Facilities Self-Registration Website Launched - November 3, 2021](#)
- [Notes from Information Sessions on GACC Decrees 248 and 249 - October 22, 2021](#)
- [GACC Issues Explanatory Letter on Decree 248 - October 8, 2021](#)
- [Interpretative Guidance on Imported Food Labeling Requirements in Decree 249 - August 13, 2021](#)
- [Decrees 248 and 249 Status Update on Facilities Registration and Food Safety Measures - May 25, 2021](#)
- [Administrative Measures on Import and Export Food Safety - Decree 249 - May 7, 2021](#)
- [Overseas Facilities Registration Regulation - Decree 248 - April 20, 2021](#)
- [China Notified the Draft Administrative Measures on Import and Export Food Safety - December 11, 2020](#)
- [China Notifies Revised Overseas Facilities Registration Regulations as TBT 1522 - December 2, 2020](#)
- [China Released Draft Administrative Measures for Registration of Overseas Producers of Imported Foods - December 6, 2019](#)

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**BEGIN TRANSLATION**

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

## **Part I: Overview**

The *Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food* was reviewed, passed and issued in the executive meeting of the General Administration of Customs of China (GACC) on March 12, 2021, and shall come into force on January 1, 2022. The *Administrative Measures for Registration of Overseas Manufacturers of Imported Food*, released as Decree 145 of the former General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) on March 22, 2012, revised to be GACC Decree No. 243 on November 23, 2018, is abolished at the same time.

The revision and issuance of the *Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food* (GACC Decree No. 248) is a comprehensive implementation of the President Xi Jinping's "Four Strictest" requirements for food safety, the materialization of the policies adopted by the Communist Party Central Committee and the State Council of China including "Opinions on Deepening Reform and Strengthening Food Safety", "Planning Outlines of Healthy China 2030" and other policies, and the latest results related to the "Five keys in Customs Constructions" and strengthened supervision on imported food safety.

### **1. The necessity for revision**

Imported food safety concerns the health and safety of the people and is a major livelihood issue. The establishment of the management system for overseas manufacturers of imported food started as early as 1999; in 2002, for the first time, China issued the *Regulations on the Registration and Administration of Overseas Manufacturers of Imported Food* (by the former General Administration of Quality Supervision, Inspection and Quarantine Decree No. 16). In 2009, according to the China's first food safety law - the *Food Safety Law of the People's Republic of China*, the *Regulations on the Registration and Administration of Overseas Manufacturers of Imported Food* (by the former General Administration of Quality Supervision, Inspection and Quarantine Decree No. 16) was revised. On May 1, 2015, the *Regulations on the Registration and Administration of Overseas Manufacturers of Imported Food* (by the former General Administration of Quality Supervision, Inspection and Quarantine Decree No. 145) was formally implemented, and played an important role in ensuring imported food's safety through "source management" and promoting stable trade development.

With the rapid expansion of China's food imports and consumers' demands for greater food safety, these regulations were no longer sufficient to meet the demand of current situation. Firstly, Article 96 of the *Food Safety Law of the People's Republic of China*, "Overseas food manufacturers that export food to China should be registered by the national department of inspection and quarantine on imports and exports ", was not implemented to its fullest extent;

secondly, the pre-examination on registration applications was redundant but the supervision during and after the registration was insufficient, which cannot adapt to the deepened reform requirements of “decentralization, management and service” and the demands from a large number of applications by overseas companies; and thirdly, for different types of overseas food manufacturers, the management measures are not differentiated enough to "facilitate those honest and in compliance with the law, and punish those untrustworthy and in violation of laws".

## **2. The Main Contents of Revision**

The *Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food (GACC Decree No. 248)* is revised from 23 articles in previous regulations to 28 articles. It has four sections including “General Regulations”, “Registration Conditions and Procedures”, "Registration Management" and "Supplementary Provisions".

### **(1) Fully implement the *Food Safety Law of the People’s Republic of China’s* regulation pertaining to overseas food manufacturers that export foods to China should be registered.**

The scope of implementation has broadened from the food manufacturers that were listed in the *Catalogue of Registered Overseas Food Manufacturers* to the full-category food manufacturers specified in Articles 2 and 4 of the *Food Safety Law of the People’s Republic of China*, to govern food safety in imports from the origin by full exertion.

### **(2) Introduce the principle of risk management in the *Food Safety Law of the People’s Republic of China*, further improve the managerial effectiveness of the registration process.**

Based on the analysis of the source of food raw materials, production and processing technology, food safety compliance history, consumer groups, eating styles, etc., considering international practicing, it is determined to adopt the “Official Recommendation Model” for the overseas manufacturers of 18 categories of foods (Article 7 and 8); for other overseas food manufacturers, use the simplified self-registration model (Article 9). It is also permitted for the Customs to adjust registration methods and application materials of relevant food manufacturers if the risk situation for certain types of food changes (Article 6).

### **(3) Clarify food producers’ obligations**

In order to ensure that the food exported to China meets with the requirements, overseas food manufacturers should establish effective food safety and sanitation management and protection systems (Article 5); when registered manufacturer found that they could not meet the registration requirements, it shall voluntarily suspend their exports to China and immediately take corrective measures (Article 22).

### **(4) Specify overseas competent authorities’ liabilities in overseeing, recommendation and supervision.**

It is specified that, before recommending to GACC for registration, the host country's competent authority should conduct review and inspection on those recommended food manufacturers to ensure that they meet all the requirements of registration (Article 8). It is specified that competent authority of the host country (region) should implement effective supervision of registered enterprises. It is also specified the responsibility of the overseas competent authority to supervise and urge registered enterprises to continuously meet the registration requirements (Articles 22 and 23).

**(5) Clarify the responsibilities of the “applicant”.**

It clarified that the competent authority of the host country (region) or the overseas manufacturers of imported food shall be responsible for the authenticity, completeness and legality of the submitted materials (Article 12).

**(6) Further strengthen supervision during and after the registration.**

Summarize the previous experience in the registration and management of overseas manufacturers, supplement and refine the applicable circumstances of registration change, renewal, cancellation, and revocation, and improved the operability of relevant provisions (Articles 19-21, 24).

**(7) Adjust corresponding expressions in accordance with relevant laws and regulations.**

According to the relevant provisions of the "*Food Safety Law of the People's Republic of China*", "reserve" is changed to "storage". Clarified that this regulation does not include production, processing, and storage facilities of food additives and food-related products (Article 2).

**3. The revision procedures**

In July 2019, the Import and Export Food Safety Bureau of the General Administration of Customs officially launched the revision work of "*Regulations on the Registration Management of Overseas Manufacturers of Imported Food*" (Promulgated by Decree No. 145 of the former General Administration of Quality Supervision, Inspection and Quarantine on March 22, 2012, amended by Decree No. 243 of the General Administration of Customs on November 23, 2018) and established a revision drafting group. In the revision process, GACC followed legislative work requirements, extensively solicited and carefully listened to the opinions from customs system and social, adopted reasonable suggestions, and comprehensively understood the status, industry needs, and reform needs of overseas enterprise registration management.

From August to November 2019, agreements were made on general thoughts to optimize and improve the registration management system for overseas manufacturers of imported food.

On November 26, 2019, the "*Regulations on the Registration and Administration of Overseas Manufacturers of Imported Food (Draft for Comments)*" collected opinions from the Guangdong

Branch, Tianjin and Shanghai Special Offices, all directly affiliated customs and various departments within the General Administration of Customs. As of December 6, 2019, the Guangdong Branch and the 11 directly affiliated customs have responded with 53 opinions, the departments within the General Administration of Customs have responded with 7 opinions.

From November 26 to December 25, 2019, General Administration of Customs released the "*Regulations on the Registration and Administration of Overseas Manufacturers of Imported Food (Draft for Comments)*" was published on GACC website for public comments. Publics provided a total of 514 relevant comments and suggestions through online messages, emails and written feedback.

From January to August 2020, the drafting team compiled 580 comments based on the opinions and suggestions from relevant GACC departments, the customs system, and the publics, analyzed the provisions one by one, and communicated with relevant parties. After adopting reasonable suggestions from all parties, several internal discussions and improvements were made. The "*Regulations on the Registration and Management of Overseas Manufacturers of Imported Food of the People's Republic of China (Draft for Review)*" were formed and reported to the GACC policy and regulation department for legislative review.

From November 16, 2020 to January 16, 2021, the General Administration of Customs completed the "*Regulations on the Registration and Management of Overseas Manufacturers of Imported Food (Draft)*" and notified the World Trade Organization (WTO) for comment in accordance with the relevant regulations of the WTO on transparency. The General Administration of Customs researched and provided written replies to 14 comments from 12 countries (regions) including Europe, America, and Asia-Pacific.

On April 12, 2021, the "*Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food*" (General Administration of Customs Decree No. 248) was officially promulgated and will come into force on January 1, 2022.

## **Part Two: Interpretation**

**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.

### **【Subject of Article】**

This article is about the legislative purpose and legislative basis of this provision.

## 【Interpretation】

### 1. Legislative purpose

In order to implement the "Food Safety Law of the People's Republic of China" on the registration requirements of overseas food manufacturers of imported food, further strengthen the management of manufacturers of imported food, optimize the registration procedures, clarify the responsibilities of all parties, refine management requirements, highlight the management orientation of "facilitating integrity and law-abiding and punishing untrustworthy violations", play the important role of the overseas manufacturers registration system during the source control of imported food safety, and ensure the safety of imported food, it is necessary to revise the "*Regulations on the Registration and Administration of Overseas Manufacturers of Imported Food*" (The original promulgated by General Administration of Quality Supervision, Inspection and Quarantine Decree No. 145 on March 22, 2012 and the amended by General Administration of Customs Decree No. 243 on November 23, 2018).

### 2. Basis of Legislation

*Regulations of People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food* (General Administration of Customs Decree No. 248) (hereinafter referred to as the "Registration Provisions") is based on laws such as the *Food Safety Law of the People's Republic of China* and its implementing regulations, the *Import and Export Commodity Inspection Law of the People's Republic of China* and its implementing regulations, the *Law of the People's Republic of China on Animal and Plant Quarantine* and its implementing regulations, and the *Special Provisions of the State Council on Strengthening the Safety Supervision and Administration of Food and Other Products*, added the *Law of the People's Republic of China on Animal and Plant Quarantine* and its implementing regulations, and the *Special Provisions of the State Council on Strengthening the Safety Supervision and Administration of Food and Other Products*.

Article 96 of the *Food Safety Law of the People's Republic of China* stipulates that "overseas manufacturers exporting food to China shall be registered with the State Agency of Entry-Exit Inspection and Quarantine. If a registered overseas food manufacturer provides false materials or the imported food causes a major food safety incident due to its own reasons, the State Agency of Entry-Exit Inspection and Quarantine shall revoke the registration and make a public announcement." This is the most fundamental legal basis for the registration and management of overseas manufacturers of imported food. Articles 92 and 94 of the *Food Safety Law of the People's Republic of China* stipulate that imported food products shall comply with the China national standards for food safety and this is the basis for overseas manufactures and their products shall comply with the requirements of Chinese standards. Article 95 of the *Food Safety Law of the People's Republic of China* stipulates that the measures should be taken in response to overseas food safety incidents or imported food safety problems. This is the basis for taking corresponding measures against the problem products and their manufacturers.

Article 50 of the *Regulations on the Implementation of the Food Safety Law of the People's Republic of China* stipulates that "if the State Entry-Exit Inspection and Quarantine Agency discovers that the registered overseas food manufacturers no longer meet the registration

requirements, it shall request them to take corrective actions within the prescribed time limit and suspend the import of the food produced by them during the rectification period; if the manufacturer cannot meet the registration requirements after rectifications, the State Entry-Exit Inspection and Quarantine Agency shall revoke its registration and make a public announcement accordingly.” Article 52 of the *Regulations on the Implementation of the Food Safety Law of the People's Republic of China* stipulates that if food safety incidents occurring outside China may affect China, or serious food safety problems are found in imported foods, food additives and food-related products, the State Entry-Exit Inspection and Quarantine Agency shall promptly issue early warning of risks and may take measures to return or destroy related foods, food additives and food-related products; or conditionally limit imports; or suspend or forbid imports et al. This is the basis for more detailed control measures for the problem products and their production enterprises.

Article 6 of the *Import and Export Commodity Inspection Law of the People's Republic of China* stipulates that registration is part of the conformity assessment procedures. Article 8 of the *Regulations on the Implementation of the Import and Export Commodity Inspection Law of the People's Republic of China* stipulates that the classification management shall be carried out on import and export manufacturers; Article 14 stipulates that the information on imported commodities shall be assessed and measures shall be taken accordingly; Article 15 stipulates that the staff of the entry and exit inspection and quarantine agency shall receive cooperation from relevant institutions and individuals when they carry out their duties in accordance with the law, and no unit or individual may illegally interfere with or obstruct; and Article 32 stipulates to implement registration management for imported food manufacturers, and the manufacturers shall register with GACC. Article 49 stipulates that if registered imported food manufacturers are discovered not meeting the relevant requirements, they will be requested to take corrective action within a specified period. If the rectification fails or over violation is found, the registration shall be revoked. This is the basis for Articles 6, 25, 24, 4, 18, 23 and 24 of the Registration Provisions.

The "*Entry and Exit Animal and Plant Quarantine Law of the People's Republic of China*" provides a clear basis for the quarantine requirements of overseas food manufacturers and the competent authorities of the country (region). Article 17 of the "*Implementation Regulations of the Entry and Exit Animal and Plant Quarantine Law of the People's Republic of China*" stipulates that "the State implements a registration system for overseas production, processing, and storage facilities that export animal and plant products to China". This is the basis of registering overseas food storage facilities.

Article 8 of the "*Special Provisions of the State Council on Strengthening the Supervision and Administration of Food and Other Products*" stipulates that imported products shall meet the mandatory requirements of China's national technical specifications and the inspection requirements in the agreements between China and the exporting countries (regions); for imported products, implement classified management according to the integrity and quality management level of the producers and operators, and the results of the risk assessment of imported products.

In summary, relevant laws and regulations provide a sufficient legislative basis for the "Registration Provisions" and provide strong upper-level legal support. Many of the provisions of this Registration Provisions come directly from relevant laws and regulations. It embodies the spirit of higher-level law legislation and is the concretization of relevant laws and regulations. It ensures the implementation of laws and 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.

#### 【Subject of Article】

This article is about the scope of application of this provision.

#### 【Interpretation】

According to Article 150 of the *"Food Safety Law of the People's Republic of China"*, food refers to all kinds of finished products and raw materials for human consumption or drinking, as well as products that are traditionally both food and Chinese Traditional Medicines. However, it does not include products for the purpose of treatment.

Food production and processing refers to processing the food raw materials or semi-finished products through labor, machinery, energy, etc. and then transforming them into products suitable for consumer consumption or eat. Therefore, the corresponding facilities, places, fishing boats, etc. engaged in food production and processing activities belong to food production and processing facilities.

According to the expression in Article 2 (5) of the *"Food Safety Law of the People's Republic of China"*, this regulation changes the original article 2 "reserve" to "storage", which is consistent with the expression of the upper law. Articles 2 and 33 of the *"Food Safety Law of the People's Republic of China"* have clear requirements about the environment of food storage places and the isolation from toxic and harmful pollution sources, the safety and cleanliness of storage containers, tools and equipment, temperature and humidity, etc. Therefore, the places and containers suitable for food storage, and facilities storing foods in accordance with food storage safety and sanitation requirements are all food storage facilities.

Food production and processing and food storage are important phases that affect food safety. For example, for foods that require specific storage conditions and in bulk, if improper control of temperature, humidity, and storage environment, it is easy to cause food to be decomposition or contamination, then leading to food safety issues. Therefore, overseas production, processing, and storage facilities that export food to China are applicable to these regulations.

According to Article 150 of the "*Food Safety Law of the People's Republic of China*", food additives refer to artificial or natural substances added to food for the purpose of improving the quality, color, aroma and taste of food, as well as for the needs of anti-corrosion, preservation and processing technology. This includes nutritional supplements.

Food-related products generally include packaging materials and containers used for food, tools and equipment used for food production and operation, and detergents and disinfectants used for food.

According to the definition of food additives and food-related products in the *Food Safety Law of the People's Republic of China*, considering that these two types of products and their production, processing, and storage requirements are different from food, this article clarifies the production, processing, and storage of food additives and food-related products facilities do not apply to this regulation.

**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.

#### **【Subject of Article】**

This article is about the management scheme for overseas manufacturers of imported food.

#### **【Interpretation】**

According to the State Council's institutional reform plan announced on March 13, 2018, the General Administration of Customs is responsible for the registration management and inspection and quarantine management of overseas manufacturers of imported food.

The General Administration of Customs is uniformly responsible for the registration management of overseas manufacturers of imported food, which is mainly reflected in the following aspects:

1. The General Administration of Customs conducts risk analysis to determine the registration method and application materials for overseas manufacturers of imported food. GACC can adjust it according to the situation;
2. The General Administration of Customs may negotiate the registration method and application materials for overseas manufacturers of imported food with the competent authorities of the home countries (regions);
3. The General Administration of Customs shall determine the registration application materials such as the content of the registration application form and the filling requirements according to the needs of the work;
4. The General Administration of Customs, on its own or by entrusting relevant agencies to organize an evaluation team, conducts evaluation and review of overseas manufacturers of imported food that apply for registration;
5. The General Administration of Customs shall conduct re-evaluation of whether the overseas manufacturers of imported food continue to meet the registration requirements, and review the rectification of the enterprises;

6. The General Administration of Customs shall, based on the assessment and review, make decisions on approval for registration, disapproval, approval for modification, renewal registration, cancellation of registration, deregistration, suspension of imports, and resumption of imports, etc. GACC will issue written notices, announcements, or public notice, etc.;
7. The General Administration of Customs will assign a China registration number to the registered overseas manufacturers of imported food, and uniformly publish the list of registered overseas manufacturers of imported food.

**Article 4** Overseas manufacturers of imported foods shall obtain registration with the GACC.

**【Subject of Article】**

This article is about the registration obligations of overseas manufacturers of imported food.

**【Interpretation】**

This article is the full implementation of Article 96 of the *Food Safety Law of the People's Republic of China*.

According to the Part 15 "Imported Food Inspection" of Food and Agriculture Organization (FAO) "Food Quality Control Manual", it is the basic obligation of a country to ensure the safety of food provided to its consumers, and the government must ensure the control of imported food. Therefore, to protect the safety and health of consumers, animals, and plants in their own countries (regions), many countries (regions) have implemented registration systems for exporting countries' food manufacturers. Evaluation, qualified manufacturers are allowed to register and allow the import of food produced by them.

With the rapid growth of China's imported food types and trade volume in recent years, as well as consumers' increasing requirements for imported food safety, in accordance with the relevant provisions of the *Food Safety Law of the People's Republic of China*, the registration management of overseas manufacturers of imported food is consistent with China's domestic food safety supervision requirements. It further ensures the safety of imported food.

**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.

#### 【Subject of Article】

This article is about the requirements for the registration of overseas manufacturers of imported food.

#### 【Interpretation】

The registration requirements for overseas manufacturers of imported food refer to the conditions that overseas manufacturers should take or maintain to obtain registration qualifications. In terms of content, in accordance with Article 101 of the *"Food Safety Law of the People's Republic of China"* and the relevant provisions of the International Food Code (CAC) on "equivalence", this article adjusts the expression of the original provision (1); deletes the requirements in original provision (2), because the related requirements of it has been reflected in the *"Measures of the People's Republic of China on Import and Export Food Safety Administration"* (General Administration of Customs Decree No. 249); provision (3) of this article is revised to clarify the main responsibility of the enterprise; provision (4) of this article is added. This is to connect the relevant inspection and quarantine requirements established between the General Administration of Customs and the country's (region's) competent authority. It maintains the effective implementation of relevant inspection and quarantine requirements.

The requirements for overseas manufacturers of imported food to obtain registration qualifications are: the first provision is that the country (region) where the manufacturer is located meets the requirements; the second provision is that the manufacturer's own qualifications should be legally controlled in their country (region); the third provision is that the manufacturer's own safety and health management situation should meet the requirements. Its production and export should meet the requirements of their country (region). When the manufacturer exports food to China, it should comply with relevant Chinese laws, regulations, and national food safety standards; the fourth provision is supplementary requirements. The manufacturer should also comply with relevant inspection and quarantine requirements agreed between the GACC and the competent authority of the manufacturer's country (region).

An overseas manufacturer of imported food should apply for registration in accordance with the corresponding conditions listed in this article. First, confirm whether the food safety management system of their country (region) has had the equivalence assessment and review of the GACC. If it is not clear, the manufacturer should contact the competent authority of their country (region) to clarify; second, the manufacturer should confirm that it has the qualifications approved by the competent authority of their country (region) and is under its effective regulatory; third, the manufacturer itself should establish an effective food safety and health management and protection system, its production and export meet the requirements of their country (region). When an manufacturer exports food to China, it shall fulfill the main responsibility and ensure that the food exported to China complies with relevant Chinese laws, regulations and food safety National Standards; fourth, the manufacturer should also confirm

with the competent authority of their country (region) whether there are relevant inspection and quarantine requirements agreed upon with the General Administration of Customs. If so, the relevant agreed inspection and quarantine requirements should also be met.

**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.

#### 【Subject of Article】

This article is about the registration method of overseas manufacturers of imported food.

#### 【Interpretation】

Based on the risk analysis, different types of overseas manufacturers of imported food may adopt different registration methods. Registration of overseas manufacturers of imported food is divided into registration recommended by the competent authority of their country (region) and manufacturers self-registration.

Adopting different registration methods for different types of overseas manufacturers of imported food is based on related factors including the source of food raw materials (such as animal-derived raw materials, plant-derived raw materials, etc.), production and processing techniques (such as heating, dehydration, pickling, etc.), food safety monitoring and testing historical data, consumer groups (for example, products for infants or patients with certain diseases, etc.), eating methods (for example, direct eating, eating after heating) and et al. It also considers the status of food safety management in different countries (regions), refers to the management methods of overseas manufacturers of imported food in different countries (regions).

However, with the development and progress of science and technology, analytical methods and cognition, new food safety risks may be identified and created in the future, in the other hand certain food safety risks may also be confirmed to be negligible or can be eliminated. Therefore, if the risk analysis or evidence shows that the risk of a certain type of food has changed, the General Administration of Customs shall adjust the registration method and application materials of the corresponding food overseas manufacturers.

When applying for registration, an overseas manufacturers of imported food shall confirm its own product category and submit application in a corresponding manner that meets this Registration Provisions.

**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.

**【Subject of Article】**

This article is about the category of imported food that should be recommended by the competent authority of the country (region).

**【Interpretation】**

After analysis and evaluation, it is identified that overseas manufacturers of 18 categories of imported food should be recommended by the competent authority of their country (region). The HS code range of 18 categories and other categories of imported food could be searched at GACC's website. The HS code range will be adjusted simultaneously according to the update of the tariff code.

**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.

**【Subject of Article】**

This article is about the work requirements and application materials submission requests for the competent authority of the country (region) when recommending registration to the GACC.

### 【Interpretation】

In order to implement the recommendation responsibility of the competent authority of the country (region) and ensure that the recommended manufacturers actually meet the registration requirements, this article clarifies that the competent authority of the country (region) should first review and inspect the manufacturers recommended for registration, and then recommend them after confirming that they meet the registration requirements. When the competent authority of the country (region) recommends registration, they need to submit the five application materials listed in this article.

Supervising and inspecting food companies is one of the main responsibilities of the competent authorities of exporting countries (regions). After the competent authority of the country (region) has completed the review and inspection of the manufacturers and confirmed that they meet the registration requirements, it should provide relevant application materials to the General Administration of Customs when recommending registration.

The General Administration of Customs, in accordance with Chinese laws, regulations, national food safety standards, and the characteristics of different products' manufacturers, develops corresponding registration requirements and comparison checklists for overseas manufacturers of imported food. The overseas manufacturers of imported food and the competent authority of the country (region) can use this check list to conduct audit and inspection of the relevant manufacturers. The results of the audit and inspection can be used as the fifth application materials listed in this article, i.e. "Reports of examinations/inspections/review conducted by the competent authority of the country/region to relevant manufacturers." When the General Administration of Customs conducts registration evaluation, review, and re-examination, GACC will compare this checklist regarding the laws, regulations, and standards. This checklist enables overseas manufacturers of imported foods and competent authority in their country (region) to basically align with the content of the assessment and review of the General Administration of Customs.

**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.

### 【Subject of Article】

This article is the provision for registration application and submitted materials by overseas producers of food categories other than those listed in Article 7.

**【Interpretation】**

This article clarifies the requirements for registration applications for overseas producers of foods other than the 18 categories listed in Article 7; overseas producers of foods other than the 18 categories could file registration application to GACC by themselves or by their entrusted agents, instead of through recommendation by the competent authorities of their countries. This further simplifies the application process requirements.

The agents entrusted can be domestic or foreign organizations and individuals that conform to local laws and regulations. While entrusting an agent to file for registration application to the Customs, the overseas producer shall provide the applications materials, and the entrustment letter. The entrustment letter shall contain: basic information of the principle (the overseas producer) and its entrusted agent, the entrusted matters and the authority of the agent, the starting and ending date of the entrustment, the date of entrustment, signature or seal of the principle. If the principle alters the content of the entrustment or terminate the entrustment early, such change and the termination shall be notified to the Customs in writing.

**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.

**【Subject of Article】**

This article is the provisions about the content of the application for registration of overseas manufacturers of imported food.

**【Interpretation】**

To clarify and regulate the application of imported food production enterprises outside of the country, this article specifies the content of the application for registration of enterprises. Overseas producers of imported foods should fill the application (form) according to items listed in this article, and to ensure accurate, complete and standardized filling.

GACC will develop the registration application forms for overseas producers and samples of application form filling out. Details can be found on the official website of GACC.

**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.

**【Subject of Article】**

This article is the additional provision regarding registration application materials and registration methods.

**【Interpretation】**

This article clearly stipulates that the registration (forms) shall be filled in Chinese or English for submission.

Considering that China may already have agreed mutually (on method of filling the application and materials) with relevant countries (regions), for the purpose of fulfilling the mutually agreed items, this article clarifies that if there is existing agreement on the registration method and application materials, requirements of agreements by the two sides shall be implemented.

**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.

**【Subject of Article】**

This article elaborates on foreign competent authorities' responsibilities or the overseas producers of imported foods for the applications materials.

**【Interpretation】**

This article specifies the foreign competent authority or overseas producers are to be held accountable for truthfulness, completeness, and legality of the submitted materials. The application materials submitted by the foreign competent authority and the overseas producers are the foundation for evaluation and review by the Chinese customs, which are the critical basis for the decision of granting or rejecting registration or the post-registration oversight. The foreign competent authorities or the overseas producers shall not submit false materials to deceive Chinese customs, otherwise they shall bear the corresponding legal liabilities.

**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.

**【Subject of Article】**

This article is about the provisions of evaluation and review.

**【Interpretation】**

GACC has been organizing review team to carry out assessments and reviews. With the diversification of management approaches and changes in the higher level laws/regulations, this provision proposes that relevant agencies can be entrusted to carry out the assessment and reviews. The detailed implementation methods will be developed based on the higher level law and regulations, and will be released by GACC separately.

To ensure the fairness of the evaluation and review, this article specifies that the review team shall consists of at least 2 evaluation reviewers. This article also clarifies that overseas production enterprises of imported food and the competent authority of the country (region) are obliged to assist GACC in carrying out the assessment and reviews.

Based on risk assessment and actual work needs, GACC can adopt different types of assessment and reviews for different overseas producers in different countries (regions). The types of assessment and reviews for overseas producers are as follows:

1. Written inspection: GACC organizes the evaluation team to inspect documents and materials submitted by the producer or the foreign competent authority. Based on the documents and the materials, GACC may request the competent authority or the overseas producer to supplement the missing information or materials.
2. Video inspection: GACC sets up review teams to inspect the producer's food safety hygiene management systems and the facility's sanitation conditions through an Internet video connection. The producer to be inspected and the relevant foreign competent authority shall provide necessary assistance for the video inspection. GACC can instruct the producer and the foreign competent authority to take rectification measures and report the rectification (results) for the problems detected in the video inspection.
3. On-site inspection: GACC sets up review teams to visit the overseas producers that have applied for registration to conduct on-site inspection on the producer's food safety and sanitation management and condition. The producer to be inspected and relevant foreign competent authority shall provide necessary assistance. GACC can instruct the producer and the foreign competent authority to take rectification measures and report the rectification (results) for the problems detected in the on-site inspections.

The contents and criteria of the assessment and review are implemented pursuant to relevant guidance by the three organizations of the WTO (OIE, IPPC, CAC), relevant inspection and quarantine protocols agreed between GACC and relevant foreign governmental, as well as relevant Chinese laws and regulations and national food safety standards.

Based on risk assessment results and international practices, GACC will engage with foreign competent authorities in advance before it sets up evaluation teams to conduct assessment and reviews.

**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).

#### 【Subject of Article】

This article is the provision about result of overseas producer registration.

#### 【Interpretation】

According to evaluation result, GACC makes decision on whether or not to register overseas producers of imported foods.

Under the original provisions, the registration number of an overseas producer is the number allocated by the competent authority of the country; however, as the food safety management systems and numbering rules vary from country to country, it happens a lot that registration numbers overlap or mix up. The new Regulations set up new registration number requirements, which allocate in a unified manner the registration number in China for registered producers of different categories of products.

Given overseas producers of different categories of products may adopt different registration methods: some could directly apply for registration, some are recommended for registration by foreign competent authority. This article has some additional provisions for target of notification, that is, GACC will notify the foreign competent authority or the overseas producers of imported foods through the same paths for registration application.

**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.

#### 【Subject of Article】

This article is about the labeling of registration numbers.

#### 【Interpretation】

The purpose of labeling the registration number on the inner and outer package of foods exported to China by a registered overseas producer is to safeguard the Chinese consumers' right to know, to clearly and accurately convey imported food registration information to consumers, and to enhance consumer confidence.

This article clarifies that a registered facility shall mark the registration number. A registered facility can choose to mark its registration number in China, or the registration number approved by the competent authority in the country (region) where it is located, which allows the facility convenience and the right to choose independently. In the long run, we encourage overseas facilities to mark their registration numbers in China.

The inner and outer package mentioned in this article refer to the transportation package and the sales units that contains individual packages. For transportation package, the registration number should be clearly and accurately marked on the transportation package. For a sales unit that contains individually packaged foods that can be sold separately, the registration number should be marked on the food label, following provisions of the National Food Safety Standard – General Rules for the Labelling of Prepackaged Foods.

**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.

**【Subject of Article】**

This article is about the validity period of registration.

**【Interpretation】**

According to the Article 15 of the Implementing Regulations of the Food Safety Law, the food production and operation licensing is valid for five years. According to WTO principle of national treatment, registration of overseas producers of imported foods is valid for 5 years, which is consistent with China's requirements for the validity period of food production and operation licensing. In order to clarify the valid period, GACC announces the starting and the ending date of the validity period of registration when granting registration of an overseas producer of imported food.

An overseas producer of imported food that has obtained registration before the implementation of these Regulations, its registration is still valid; the producer could apply for and before the expiration of the validity period, it can apply for renewal of registration pursuant to Article 20 of these Registration before the valid period expires. Fail to apply for registration renewal, the producer's registration will be revoked.

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

**【Subject of Article】**

This article is about the unified announcement of the list of overseas producers of imported foods.

**【Interpretation】**

This article clarifies that GACC is the authority that uniformly announces the list of registered overseas producers of imported foods imported food borders.

The official website of GACC will publish the lists of registered overseas producers of imported foods.

**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.

**【Subject of Article】**

This article is about review of overseas producers of imported foods that have been registered.

**【Interpretation】**

In order to strengthen the supervision and management of registered overseas producers of imported food during and after production, urge registered overseas producers of imported food to continue to comply with Chinese laws, regulations and standards. Within the validity period of the registration, the General Administration of Customs will focus on the source of raw materials, production and processing technology, historical data of food safety inspection and monitoring, consumer groups, eating methods, etc. of relevant imported food overseas producers. GACC will conduct risk assessment based on the notification from the competent authority of the country (region) and the collected risk public information and organize the review team to review the imported food overseas production producers.

The review is carried out by the review team organized by GACC with advanced communication and negotiation with local country (Region)'s competent authorities. Regarding to the specific requirements of relevant agencies to the review, GACC will make and announce separately. In order to ensure the fairness of the review work, this article specifies that the review team shall have at least 2 evaluation reviewers.

The specific evaluation and review methods shall refer to Article 13 of the Regulations. For different types of overseas facilities in different countries (regions), according to risk analysis and actual work needs, GACC will organizes review in different forms or a combination of forms to develop. Imported food overseas production producers and their competent authority of the country (region), will have review duty to assist with GACC.

After the review of overseas production producers of imported food, if any problems are found, GACC will adopt corresponding measures comply with Article 21, Article 23, and Article 24.

**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.

#### **【Subject of Article】**

This article is about the change of registration information of registered overseas production producers of imported food.

#### **【Interpretation】**

This article clarifies that if the registration information of imported food overseas production producer changed, an application should be submitted to GACC to update the relevant information. To ensure the accuracy and standardization of related information changes, the registered imported food overseas producers shall comply with the following requirements when applying for change:

Firstly, submit a change application through the same channel as when applying for registration. That is, If the application of registration is recommended by the competent authority of located country (region) to GACC, the relevant change application should also be submitted by the competent authority of located country (region) to GACC; if the application of registration is submitted by producers themselves or by agents, the relevant change application should be submitted by producers themselves or entrusted agents to GACC.

Secondly, when submitting a change application, the materials that should be submitted include comparison table of changed registration information and proof materials related to the changed information. The comparison table of changed registration information is used to explain which registration items have been changed. The proof materials related to the change information is used to explain the accuracy and necessity of the change information. For example, an overseas producer of imported milk powder changes its facility name, a comparison table of changed facility name is required to explain how the facility name changes, at the same time, it is necessary to provide the proof document that the change of name approved by the competent authority of the country (region).

Thirdly, GACC will conduct evaluation after receiving the application for change in accordance with the relevant requirements of Article 13 of these regulations. After evaluation, if the relevant changes and adjustments will not affect the health management and control of food safety of overseas producers of imported food (such as change in the name of facility, etc.), the application will be granted. If the relevant changes and adjustments may affect the health management and control of food safety of overseas producers of imported food (such as plant and equipment renovation or expansion or major adjustments on food safety health management system), GACC will require producers to submit new registration applications and applications materials in accordance with the corresponding application channels that meet the requirements of these regulations. After the new registration application is approved, the original registration number in China will be automatically invalid and the original registration qualification will be cancelled.

Fourthly, if the production site of producer moves, the legal representative changes, or the registration number granted by the country (region) changes, relevant producers should not apply for adjustment of relevant registration items in the manner of change but specify the corresponding application channels required by this regulation, submit new registration applications and application materials. After the new registration application is approved, the original registration number in China will be automatically invalid, the original registration qualification will be cancelled.

Among which, the relocation of production sites refers to the actual production site (factory area) producing food for export to China is moved to a new physical location. The change of the management office is not the relocation of the production site. The change of legal representative refers to the change of actual owner of the facility. If the actual owner of the facility remains the same, but the personnel performing the management of the production site (factory) on behalf of the actual owner changes, the facility can apply for registration change first. GACC will evaluate the actual impact of the corresponding change on the management and control of the enterprise's food safety and sanitation and decides whether the registration could be changed. If the assessment finds that the changes and adjustments may affect the management and control of food safety and sanitation of the facility, GACC will instruct the facility to submit new registration applications and materials in accordance with the corresponding application path that comply with the requirements of this regulation. After the new registration application is approved, the original registration number in China will automatically become invalid and the original registration qualification will be revoked.

If GACC finds that a registered facility has not timely reported relevant changes and adjustments that may affect the management and control on food safety and sanitation of the overseas facility (such as plant and equipment reconstruction or expansion, or major adjustments to the food safety and sanitation management system), GACC will take corresponding measures according to relevant provisions in Articles 23 and 24 of these Regulations.

**Article 20** If an overseas producer of imported foods intends to renew its registration, it shall, within 3 to 6 months before the registration expires, apply to GACC for renewal of registration through the registration path.

Application materials for registration renewal should include:

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

GACC renews registration of producers that conform to the registration requirements and extends valid period of registration for 5 years.

**【Subject of Article】**

This article is about the registration renewal for registered overseas producer of imported food.

**【Interpretation】**

This article revises and refines Article 10 of the previous regulations (editor's note: AQSIQ Decree 145), changing the period of application for registration renewal before the expiration of the registration from "one year" to "6 months to 3 months before the expiration". For example, if the registration of an overseas producer will expire on December 31, 2022, the producer should apply to GACC for registration renewal between July 1 and September 30, 2022. The purpose of this setting is to ensure that GACC has sufficient time to complete the relevant evaluation and review of the application after the producer applies for registration renewal; this also avoids the expiration of the valid period due to insufficient time to complete evaluation (because the renewal application is submitted too close to the registration expiration date), which ensures registered overseas producers of imported foods that meet the requirements can continue exporting products to China.

If there is no change of relevant information, an overseas producer of imported food that applies for registration renewal shall apply for renewal to GACC through the same path for registration. That is, if the registration was recommended by the competent authority of the country (region) to GACC, the application for registration renewal should also be submitted by the competent authority of the country (region) to GACC; if the producer was self-registered or registered through its entrusted agent, the application for registration renewal shall be submitted to GACC by the facility itself or through its entrusted agent.

If there is no change of the registration information, a facility that intends to apply for registration renewal should first apply for modification of registration in accordance with Article 19 of these Regulations, and submit the renewal application after the information modification is completed; or before the expiration of registration, the facility submits a new registration application in time; once the new registration application is approved, the original registration number in China will automatically become invalid and the original registration qualification will be revoked.

**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.

**【Subject of Article】**

This article is about the revoke provisions of registered overseas producer of imported foods.

**【Interpretation】**

This article refers to relevant provisions of the "Food Safety Law", and added the contents for revoke of registration of overseas producers that meets one of the following three conditions: First, a producer fails to apply for renewal of the registration in accordance with the regulations; second, GACC revokes a producer's registration when the competent authority of the producer

or the foreign competent authority voluntarily applies to revoke the registration; third, clarifies that when a registered overseas producer no longer conforms to the requirements of Article 5 (2) of these regulations, that is, the foreign competent authority no longer approves the establishment of the overseas producer and the producer is not under effective supervision of the competent authority, GACC shall revoke the producer's registration.

After the registration of an overseas producer is revoked, the products exported to China from the producer will no longer be accepted for import declarations departed on or after the date of revoke. If the producer needs to export food to China, it should re-apply for registration with GACC.

If an overseas producer fails to apply for renewal of registration on time, its registration will become invalid when the validity period of the registration expires. For example, if an overseas producer's registration number will expire at 24:00 on December 31, 2022, and the producer fails to apply to GACC for renewal of registration between July 1st and September 30th, 2022 (that is, within 3-6 months before the validity period expires), regardless of whether GACC announces the revoke of its registration in October 2022 or not, the producer's registration will automatically expire at 0:00 on January 1, 2023.

If an overseas producer voluntarily applies for revoke or the producer no longer conforms to provisions of Article 5 (2) of these regulations, its registration shall be revoked effective on the date GACC decides to revoke its registration. For example, if an overseas producer's registration expires on December 31, 2022, but on March 1, 2022, it voluntarily applies for revoke of its registration, and GACC announce on March 5, 2022, that the producer's registration will be revoked on March 1, then the registration expires on March 1, 2022.

**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.

#### 【Subject of Article】

This article is provisions about suspension and rectification by the registered overseas producers of imported foods and the foreign competent authorities.

#### 【Interpretation】

This article revises and refines Article 14 of the original regulations, requiring the foreign competent authority or the facility to voluntarily suspend exports to China when finding

incompliances to the registration requirements; rectification measures shall be taken immediately until it conforms to registration requirements.

This revision clarifies the oversight responsibilities of the foreign competent authorities – they should suspend relevant facilities’ exports to China if problems are detected; the foreign competent authority would supervise the facilities to take rectification measures and urge the registered producers to continue to conform to the registration requirements. At the same time, it is clear that overseas producers of imported foods shall assume the main responsibility for food safety. Finding incompliances to the registration requirements, the producer itself shall voluntarily suspend its food exports to China and take immediate rectification measures until it conforms to registration requirements.

When overseas producers and foreign competent authorities take initiative rectification measures after finding problems after finding problems, their registration will not be affected as such actions are the routine oversight by foreign competent authorities, and (such actions) are not required to be report to GACC.

**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.

#### 【Subject of Article】

This article is about GACC instructing overseas producer of imported foods to take rectification measures within a given period when it finds a registered facility no longer conforms to the registration requirements.

#### 【Interpretation】

This article is a revision and improvement of Article 14 of the original regulations, clarifying that the competent authority of the country (region) shall bear the corresponding supervision responsibility as the actual supervision authority of a registered facility.

Finding a registered overseas producer of imported foods no longer meets any of the registration requirements listed in Article 5 of these Regulations, GACC shall instruct the facility to take rectifications measures within the prescribed time limit, clarify the issues to be rectified,

requirements for the rectification materials, deadline, etc. Food imports from relevant producers shall be suspended during the rectification period.

The rectification report and a written statement of compliance shall be submitted within the prescribed time limit through the same path for registration application. That is, if the facility is registered by recommendation of a foreign competent authority to GACC, the rectification materials and statements shall be submitted by the foreign competent authority; if the facility is self-registered or registered by its agent, such materials shall be submitted to GACC by the facility itself or by its agent.

After receiving the rectification report and other materials, GACC will organize the evaluation and review of the submitted documents following provisions of the Article 13 of these Regulations and notify the producer and the foreign competent authority results of the evaluation and review. Passing GACC's review, food imports from relevant producers will be 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.

#### 【Subject of this Article】

This article is about the relevant provisions revoking registration of registered overseas producer of imported foods.

#### 【Interpretation】

Revoking registration of overseas producers of exported foods that cannot conform to registration requirements is one of the most important measures for oversight during and after imports in these Regulations. This article revised the circumstances for revoking facility registration in Article 15 of the original regulation and added one circumstance which result in revoking a producer's registration. If GACC's evaluation confirms the existence of any one of the seven circumstances listed in this article, GACC revokes the overseas producer of imported foods' registration and issue a public announcement thereof.

1. Severe food safety incidents occurred.

According to Article 150 of the "Food Safety Law", "food safety incident means any incident that may be caused by food borne diseases, food contamination, or other incidents arising from food and which are hazardous to human health."

Imported foods, from production and processing to entering into the China market, go through multiple links (such as raw and auxiliary material procurement, production and processing, storage in the production origin, international transportation, storage at the destination, distribution in market) and a long international food production and trade chain; risks to food safety exist in any link of this process. If the producer causes a major food safety incident due to its own reasons (such as improper inspection and acceptance of raw materials, improper risk prevention and control in production and processing, loss of control of storage temperature, etc.), the producer's registration shall be revoked.

## 2. Problems found in inspection and quarantine.

According to the "Food Safety Law" and its implementing regulations, the "Import and Export Commodity Inspection Law" and its implementing regulations, the "Entry and Exit Animal and Plant Quarantine Law" and its implementing regulations, imported foods are inspected and quarantined before they enter the Chinese market. The incompliances of imported foods can generally be categorized into two types:

- 1) Incompliances in sanitary and safety-related items, including the detection of non-edible additives, and existence of prohibited and restricted substances, biotoxin contamination, excessive food additives, microbial contamination, contamination of contaminants, the presence of genetically modified ingredients, excessive pesticide and veterinary drug residues and radiation etc.;
- 2) Incompliances in the non- sanitary and safety-related items, including incompliances in packaging and labeling, incompliant quality, incompliant certificates, pests, other incompliant items.

Based on the causes and impacts of the identified food safety problems, and the level of impact to the society, Customs will make assessment on how serious the problems are. In the case of serious problems, the registration shall be revoked.

## 3. Major problems found in management of the producer

Once GACC learns and identifies major food safety and sanitary management problems in a producer by reviews, notifications by the foreign competent authority, information collection and analysis, complaints and reports, and petitions by letters and visits etc., and (the producer) cannot ensure safety and sanity of its food exports to China, GACC should revoke relevant facility's registration after confirming with the foreign competent authority that the producer cannot eliminated relevant risks via technical measures within 3 months.

## 4. Unqualified rectification

Receiving rectification reports submitted by the overseas producers of exported foods, GACC reviews and evaluates the reports; finding the producer fail to complete the rectification in accordance with the pre-determined requirements or time limits, or the rectification results failed to meet the pre-determined acceptance standards, GACC shall revoke the producer's registration.

#### 5. Providing false materials and concealing problems

Providing false materials and concealing relevant information refers to the circumstances when overseas producers of the imported food forge, fabricate or conceal relevant materials and data in the process of applying for registration, in exporting to China, while receiving GACC review and receiving the inspection of the foreign competent authority. If GACC has evidence to confirm that the producer did have falsification or concealment, the producer's registration shall be revoked.

#### 6. Refusing to cooperate with GACC in review and accident investigations

When GACC is conducting a review or investigating a food safety incident, the following circumstances are deemed refusing to cooperate with GACC's review and accident investigation: the relevant overseas manufacturer refuses to respond to the communication and inspection requests by GACC, or delays the responses for more than 3 months, or refuses to provide material requested by GACC, or falsely claims it cannot provide the requested material; or refuses review by GACC with unreasonable reasons. If GACC has evidence to confirm that the producer does refuse to cooperate with GACC, the producer's registration shall be revoked.

#### 7. The registration number is used in violation of regulations.

Leasing, lending and transferring registration numbers refer to the circumstances when the registered overseas imported food producers provide their registration numbers, via the forms of leasing, trading or investing, to other producers that are not registered with GACC, for exporting food to China.

Reselling registration number refers to the circumstance that the relevant enterprises or individuals obtain registration numbers of imported food overseas producers through various channels and provide the registration numbers to other producers which are not registered with GACC for paid use.

Fraudulent use of registration numbers refers to related companies or individuals using the registration number of a registered overseas producer of imported food without authorization of the producer and without confirmation by GACC. In this case, if the subject of fraudulent use has obtained its registration number, GACC shall withdraw the registration number of the counterfeiting entity. Companies/producers whose registration number has been fraudulently used may, through the competent authority of the country (region) in which it is located, explain the situation to GACC and provide corresponding proof. After assessment and confirmation by GACC, the registration number may be kept, or a new registration number may be issued to the producer.

If the registration of an overseas producer of imported foods has been revoked by GACC, its import application for shipment to China will no longer be accepted by GACC starting from the effective date of the revocation. If the import procedure has been declared but has not been

completed, the shipment shall be returned or destroyed in accordance with the relevant regulations.

**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.

**【Subject of Article】**

This article is the regulation about suspending the acceptance of registration applications from overseas producers of imported foods when serious problems such as epidemics or public health incidents are detected.

**【Interpretation】**

This article is an amendment to Article 18 of the original regulations, with some adjustments. Article 95 of the *Food Safety Law* stipulates that, “In the event that a food safety incident occurs overseas that may impact China, or a major food safety problem has been detected in imported food, food additives, or Food-Related Products, the state entry-exit inspection and quarantine administration shall issue a risk alert or take control measures in a timely manner and notify the food and drug administration, health administration, and agriculture administration under the State Council.” Article 52 of the *Implementation Regulations of the Republic’s Food Safety Law* stipulates that, “If the food safety incidents occurring overseas may have an impact on China, or in the case of serious food safety problems found in imported foods, the national entry-exit inspection and quarantine authority should promptly carry out risk warning, and the following control measures can be adopted for related foods: 1) return or destroy the goods; 2) restrict imports conditionally; 3) suspend or prohibit imports. Article 5 of the *Law on the Entry and Exit Animal and Plant Quarantine* stipulates that, “The State prohibits the entry of animals and plants, animal and plant products and other quarantine items from countries and regions where animal and plant epidemics are endemic.”

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, it indicates possible and serious deficiencies or risk of losing control in the food safety management system of the competent authority of the country (region) where the overseas producers are located. In this case, GACC shall, in accordance with the relevant laws and regulations, promptly take emergency preventive measures such as suspending the import of the foods concerned.

During the suspension of relevant food imports from relevant countries (regions), for the follow-up development of the epidemic situation and the investigation of public health incidents, further information needs to be collected and risk assessment needs to be conducted. According to Article 6 of these Regulation, “If risk analysis or evidence presents that the 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.” Therefore, if an epidemic or public health incident is found to be a serious problem, during the suspension of the relevant foods importing from the relevant country (region), the registration application of the relevant food producers from that country (region) shall not be accepted until the relevant risk assessment has been completed.

**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.

**【Subject of Article】**

This article is about the concept of "the competent authority of the country (region) ".

**【Interpretation】**

The “competent authority of the country (region)” as the governing agency for the oversight of the producer of imported food in the country (region), play an important role in registration management of overseas producers of imported foods; this article clarifies the definition. According to the provisions of this article, "the competent authority of the country (region)" refers to government agencies in charge of safety and sanitation oversight of food producing facilities in the country/region, and compared with Article 21 of the original regulations, the relevant expressions have been adjusted and the original description of “officially authorized institutions and industrial organizations, etc.” have been deleted, which further clarified the official status of the “competent authority of the country (region)”.

Different countries (regions) have different competent authorities of food production facilities, and some countries have different agencies to be responsible for oversight of different foods categories. For example, Ministry of Health, Labor and Welfare, and The Ministry of Agriculture, Forestry and Fisheries of Japan, the U.S. Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS), U.S. Bureau of Alcohol, Tobacco, Firearms and Explosive (ATF) and other agencies, in some countries, different production processes of the same product are also managed by different departments.

During the actual implementation of these Regulations, when the responsibilities of “competent authority of the country (region)” falls to different government agencies, then each agency should engage with GACC according to its own responsibility, or designate one agency to be the single contact point engaging with GACC; the competent authority/authorities is/are responsible for organizing official recommendations, assisting evaluation/review and re-examination, and oversight of the facilities in the country(region)

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

**【Subject of Article】**

This article is the provisions that GACC is responsible for interpreting these regulations.

**【Interpretation】**

This article originated from Article 22 of the original regulations. According to Article 33 of the “Procedurals Rules of Regulations Development” of the State Council, the rule-making authority has the rights to interpret the rules it developed. GACC is the agency that formulated these Regulations, and therefore has the authority to interpret them, and is responsible for further clarifying specific meanings and provisions in these Regulations. Furthermore, when new situations arise after formulation, GACC need to provide interpretation to clarify the basis of applying these rules. The interpretation of the rules has the same effect as the actual rules.

**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.

**【Subject of Article】**

This article is about the date when these Regulations become effective.

**【Interpretation】**

This article clarifies that these Regulations will come into effect on January 1, 2022, that is, the revised Regulations on the Registration and Administration of Overseas Producers of Imported Food of the People’s Republic of China will come into effect on January 1, 2022. GACC, overseas producers of imported food and their competent authorities, etc. and other entities relevant to these Regulations shall perform their obligations and excise their rights according to the requirements of these Regulations from January 1, 2022. This article also clarifies that the original "Administrative Measures for Registration of Overseas Produces of Imported Foods” will be abolished at the same time, the old Regulations shall be replaced by the new Regulations seamlessly.

These regulations were announced on April 12, 2021, and will be implemented as of January 1, 2022; the transition period is in line with the WTO required transition time. These are 8 months between its announcement and implementation, which is granted as there are substantial changes, especially when the registration scope expands from four categories (meat, aquatic products, dairy products, and bird nest products) to all food categories. All relevant parties should take good use of the period to prepare for the implementation of these Regulations.

**END OF TRANSLATION**

**Attachments:**

No Attachments.