

Official Interpretation of <The Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food> (Decree of the General Administration of Customs of the People's Republic of China No.248)

Chapter I Overview, which is omitted

Chapter II 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.

[Main idea] This provision clarifies the legislative purpose and legislative basis of this Regulation.

[Interpretation]

I. legislative purpose

In order to implement the provisions of <the Food Safety Law of the People's Republic of China> requiring overseas food manufacturers to register, to strengthen the administration of the overseas food manufacturers, optimize the registration procedure, clarify the responsibilities of all parties involved, refine the administrative requirements, emphasize the management orientation of 'facilitating the honest and law-abiding and punishing the dishonest and credit-losing', give full play to the important role of the registration system in governing the source of imported foods, safeguard the safety of imported foods, it is necessary to revise and update the original <Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Foods> (issued on 22nd March 2012 according to Decree of the former General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China No.145), and its revision (issued on 23rd November 2018 according to Decree of the General Administration of Customs of the People's Republic of China No.243).

II. Legislative basis

The legislative basis (superior laws) of <The Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food> (Decree of the General Administration of Customs of the People's Republic of China No.248), hereinafter referred to as '**This Regulation**' includes: 1. <the Food Safety Law of the People's Republic of China> and its implementing regulations, 2. <the Law of the People's Republic of China on Import and Export Commodity Inspection> and its implementing regulations, 3. <the Law of the People's Republic of China on the Entry and Exit Animal and Plant Quarantine> and its implementation regulations, 4. <the Special Provisions of the State Council on Strengthening the Supervision and Administration of

Food and Other Products Safety>.

As it is referred to in Article 50 of <Regulations of the People's Republic of China on the Implementation of the Food Safety Law>, 'Where the national entry-and exit inspection and quarantine department finds that a registered overseas manufacturer of imported foods no longer meets the registration requirements, it shall order it to make rectification within the prescribed time limit and suspend the import of its food products during the rectification period. If it still fails meet the registration requirements after rectification, the State entry-exit inspection and quarantine department shall cancel the registration of this overseas manufacturer of imported foods and make an announcement.'; and in Article 52 'Food safety incidents happened outside China may have an impact on our country, or where severe problems are found in imported foods, food additives, food related products, the national entry-exit inspection and quarantine department shall timely execute risk warning, and may take the following control measures against the relevant foods, food additives and food related products: (1) return or destroy the relevant goods; (2) conditionally restrict the import of the relevant goods; (3) suspend or prohibit the import of the relevant goods.' These provisions set out the legislative basis for formulating refined control measures on problematic products and their manufacturers.

As it is set out in Article 6 of <the Law of the People's Republic of China on Import and Export Commodity Inspection>, 'Registration is one of the conformity assessment procedures for imported goods', and in Article 8 of <The Regulations for the Implementation of the Law of the People's Republic of China on Import and Export Commodity Inspection>, 'Entry-exit inspection and quarantine institutions shall implement classified management of import and export enterprises.'; and in Article 14, 'the General administration of quality supervision, inspection and quarantine import and export commodity shall, according to the early warning mechanism, collect and assessed the information on imported goods, determine their risk categories and take corresponding measures.'; and in Article 15, 'Relevant units and individuals shall cooperate with the personnel of the entry-exit inspection and quarantine institutions in performing their duties according to law, and no unit or individual shall illegally interfere or obstruct them.'; and in Article 32, 'The state shall implement sanitation registration administration for overseas manufacturers of imported foods, who should apply for registration to the General Administration of Customs of the People's Republic of China'; and in Article 49, 'Where an registered overseas manufacturer of imported foods fails to meet the requirements after the inspection, the entry-exit inspection and quarantine authority shall order it to make rectification within a time limit. If it still fails to meet the prescribed requirements or there are other illegal acts, or if the circumstances are serious, this manufacturer's sanitation registration shall be revoked'. The above provisions set out the legislative basis for Article 6, 25, 24, 4, 18 and 23 of this Regulation.

<The Law of the People's Republic of China on the Entry and Exit Animal and Plant Quarantine> clarifies the basis for the quarantine requirements of overseas manufacturers of imported foods and the competent authorities of the countries where

they locate; and as it is stipulated in Article 17 of <Regulations on the Implementation of the Law of the People's Republic of China on the Entry and Exit Animal and Plant Quarantine>, 'The State shall apply a registration system to foreign production, processing and storage units that export animal and plant products to China', which provides the basis for implementing a registration system for overseas storage units of imported foods.

According to Article 8 of <The State Council on Strengthening the Supervision and Administration of Food and Other Products Safety>, 'The imported products shall meet the mandatory requirements of China's national technical specifications and the inspection requirements stipulated in the agreement signed between China and the exporting countries. According to the production operators' integrity and quality management levels as well as the risk assessment results of the imported products, the imported products shall be subject to classified management.'

In conclusion, relevant laws and regulations provides sufficient legislative basis and the strong support as superior laws for this <**Regulations on Registration**>, and many provisions of these Regulations derive directly from the provisions of the relevant laws and regulations, reflects the legislative spirit of these superior laws, are the concrete embodiment of the relevant laws and regulations, and ensure the implementation of these 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.

[Main idea] This Article is clarifying the scope of application of this Regulation.

[Interpretation] According to Article 150 of <The Food Safety Law of the People's Republic of China>, 'Food means the finished products and raw materials for people to eat or drink, as well as items which are traditionally both food and Chinese medicinal materials, excluding items used for the purpose of treatment.'

Food production and processing refers to the process in which raw materials or semi-finished products of food are processed by labor force, machine and energy, and transformed into products suitable to eat or for consumer consumption. Therefore, enterprises, sites or fishing boats engaged in food production and processing activities belong to food production and processing enterprises.

As it is set out in Article 2 (5) of <The Food Safety Law of the People's Republic of China>, the term 'keep in storage' has been modified to 'storage and warehousing' in Chinese, which is consistent with the superior law. And specific requirements regarding 'the places for food storage and its environment, a prescribed distance from toxic and hazardous

sites and other pollution sources, as well as containers, tools and equipment for storing food should be safe, kept clean and satisfy the necessary temperature, moisture, and other special requirements for food safety' has also been set out in Article 2, 33 of <The Food Safety Law of the People's Republic of China>. Thus, Enterprises that have places and containers for food storage, and engage in food storage activities in accordance with the sanitation and hygiene requirements of food storage belong to food storage enterprises.

Food production and food storage are all important links affecting food safety. For example, food that has specific requirements for storage conditions and bulk food are sensitive to temperature and humidity, and improper storage conditions can easily cause food spoilage or contamination, resulting in food safety problems. Thus, overseas enterprises engaging in the manufacturing, processing and storage of foods that are exported to China are subject to this Regulation.

As it is set out in Article 150 of <The Food Safety Law of the People's Republic of China>, 'Food additive refers to any synthetic or natural substance added to food for improving its quality, color, flavor, or taste or as needed by antiseptic, freshness-keeping, or processing techniques, including nutrient supplements.'

Food related products refer to packing materials and containers used for food, tools and equipment for food production or trade, and detergents and disinfectants.

According to the definitions of food additives and food related products set out in <The Food Safety Law of the People's Republic of China>, and considering that these two product categories as well as their production, processing and storage requirements are different in nature, this provision has made it clear that enterprises engaging in the production, processing and storage of food additives and food related products are not subject 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.

[Main idea] This provision clarifies the administration system of overseas manufacturers of imported foods in China.

[Interpretation] According to the Institutional Reform Plan of the State Council (issued on 13th March 2018), the General Administration of Customs (GACC) exercises the responsibilities of registration, and inspection and quarantine administration of overseas manufacturers of imported foods in China.

GACC is uniformly responsible for the registration and administration of overseas manufacturers of imported foods, encompassing the following aspects:

- (1). GACC shall carrying out risk analysis, determine the required application materials and methods of overseas manufacturers of imported food, and make adjustment

- according to the applicants' actual situation;
- (2). GACC may decide through discussion with the competent authority of country/region where the applicant enterprise is located regarding the registration methods and application materials of overseas manufacturers of imported food;
 - (3). GACC shall, according to work needs, determine the content of application materials for registration and requirements of filling forms such as Manufacturer's Application for Registration;
 - (4). GACC shall, on its own or entrust relevant institutions, to set up a review team to evaluate and review the overseas manufacturers of imported food that apply for registration;
 - (5). GACC shall carrying out a review of the overseas manufacturer of imported foods to determine whether it continue to conform with the registration requirements, and review the registration of the manufacturers;
 - (6). GACC shall, based on the evaluation and review result, make decisions to permit or reject the register, to change or renew or cancel the registration, or suspend import, or publish a written notice or announcement;
 - (7). GACC shall grants Chinese registration numbers to the overseas manufacturers that meet the requirements, and publish lists of the registered overseas manufacturers of imported foods in the form of consolidated announcement.

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

[Main idea] This provision clarifies the registration responsibilities of the overseas manufacturers of imported foods.

[Interpretation] This provision is the comprehensive implementation of Article 96 of <the Food Safety Law of the People's Republic of China>.

According to No.15 <Manual for the Inspection of Imported Food> of the <Manuals of Food Quality Control> published by the Food and Agriculture Organization of the United Nations, it is the obligation of the State to ensure the safety of food supplied to its consumers, the government must ensure the control over the food it imports. With the purpose of protecting its' own consumers, many countries (regions) in the world have implemented the registration system for food manufactures of the exporting countries, in which the competent authority of the importing country evaluates the qualifications of overseas manufactures of imported foods and assesses the export management system of the exporting countries, registers the qualified ones and permits the food imports from the registered enterprises.

With the rapid growth in trade volume and categories of food imports in China in recent years, and with the increasing demands of Chinese consumers for the safety of imported foods, it is according to the relevant provisions of <the Food Safety Law of the People's Republic of China> to apply the concept of 'source management' and implement a registration system in administering all types of overseas manufacturers of imported foods, which is consistent with China's food safety regulatory requirements, and further guaranteeing the safety of imported foods.

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.

[Main idea] This provision sets out the registration conditions for overseas manufacturers of imported foods.

[Interpretation] The registration conditions for overseas manufacturers of imported foods refer to the conditions that the applicant enterprise should have or maintain in order to obtain registration. According to Article 101 of <the Food Safety Law of the People's Republic of China> and the relevant provisions of <Codex Alimentarius> published by the Codex Alimentarius Commission (CAC) regarding the principle of 'Equivalence and Mutual Recognition', this Article has made adjustments to sub-Article (1) of the original provision; deleted the relevant requirement of sub-Article (2) of the original provision, as that content has been covered by the Decree of the General Administration of Customs No. 249 regarding the publication of <The Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food>; modified sub-Article (3) of the original provision in order to clarify the main responsibilities of the enterprise; added in sub-Article (4) the content to link up the inspection and quarantine requirements that have been agreed upon discussion between GACC and the competent authority of country/region where the applicant enterprise is located, in order to maintain the effective implementation of relevant requirements.

The criteria for obtaining a registration in China includes (1) the country/region where the manufacturer is located has passed GACC's equivalence assessment and/or review; (2) the establishment of the manufacturer has been approved by and is under effective regulation by the competent authority of the country/region; (3) The manufacturer has established a food safety and sanitation management and protection system that conforms to relevant requirements, and meets the regulatory requirements of the country/region for producing and exporting food, and ensures that foods exported to China comply with relevant Chinese laws, regulations, and China's national food safety standards; and sub-Article (4) specifies the supplementary requirements on the relevant inspection and quarantine that have been agreed upon after discussion by the GACC and the competent authorities of the country/region, and to which the manufacturers should

also conform.

The overseas manufactures of imported foods should submit the registration application with reference to the above criteria as set out in this Article. First, the applicant shall make sure that the food safety management system of the country/region where it is located has passed GACC's equivalence assessment and/or review, if it is unsure, the applicant shall contact the competent authority of the country/region and get a clear reply. Second, the applicant should confirm that its establishment has been approved and qualified by and is under effective regulation by the competent authority of the country/region where it is located. Third, the applicant shall establish a food safety and sanitation management and protection system, and meets the regulatory requirements of the country/region for producing and exporting food, so that when exporting food to China, the applicant manufacture should take its principal responsibility and comply with relevant Chinese laws, regulations, and China's national food safety standards. Fourth, the applicant shall also contact and confirm with the competent authority of the country/region where it is located that whether there is any special inspection and quarantine requirements reached through discussion between GACC and the competent authority of country/region where the applicant enterprise is located, if this is the case, the applicant should also meet the relevant requirements as an addition.

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.

[Main idea] This provision specifies the registration paths/methods for overseas manufacturers of imported foods.

[Interpretation] based on GACC's risk analysis, the registration methods for overseas manufactures of different categories can be classified into two types, (1) recommendation for registration by competent authority of the country/region, and (2) application for registration by a manufacturer. The approach of registering different categories of manufacturers by different methods is determined by GACC's analysis of various factors, including raw materials (for example, animal raw materials versus plant raw materials), production methods and processing technologies (for example, heating, drying or pickling technology), historical data on food safety monitoring and testing, consumer groups (for example, for infants, children or patients with certain diseases), consumption methods of food (served directly versus served after heating), and in consideration of the different food safety and sanitation management conditions of different countries, as well

as referencing from the international practices in administering foreign manufacturers of imported foods.

Nevertheless, with the development and progress of science and technology, in future it is possible that certain food safety risks can be discovered and identified via new analysis methods, or certain food safety risks be eliminated and neglected. Thus, 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.

Overseas manufactures of imported foods should determine the classification of their products and submit the registration application according to the applicable method of application as set out in this Regulation.

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.

[Main idea] this provision clarifies the recommendation for registration by competent authority of the country/region.

[Interpretation] Based on GACC's risk analysis, the overseas manufacturers of the following 18 categories of imported foods should lodge their application for registration through recommendation by competent authority of the country/region. The HS Codes of the above mentioned 18 categories of foods, as well as those of other categories of foods can be found on the official website of GACC, which may be updated and adjusted with the Tariff Codes.

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.

[Main idea] This provision sets out the required work and materials for **type 1 applicants**, of whom the application should be submitted through recommendation by the competent authority of the country/region where the enterprise is located.

[Interpretation] In order to implement the responsibility of the competent authority of the country/region for recommendation and to make sure that the recommended manufacturer does conform to registration requirements, this Article has made it clear that the competent authority of the country/region where the manufacturer is located shall carrying out an initial evaluation and review of the recommended manufacturing enterprise, and make the recommendation only if that enterprise is qualified for the registration. So that when the competent authority of the country/region makes the recommendation, they should ensure that the enterprise is qualified for the registration and submits the 5 materials as set out in this Article.

Implementing inspection and supervision measures on food production enterprises is one of the main responsibilities of the competent authority of the exporting country/region. After the initial evaluation/review and confirming that the enterprise is qualified for the registration, the competent authority of the country/region where the enterprise is located shall make the recommendation for registration and submit the aforementioned 5 materials.

GACC shall, on the basis of China's laws and regulations and the national food safety standards, as well as characteristics of enterprises producing different food products, formulate an inspection checklist and the corresponding requirements for registration for each food category. Overseas manufacturers and its competent authority of the country/region where it is located may use this checklist as a reference when carrying out the initial evaluation/review. If qualified, the competent authority shall submit the completed checklist (which is considered as item 5 of the application materials and the report of examinations/inspections/review) together with other application materials to GACC. So that when GACC is evaluating/reviewing the application, it shall also comply with the laws, regulations and standards that are consistent with this checklist, in order to make sure that content for evaluation/review conducted by GACC are basically in consistency with that by the competent authority of the exporting country/region.

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

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

[Main idea] This provision sets out the required application materials for **type 2 applicants** (overseas manufacturers of imported foods other than those listed in Article 7).

[Interpretation] In order to simplify administrative procedures, overseas manufacturers other than the 18 categories set out in Article 7 shall, by themselves or by agents, file applications for registration with the GACC, instead of applying for registration through recommendation.

The agents entrusted by the parties involved may be an organization or an individual that complies with the local laws and regulations. In addition to the required application materials, the agent should also submit to GACC a Letter of Entrustment, which should specify the basic information of the entrusting party and the entrusted party, the entrusted matters, the scope of authority of the entrusted, dates of commencement and termination of the entrustment, date of entrustment, signature or seal of the entrusting party. In case the name of the entrusted party or entrusted matters change, or there is an early termination of the entrustment, the parties involved should notify GACC in written notice.

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

[Main idea] this provision sets out the content of the application package.

[Interpretation] In order to standardize the content of the application letter, this Article sets out the information that should be included in the application. Overseas manufacturers of imported foods should fill in the form in an accurate and holistic manner with reference to this Article.

GACC shall provide **a Sample Form** with examples and demonstrations for each category of food producing enterprise, which can be found on GACC's official website.

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

[Main idea] This provision specifies the supplementary requirements, as well as the application materials or methods in exceptional circumstances as otherwise agreed by GACC and the exporting country/region.

[Interpretation] This Article clarifies that the application materials **should be written in either Chinese or English**.

As China has reached separate agreements with certain countries/regions, and in order

to ensure the smooth implementation of the agreed matters, if relevant country /region and China have otherwise reached agreements on registration method and application materials, registration shall be carried out according to the agreement.

Article 12 Competent authority of the country /region or overseas manufacturers of imported foods shall be held accountable for truthfulness, completeness, and legality of the submitted materials.

[Main idea] this provision clarifies the accountability of the competent authority of the country /region or the overseas manufacturer of imported foods for the application materials.

[Interpretation] The submitted materials shall be used as important evidences for GACC to carry out the evaluation /review of the applicant enterprise, and make decision about whether or not to approve the registration. Thus, the competent authority of the country /region or overseas manufacturer of imported foods shall be held accountable for truthfulness, completeness, and legality of the submitted materials. Otherwise, they shall bear the corresponding legal liability.

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

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

[Main idea] this provision specifies GACC's evaluation /review process in detail.

[Interpretation] For years, the evaluation/review work has been carried out by the review team set up solely by GACC. With the development of technology and the diversification of management methods and the revision of the relevant legislation, this Regulation has set out new methods for carrying out the evaluation/review. Detailed measures for implementation will be formulated based on the amendments of the superior laws and be announced separately by GACC.

In order to ensure the impartiality of the review, this Article also clarifies that a review team shall be composed of at least two reviewers, and overseas manufacturers of imported foods and the competent authorities of the country/ region shall be held liable for assisting GACC in carrying out the evaluation/review.

GACC shall carry out the evaluation/review in different forms for different categories of foreign manufacturers in different countries, and the forms of evaluation/review include the following:

1. Document review: GACC shall set up a review team, and based on the submitted materials, evaluate the applicant enterprise and the competent authority of the country/region where the enterprise located. GACC may request additional information or materials from the applicant enterprise or from the competent authority of the country/region

2. Video inspection: GACC shall set up a review team and carry out the evaluation of the sanitation and hygiene management system and sanitary conditions of the enterprise's establishments in the form of internet video connection. Overseas manufacturers of imported foods and the competent authorities of the country/region shall assist GACC in carrying out the aforementioned the evaluation/review, and in case there is any problems or incompliance issues discovered, GACC may request the applicant or the competent authority of the country/region to rectify and take corrective actions and submit corrective report accordingly.
3. On-site inspection: GACC shall set up a review team to go abroad for an on-site inspection of overseas manufacturer of imported foods, including sanitation and hygiene management system and sanitary conditions of the enterprise's establishments. Overseas manufacturers of imported foods and the competent authorities of the country/region shall assist GACC in carrying out the aforementioned the evaluation/review, and in case there is any problems or incompliance issues discovered, GACC may request the applicant or the competent authority of the country/region to rectify and take corrective actions and submit corrective report accordingly.

The content and criteria for the evaluation/review shall be formulated based on the guidelines set out by the World Organization for Animal Health (OIE), the International Plant Protection Convention (IPPC) and the Codex Alimentarius Commission (CAC), which are known as the 'Three Sisters Organization' of the World Trade Organization (WTO), and according to the inspection and quarantine requirements agreed upon between GACC and the competent authority of the country/region where the enterprise is located, as well as the relevant laws and regulations and national standards for foods of China.

For detailed matters regarding the evaluation/inspection/review, GACC shall contact the applicant enterprise and the competent authority of the country/region where the enterprise is located in advance in accordance with international practice and results of GACC's risk analysis.

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

[Main idea] this provision specifies the notification of application results.

[Interpretation] GACC shall, based on the information learned in the evaluation/review process, make decision on whether or not to register the applicant enterprise.

Under the original Regulations (GACC Decree No.243), overseas manufacturers of imported foods may use 'the registration number approved by the competent authority of the country/region where enterprise is located' when registering with GACC,

Nevertheless, Considering that different countries implement different food safety management systems and different number rules, overlapping registration numbers often occur, which have caused confusion. This time, the **new Regulations establish the new uniform numbering rules and all the registrants shall be granted a new registration number in China.**

Taken into consideration that, based on GACC's risk analysis, manufacturers in different countries are classified to different categories and subject to different application methods, some submit application through the competent authority of the country/region, while others submit applications by themselves, GACC will notify in writing the applicant through the original application path (either the applicant, the agents, or the competent authority of the country where the enterprise is located) about the application result.

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

[Main idea] this provision set out the requirements for labeling the registration number.
[Interpretation] In order to provide consumers with adequate and transparent information, to clearly and accurately communicate registration information to the end consumers, and to improve consumers' confidence, a registered manufacturer shall mark its 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.

This Article clarifies that a registered overseas manufacturer can choose at its own discretion to label either its Chinese registration number or the registration number/business license number approved by the competent authority of the country/region where the enterprise is located, in order to provide enterprise with the freedom of choice and convenience. In the long run, we encourage the registrants to use its Chinese registration number.

'**The inner and outer packaging of the foods**' refers to both the shipping packaging and the packaging of a selling unit that contains independent prepackaged foods can be sold independently. The registration number should be accurately and clearly labelled on the shipping packaging of the product, and for a selling unit that contains independent prepackaged foods can be sold independently, the registration number should be marked on the food label, which should also comply with the relevant requirements set out by the National Food Safety Standard General Rules for the Labeling of Prepackaged Foods GB7718.

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

The GACC shall determine the starting and the ending dates of the validity period of

registration when it registers an overseas manufacturer of imported foods.

[Main idea] this provision specifies the term of validity of the registration.

[Interpretation] According to Article 15 of <the Regulations for the Implementation of the Food Safety Law of the People's Republic of China>, the term of validity of a food production or marketing license is five years. And in accordance with the WTO's principle of national treatment, the term of validity for the registration of an overseas manufacturer of imported foods is five years, which is consistent with the term of validity of a production/marketing license of a food manufacturer in China. In addition, GACC will clarify the dates of commencement and termination of a registration when GACC registers the enterprise.

For overseas manufacturers that have already registered with GACC prior to the implementation of this Regulation, their registration are still valid, and the registrants can apply to GACC for a renewal within three to six months before their registration expires, and Article 20 of this Regulation sets out the details for renewing the registration. For enterprises that fail to apply for renewal of registration, its registration will be cancelled at the date of termination.

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

[Main idea] this provision specifies that the list of registered manufacturers will be published in consolidated announcements.

[Interpretation] it has been clarified that GACC will publish on its official website the list of the registered manufacturers (name of the main body) periodically in consolidated announcements.

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

[Main idea] This provision specifies the details for GACC's re-evaluation of the registrants.

[Interpretation] In order to strengthen the operational and post-operational oversight, supervise and ensure the continued compliance of the registered overseas manufactures of imported foods, GACC shall carry out risk analysis based on a series of factors including historical records and date, consumer groups, edible method, and incorporating the notifications from the competent authority of the country/region where certain manufacturers is located, and the risk consensus information collected, and if necessary, shall set up a review team to re-evaluate the registered overseas manufactures of imported foods.

The re-evaluation work will be carrying out by a review team set up by GACC, who will communicate ahead of time with the competent authority of the country/region where certain manufacturers is located. Specific requirements for reevaluation will be formulated and announced by GACC separately.

In order to ensure the impartiality of the re-evaluation work, a review team is composed of at least two reviewers.

GACC shall, based on its work needs and risk analysis, classify the overseas manufacturers in different countries to different categories, and carry out the re-evaluation/review in different forms (or in combined forms) in conformity with the review methods, whichever applicable, as set out in Article 13 of this Regulation. And overseas manufacturers of imported foods and the competent authorities of the country/ region shall be held liable for assisting GACC in carrying out the re-evaluation/review.

If problems and incompliance issues are discovered during the re-evaluation process, GACC shall take corresponding measures in accordance with the provisions as set out in Article 21, 23 and 24 of this Regulation.

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

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

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

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

[Main idea] this provision set out the requirements for change of registration.

[Interpretation] If an overseas manufacturer's registration information changes while the registration is valid, it shall submit an application for change of registration to GACC. In order to ensure the accuracy and standardization of the change of registration information, registrants who apply for change of registration should comply with the following requirements:

1. Lodging the application for change of registration through the same path as the original application, that is, if the original application for registration was submitted through the competent authority of the country/region, the application for change of registration should also be submitted through competent authority of the country/region to GACC, otherwise, if the original application for registration was submitted by the applicant enterprise itself or by an entrusted agent, the application for change of registration should be submitted to GACC via the same path.
2. The application package should also include (1) a Comparison Table exhibiting the information to be changed and the original information, which Indicates which items are to be changed; as well as (2) the supporting evidences and proof materials related to the change, which indicate the authenticity and necessity of this change. For

example, if an overseas manufacturer of imported foods changes its enterprise name, apply to GACC for change of registration, the application package shall include a comparison table exhibiting the original name and the new name of the enterprise, and as a proof the package should also attach the document of approval issued by the competent authority of the country/region where enterprise is located.

3. Upon receiving the application, GACC shall assess the changed information in accordance with the requirement of Article 14 of this Regulation. If GACC considers that the changes doesn't affect the food safety and sanitation and hygiene management and control system, (for example, the enterprise's name change), GACC shall approve the change of registration. Otherwise, if GACC considers that the changes affects the food safety and sanitation and hygiene management and control system of the enterprise (for example, renovation and expansion of the enterprise's establishments, plant and equipment renewal, or update of the enterprise's food safety and sanitation and hygiene management and control system), the enterprise will be requested to lodge a new application for registration through the applicable path (either through recommendation or file an application by itself/agent), and the application shall be processed as a new application. GACC shall assign a new registration number for this enterprise when the new application for registration is approved, and the original registration number automatically becomes void.
4. In case the enterprise relocates its production site, changes its legal person, or there is alteration of the enterprise's registration number/business license number assigned to it in its own country/region, the enterprise should lodge a new application for registration to GACC through the applicable path (either through recommendation or file an application by itself/agent), instead of lodging an application for change of registration information. GACC shall assign a new registration number for this enterprise when the new application for registration is approved, and the original registration number automatically becomes void.

The aforementioned relocation of the enterprise's production site refers to the emprise's production site which produces the goods to be exported to China physically relocates to a new address. Instead the change of the address of the enterprise's registered or principal office will not be regarded as relocation of enterprise's production site.

Change of the enterprise's legal person refers to the actual owner of an enterprise changes. In case the actual owner of the enterprise remain unchanged, but the principal personnel performing the management of the production site of the enterprise on behalf of the actual owner of the enterprise changes, the registered enterprise may apply for change of registration information first, GACC shall assess that to what extend this change shall affect the actual food safety and sanitation and hygiene management and control system of the enterprise, and make a decision about whether or not to approve the change of registration. If GACC believes that this change of principal personnel will change based on the assessment actual food safety and sanitation and hygiene management and control system of the enterprise, the enterprise will be requested to lodge a new application for registration through the applicable path (either through

recommendation or file an application by itself/agent), GACC shall assign a new registration number for this enterprise when the new application for registration is approved, and the original registration number automatically becomes void.

Where GACC discovers that the enterprise has made changes in registration which have not been declared in time, and which may affect the actual food safety and sanitation and hygiene management and control system of the enterprise, (for example, major adjustments to the food safety and sanitation and hygiene management and control system of the enterprise, or renovation or expansion of the enterprise's production site.) GACC shall take corresponding measures according to requirements as set out in Article 23 and 24 of this Regulation.

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

Application materials for registration renewal shall include:

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

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

[Main idea] this provision specifies the requirements for renewal of registration.

[Interpretation] this Article is a modification and amendment to the original provision set out in the original Regulation (GACC Decree No. 243), which revised the time limit for registration renewal from previously 'within 1 year before expiration' to 'within three to six months before expiration'. For example, if an enterprise's registration expires on 31st December 2022, the enterprise should apply for renewal of registration to GACC within the period from 1st July 2022 to 30th September 2022. The intention of this revision is to ensure that GACC has reasonable time to complete the assessment, and to avoid the situation where the evaluation cannot be completed by the expiration date of the registration, and ensure that registered enterprises that meet the relevant requirements can continue to do business in China.

For enterprises **applying for renewal of registration**, of which the relevant **registration information has not been changed**, it should lodge its application through the same path as the original application (either through recommendation registration submitted through the competent authority of the country where the enterprise is located, or file an application by the enterprise itself/agent).

For enterprises **applying for renewal of registration**, of which the relevant **registration information has changed**, it should first apply for change of registration information to GACC in accordance with the requirements of Article 19 of this Regulation, after the changes in registration are approved by GACC, the enterprise shall lodge the application for registration renewal. Alternatively, the enterprise can lodge a new application for registration, GACC shall assign a new registration number for this enterprise when the

new application for registration is approved, and the original registration number automatically becomes void.

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

1. The manufacturer fails to apply for registration renewal following relevant provisions;
 2. The competent authority or the overseas manufacturer applies to revoke the registration;
 3. The manufacturer no longer conforms with provisions in Article 5.2 of these Regulations.
- [Main idea] this provision specifies the circumstance that leads to cancellation of registration.

[Interpretation] this Article is formulated according to the relevant provisions of <the Food Safety Law of the People's Republic of China>, and has clarified the following three circumstances under which GACC shall revoke the registration of an overseas manufacturer of imported foods: (1) the manufacturer fails to apply for registration renewal as required; (2) the competent authority or the overseas manufacturer applies to revoke the registration; (3) the manufacturer no longer conforms to provisions set out in Article 5.2 of this Regulation, that is, the competent authority of the country/region no longer approves the establishment of the manufacturer, who is no longer under effective regulation by the competent authority.

After the date of cancellation of registration, GACC will no longer accept the declaration for the exported goods by this manufacturer. If the manufacturer needs to export food to China, it shall re-apply for a registration to GACC.

Where the manufacturer fails to apply for registration renewal on time, its registration will be automatically revoked by the date of expiration. For example, if an enterprise's registration expires at midnight 31st December 2022, and it fails to lodge an application for registration renewal to GACC within the period from 1st July 2022 to 30th September 2022 (within three to six months before expiration). Thus, regardless of whether this enterprise is included in GACC's consolidated announcement of October 2022, the enterprise's qualification and registration will automatically expire on 31st December 2022.

For manufacturer no longer conforms to the requirements set out in Article 5.2 of this Regulation, its qualification and registration will automatically expire at the time when GACC decides to revoke its registration. For example, if an enterprise's registration expires on 31st December 2022, and the enterprise applies to revoke the registration on 1st March 2022. Thus, regardless of whether this enterprise is included in GACC's consolidated announcement of 5th March 2022, the enterprise's qualification and registration will automatically expire on 1st March 2022.

Article 22 The competent authorities of the countries /regions shall have effective

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

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

[Main idea] this provision specifies the circumstance when the competent authority of the country/region discovers noncompliance problems.

[Interpretation] this Article is a modified and refined provision of Article 14, that is, in case the competent authority discovers any noncompliance circumstance incurred by a registered manufacturer, **the competent authority of the country/region shall take voluntary measures including suspending the manufacturer's export to China** and request the manufacture to rectify until it conforms to the registration requirements.

In this revision, this Regulation clarifies the responsibility of the competent authority of the country/region where the manufacturer is located, requiring the competent authority to continuously supervise the registered manufactures, in order that the registrants continuously conform with the relevant registration requirements. At the same time, this provision also clarifies **the principal responsibility of the registered manufacturers with regard to food safety**, who are liable to take voluntary measures in case of noncompliance circumstance, such as suspending its food export to China, and immediately carrying out rectification, until the manufacturers conform to registration requirements.

Although GACC does require the competent authorities of the foreign countries/regions to inform GACC about their daily supervision work, for the competent authorities who discover and rectify the noncompliance problems voluntarily, the qualifications of the registered manufacturers recommended by them shall not be affected.

Article 23:

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

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

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

with the registration requirements.

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

[Main idea] this provision specifies the circumstance when GACC finds a registered manufacturer no longer conforms to the registration requirements.

[Interpretation] this Article is a modified and refined provision of Article 14, and clarifies that the competent authority, as a referee of the recommended manufacturer, should be held liable as the supervision body of the registered manufactures.

When discovering that a registered manufacturer no longer qualifies for any of the registration criteria as set out in Article 5 of this Regulation, GACC shall request the manufacture to carry out rectification, identify problems that need to be rectified, inform GACC the date of completion of the rectification, provide GACC with acceptance documents upon completion of the rectification. And during the rectification, the manufacturer involved shall suspend its export to China.

After the manufacture completes the rectification, it shall submit a Rectification Report in writing together with a written Declaration of Conformity confirming the manufacturer's conformity to GACC's registration criteria through the same application path as the original application (either through the competent authority or by itself/agent).

After receiving the Rectification Report and the Declaration of Conformity, GACC shall set up a review team and carry out the evaluation in accordance with the requirements set out in Article 13 of this Regulation. GACC shall inform the competent authority of the country/region where the manufacturer is located the result of evaluation/review. For manufacturers that pass the evaluation/review, GACC will restore their export qualification and registration to China.

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

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

[Main idea] this provision specifies the circumstances under which GACC shall revoke the registration and make a public announcement.

[Interpretation] Revoking the registration and qualification of a manufacturer that fails to continuously conform to the registration criteria is the most important means of GACC's supervision and control on the operational and post-operational oversight. This Article has modified and refined the requirements of Article 15 of the prior Regulation, and added an additional circumstance, under which the registration should also be revoked.

If GACC finds out a registered manufacturer falls under any of the 7 circumstances, GACC shall revoke its registration and issue a public announcement thereof:

- (1). Severe food safety incidents of imported foods caused by the manufacturer.

According to Article 150 of <the Food Safety Law of the People's Republic of China>, 'Food safety accident' means an accident which stems from food and is or may be hazardous to the human body, such as food-borne disease or food contamination.'

From production and processing to entering the Chinese market, imported food needs to go through many links of the global value chains, including procurement of raw and auxiliary materials, production and processing, storage in the place of origin, international transportation, destination storage, and marketing and sales, as well as a long international food production and trade chains. In this process, there are food safety risks in any of these links. If the manufacturer causes a major food safety incident either due to non-conforming handling of the raw materials, or due to improper risk prevention and control measures in the production and processing link, or due to improper storage conditions (temperature or humidity) or other reasons, GACC shall revoke its registration accordingly.

- (2). Food safety problems detected in foods exported to China in the entry inspection and quarantine, and the circumstance is serious.

GACC, in accordance with <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, carrying out inspection and quarantine of the imported foods before they enter the Chinese market. Based on GACC's previous experience, two major categories of problematic foods can be found during inspection and quarantine:

- (i) Unqualified food safety and sanitation items: including the determination of non-edible additives, restricted or prohibited substances, biochemical contaminant, the food additives exceeding the standard, microbiological contaminant, pollutant pollution, genetically modified ingredients, pesticide and veterinary drug residues exceeding the standard, and irradiated food;
- (ii) Other unqualified items: defective packing, non-compliant labeling,

substandard quality, disqualified certificate, pest and harmful organisms, and other disqualified items.

GACC shall evaluate the food safety problem according to its cause, harm and the impact on the society. For serious cases, GACC shall cancel the registration of manufacturers of the relevant imported foods.

- (3). Significant problems exist in the manufacturer's food safety and sanitation management.

If GACC learns through re-evaluation, notification issued by the competent authority of the country/region where the manufacture is located, its judgement analysis of consensus information, complaint reports and petition letters that there are major problems in the food safety and sanitation management of manufacturer, which causes non-conformity of the manufacturer, and if, after confirming with the competent authority of the country/region, the such risk still cannot be eliminated by technical means within 3 months, GACC shall revoke the registration of the relevant manufacture.

- (4). Unqualified rectification

After the manufacturer submits the rectification report, if the GACC considers after assessment that the manufacturer fails to complete the rectification according to the established rectification requirements or rectification has not completed after the deadline, or the rectification result fails to meet the acceptance standard, the Customs shall revoke the manufacturer's registration.

- (5). False materials or conceals relevant facts in the application

If GACC finds in the process of re-evaluation that the manufacturer forges or conceals relevant materials and data in the process of applying for registration, or under effective regulation by the relevant authorities, GACC shall cancel manufacturer's registration.

- (6). Refusing to cooperate with the GACC in reviews and incident investigations

When GACC conducts a re-evaluation or investigates a food safety incident, in case the relevant overseas manufacturer refuse to communicate with GACC or reject the inspection request of GACC for more than 3 months, or refuse to provide relevant materials, refuse to provide materials that should be owned but falsely claiming to be unable to provide, or refuse GACC's re-evaluation for unreasonable reasons, are all considered cases of refusal to cooperate, if GACC has evidence to proof that certain manufacturer does refuse to cooperate, GACC shall cancel the manufacturer's registration accordingly.

- (7). Illegal use of the registration number.

Leasing or renting the registration number refers to a registered manufacturer provides its registration number to an enterprise that is not registered with GACC for

use by leasing, trading, investment and in other forms, so that the enterprise can illegally obtain the opportunity to export food to China.

Reselling the registered number refers to the relevant enterprise or individual uses the registered number of another enterprise without its authorization and without the confirmation of the GACC. The enterprise whose registration number has been falsely used may explain the situation to GACC through the competent authority of the country/region where the enterprise is located and provide relevant evidence, proofing that its registration number has been falsely used. After an evaluation and confirmation, GACC may either maintain the enterprise's registration number or grant a new registration number to the enterprise.

After the date of cancellation of registration, GACC will no longer accept the declaration for the exported goods by this manufacturer. Goods that have been declared but not yet cleared by the customs office will be returned or destroyed.

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

[Main idea] this provision specifies that under the circumstance of disease/epidemics/public health event in certain countries/regions, GACC shall suspend the acceptance of application submitted from the countries/regions concerned.

[Interpretation] this Article is the modification of Article 18 of the prior Regulation. According to Article 95 of <the Food Safety Law of the People's Republic of China>, 'Where a food safety incident occurring abroad may have an impact in China, or a serious food safety problem is discovered in any imported food, food additive, or food-related product, the entry-exit inspection and quarantine department of the state shall, in a timely manner, take risk warning or control measures, and notify the food and drug, health, and agricultural administrative departments of the State Council'. And according to Article 52 of <the Regulations for the Implementation of the Food Safety Law of the People's Republic of China>, 'Food safety incident occurring outside China may have an impact on China, or in case serious food safety problems are found in imported food additives and food-related products, the national Entry-Exit Inspection and Quarantine Bureau shall promptly issue an early warning of risk and may take the following control measures against the related foods, food additives and food-related products: (1) return or destroy the relevant goods; (2) conditionally restrict the import of the relevant goods; (3) suspend or prohibit the import of the relevant goods'. In addition, as it is referred in Article 5 of <the Law of People's Republic of China on the Entry and Exit Animal and Plant Quarantine>, 'the State shall prohibit the entry of relevant animals and plants and their products and other quarantine objects from countries /regions where such animal or plant epidemic diseases are prevalent'.

When international organizations or the competent authority of the country/region that export foods to China issue a notification of epidemic disease, or GACC discovers epidemic diseases during the inspection and quarantine of relevant food, or there are serious problems such as public health incidents, these circumstances indicate that the food safety and sanitation management system in the countries/ regions where these food exports come from has serious defects or risks of being out of control. GACC shall promptly suspend the import of relevant food and took emergency preventive measures in accordance with the law.

During the suspension of the food imports, the Customs shall further investigate and assess the follow-up development of the epidemic outbreaks, collect the relevant information and conduct a risk assessment. If there is enough evidence of a change in food safety risks in the country/region based on the risk assessment, GACC may accordingly adjust the registration methods and the required application materials for food production enterprises of the country/region concerned. Therefore, during the suspension of food imports from this country/region, and before completing the risk evaluation, GACC shall no longer accept applications for registration from food manufacturers in that country/region.

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

[Main idea] this provision clarifies the definition of 'the competent authority of the country/region where the manufacture is located'

[Interpretation] this Article is a modification of Article 21 of the prior Regulation, and has deleted the terms of 'officially authorized institution and industry association' from the prior definition, and further clarifies that 'the competent authority of the country/region where the manufacture is located' should be government agencies in charge of safety and sanitation regulation of food manufacturers in the country/region, who plays an important role in administering the food manufacturers.

However, the competent authorities in charge of food production enterprises vary from country to country, and in some countries different types of food are managed by different agencies, for example, the Ministry of Health, Labor and Welfare of Japan, the Ministry of Agriculture, Forestry and Fisheries of Japan, the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), the Food Safety Inspection Service (FSIS), the Bureau of Alcohol, Tobacco, Alcohol, Firearms and Explosives (ATF), and in some countries different links of the production chains for the same product are managed by different authorities.

In the actual implementation of this Regulation, if the responsibilities of the competent authority are assigned to different official institutions, the corresponding official bodies shall communicate with GACC respectively in accordance with their respective

responsibilities. Or one of the official institutions of the country/region shall assume the responsibilities of organizing and coordinating official recommendations, and be responsible for communicating with GACC, assisting in evaluation and review, and supervising the conformity issues of the registered manufacturers, etc.

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

[Main idea] This provision clarifies that GACC is responsible for further interpretation of this Regulation.

[Interpretation] This Article is the modification of Article 22 of the prior Regulation. According to Article 33 of <the Regulations of the State Council on Procedures for the Formulation of Rules>, 'The rules shall be interpreted by the formulating organ', GACC is the formulation organ of this Regulation, so GACC holds the right to interpret provisions of this Regulation, where the provisions of this Regulation shall have a more definite content, or new situations following the formulation of this rules demand the specification of applicable legislative basis. The interpretation of rules shall have the same legal effect as the rules themselves.

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

[Main idea] This provision specifies the implementation date of this Regulation.

[Interpretation] <Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food> (this Regulation) shall **enter into force on 1st January 2022**, the main bodies set out by this Regulation, including GACC and the competent authorities of the country/region where the manufactures are located, shall according to the provisions of this Regulation, exercise their respective powers and responsibilities within their respective authority.

This provision also clarifies that The prior <Administrative Measures for Registration of Overseas Manufacturers of Imported Foods>, released as Decree No. 145 of the former General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) on 22nd March 2012, and later revised by GACC Decree No. 243 on 23rd November 2018, shall be repealed at the same time.

This Regulation was issued on 12th April 2021, and shall enter into force on 1st January 2022. This Regulation has granted a transitional period in conformity with the WTO rules. The transitional period between the promulgation and implementation of this Regulation is more than 8 months, and in consideration of the major changes made in this revision, especially the scope of products that are subject to registration has expanded from the prior 4 categories (imported meat products, imported aquatic products, imported dairy products, and imported bird's nest products) to all categories of food products, and all parties concerned shall use the transitional period to make preparations for the

implementation of this Regulation.