#### The People's Republic of China

# Regulations on the Registration and Administration of

## **Overseas Manufacturers of Imported Food**

(Draft for Comments)

## **Chapter I General Provisions**

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

**Article 2 [Scope of Application]** These Regulations apply to the registration management of overseas manufacturers engaged in the production, processing, and storage of food exported to China (hereinafter referred to as "overseas manufacturers of imported foods").

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

**Article 3 [Administrative Body]** The General Administration of Customs is responsible for the registration and administration of overseas manufacturers of imported food.

**Article 4 [Management Objects]** Overseas manufacturers of imported food shall obtain registration from the General Administration of Customs.

#### **Chapter II Registration Conditions and Procedures**

**Article 5 [Registration Conditions]** Registration conditions for overseas production enterprises of imported food:

- (i) The enterprise is subject to the approval and effective supervision of the competent authorities in the country (region) where it is located;
- (ii) The enterprise establishes an effective management and protection system for food safety and hygiene, legally conducts food production and

- exportation in the country (region) where it is located, and ensures that food exported to China conforms to relevant Chinese laws and regulations as well as national food safety standards;
- (iii) The enterprise complies with relevant inspection and quarantine requirements agreed upon by the General Administration of Customs and the competent authorities of the country (region) where they are located.

**Article 6 [System Recognition]** If the food safety management system of the country (region) where the overseas production enterprise of imported food is located meets one of the following conditions, the competent authorities of the country (region) where they are located may obtain system recognition from the General Administration of Customs:

- (i) Accept and pass the inspection of the food safety management system of the country (region) where they are located by the General Administration of Customs:
- (ii) Sign an import and export food safety cooperation agreement with the General Administration of Customs;
- (iii) Sign an "Authorized Economic Operator" (AEO) mutual recognition agreement with the General Administration of Customs;
- (iv) Sign other cooperation agreements and joint statements with other Chinese government departments that include food safety cooperation content.

**Article 7 [List Registration]** If the food safety management system of the country (region) is recognized by the General Administration of Customs, the competent authorities of the country (region) may submit a list of food production enterprises recommended for registration in China to the General Administration of Customs, and the General Administration of Customs will register the overseas imported food production enterprises on the list and issue them registration numbers in China. The list of food production enterprises shall include the relevant information listed in Article 10 of these Regulations.

**Article 8 [Withdrawal of Recognition]** If necessary, the General Administration of Customs may select all or part of the enterprises on the list of food production enterprises recommended by the competent authorities of recognized overseas countries (regions) for registration in China, and conduct random inspections and verifications through video inspections, on-site inspections, etc. If the verification finds that the registration requirements are not met, the General Administration of Customs will not register the relevant enterprises, and may terminate the recognition of the food safety management system of the relevant overseas countries (regions) based on the risk assessment results.

Article 9 [Enterprise Application] Food production enterprises in foreign countries (regions) that have not obtained the food safety management system

recognition of the General Administration of Customs may apply for registration to the General Administration of Customs on their own or through an agent and submit the following application materials:

- (i) Enterprise registration application information;
- (ii) Documents supporting the application information, such as business licenses issued by the competent authorities of the country (region) where they are located, certification documents issued, etc.;
- (iii) Statement of the enterprise's commitment to comply with the requirements of these Regulations;
- (iv) For those included in the "Catalogue of Foods Requiring Official Recommendation Registration Letters", provide reports and recommendation letters on the review and inspection of the enterprise by the competent authorities of the country (region);

If necessary, the General Administration of Customs may require the provision of documents on the food safety, hygiene and protection system of the enterprise.

**Article 10 [Application Information]** The contents of an enterprise application for registration shall include the name of the enterprise, the country (region) where it is located, the address of the production site, the actual controller (company), contact person, contact information, the registration number approved by the competent authorities of the country (region) where it is located, the type of food to be registered, the type of production, the production capacity and other information.

**Article 11 [Recommended Catalog]** The General Administration of Customs determines and releases the "Catalog of Foods that Require Letters of Official Recommendation for Registration" based on the analysis of factors such as the source of raw materials, production and processing technology, food safety historical data, consumer groups, methods of consumption and other factors, in combination with international practices.

In the event of risk analysis or evidence showing alteration in risk of a certain kind of food, the General Administration of Customs may dynamically adjust the "Catalog".

**Article 12 [Material Requirements]** The application materials shall be submitted in Chinese or English. In the event of other agreements between the relevant country (region) and China on registration means and application materials, they shall be implemented in accordance with the agreement between the two parties.

**Article 13 [Subject Responsibilities]** Overseas manufacturers of imported food and the competent authorities of the countries (regions) where they are located shall be responsible for the authenticity, completeness and legality of the submitted materials.

**Article 14 [Inspection and Verification]** The General Administration of Customs

may organize an evaluation team on its own or entrust relevant institutions to conduct inspections and verifications on overseas manufacturers of imported food that apply for registration through the methods of review of application materials, video inspections, on-site inspections, and other forms and any combinations thereof. The evaluation team shall be composed of at least 2 assessors.

Overseas manufacturers of imported food and the competent authorities of the countries (regions) where they are located shall assist in carrying out the abovementioned inspections and verifications.

**Article 15 [Registration Decision]** The overseas manufacturers of imported food whose application materials are complete and whose verification meets the requirements shall be registered and given a registration number in China; the competent authorities of the country (region) or the overseas manufacturers of imported food shall be notified. Overseas manufacturers of imported food that do not meet the requirements shall not be registered, and the competent authorities of the country (region) or the overseas imported food manufacturers shall be notified.

**Article 16 [Registration Number]** A registered manufacturer shall mark the Chinese registration number or the registration number approved by the competent authority of the country/region on the inner and outer packaging of the foods exported to China.

**Article 17 [Registration Validity Period]** registration for overseas manufacturers of imported foods is valid for five years.

The General Administration of Customs shall determine the effective and expiration dates on the registration when approving the registration application of the overseas manufacturers of imported food.

**Article 18 [Information Publication]** The General Administration of Customs shall publish the list of the registered overseas manufacturers of imported food in an uniform manner.

## **Chapter III Registration Management**

**Article 19 [Registration Review]** The General Administration of Customs may, on its own or by entrusting relevant institutions, conduct a review on whether the overseas manufacturers of imported food continue to meet the registration requirements.

**Article 20 [Information Change]** If the registration information of an overseas manufacturer of imported food changes within the registration validity period, the manufacturer shall submit a request for change to the General Administration of Customs through the application channel of the registration with the following

materials:

- (i) A table that exhibits the changed information and the original information;
- (ii) Supporting materials related to the changed information.

The General Administration of Customs shall change the information of enterprises that meet the registration requirements.

If the relocation of the production site has a significant impact on the food safety and the enterprise's hygiene management and control, the manufacturer shall re-apply for registration.

**Article 21 [Registration Renewal]** If the overseas manufacturer of imported food needs to renew its registration, it shall submit an application for renewal to the General Administration of Customs through the application channel of the registration.

The application materials for extension of the registration include:

- (i) An application for renewal of registration;
- (ii) A commitment statement of consistent compliance with the registration requirements.

The General Administration of Customs shall extend the registration of enterprises that meet the registration requirements, and the registration validity period shall be extended by 5 years.

**Article 22 [Cancellation of Registration]**: In the event of any of the following circumstances, the General Administration of Customs shall cancel the registration of the registered overseas manufacturer of imported food and notify the enterprise or the competent authorities in the country (region) where it is located. At the same time, an announcement shall be made publicly available:

- (i) Failure to apply for renewal of registration in accordance with the regulations;
- (ii) Voluntary application for cancellation from the registered overseas manufacturer of imported food or the competent authorities in the country (region) where it is located;
- (iii) Failure to continue to meet the requirements of Subparagraph 2 of Article 5 of these Regulations.

**Article 23 [Voluntary Suspension]** The competent authorities of the country (region) where the overseas manufacturer of imported food is located shall effectively supervise the registered enterprises and urge them to continue to meet the registration requirements. If they find that they do not meet the registration requirements, they shall immediately take control measures and suspend the relevant enterprises from exporting food to China until they make rectifications and meet the registration requirements.

If an overseas manufacturer of imported food finds that it does not meet the registration requirements, it shall voluntarily suspend the export of food to China and immediately take rectification measures until it meets the registration requirements.

**Article 24 [Rectification and Reinstatement]** Where the General Administration of Customs finds that a registered overseas manufacturer of imported food no longer meets the registration requirements, it shall require it to make rectifications, and the food from the relevant enterprise exported to China shall be suspended during the rectification period.

After the rectification is completed, the enterprise shall submit a written rectification report and a written statement that it meets the registration requirements to the General Administration of Customs through the application channel of the registration.

The General Administration of Customs shall examine the rectification of the enterprise and resume the food import of the relevant enterprise if it meets the requirements.

**Article 25 [Revocation of Registration]** In the event of any of the following circumstances, the General Administration of Customs shall cancel the registration of the registered overseas manufacturer of imported food, and an announcement shall be made publicly available:

- (i) Occurrence of serious food safety incidents in connection with the imported food for reasons attributable to the overseas manufacturer;
- (ii) Serious food safety problems found in the food exported to China during the entry inspection and quarantine;
- (iii) Major food safety and hygiene management problems found in the enterprise which make the safety and hygiene of the food exported to China unguaranteed;
- (iv) Failure to meet the registration requirements after rectification;
- (v) Provision of false documents or concealment of relevant information;
- (vi) Refusal to cooperate with the General Administration of Customs in the review and accident investigation;
- (vii) Renting, borrowing, transferring, selling and reselling, or falsely using the registration number.

### **Chapter IV Supplementary Provisions**

**Article 26 [Suspension of the ban]** Where international organizations or the competent authorities in the countries (regions) exporting food to China release an epidemic announcement, or where serious problems such as epidemic and public health incidents are found in the relevant food during the entry inspection and

quarantine, the General Administration of Customs shall announce the suspension of the relevant food export from the countries (regions), and shall not accept applications for registration of the relevant food manufacturers in the countries (regions) during this period.

**Article 27 [Interpretation of the competent authority]** For the purpose of these Regulations, the competent authorities in the country (region) refer to the official departments responsible for the supervision of the safety and hygiene of the food manufacturer in the country (region) where the enterprise is located.

**Article 28 [Exemption from registration]** The overseas manufacturers of food shipped by mail, express delivery, cross-border e-commerce retail, food carried by passengers, samples, gifts, exhibits, aid, duty-free food, and food imported and exported by foreign embassies and consulates in China for public or personal use are exempted from registration.

**Article 29 [Interpretation authority]** The General Administration of Customs shall be responsible for the interpretation of these Regulations.

**Article 30 [Implementation time]** These Regulations shall come into force on X month X day, 202X. The General Administration of Customs Decree No. 248, "Regulations on the Registration and Administration of Overseas Production Enterprises of Imported Foods of the People's Republic of China" issued on April 12, 2021, shall be repealed as of the same date.