Decree of General Administration of Customs of the People's Republic of China

No. 248

The "Regulations of the People's Republic of China on Registration Administration of Overseas Production Enterprises of Imported Foods", which were deliberated and adopted at the Executive Meeting of the General Administration of Customs on March 12, 2021, are hereby promulgated and shall come into force as of January 1, 2022. The "Regulations on Registration Administration of Overseas Production Enterprises of Imported Foods" as promulgated in former General Administration of Quality Supervision, Inspection and Quarantine Decree No. 145 on March 22, 2012 and as amended in accordance with Decree No. 243 of the General Administration of Customs on November 23, 2018 shall be abolished simultaneously.

Minister Ni Yuefeng

April 12, 2021

Regulations of the People's Republic of China on Registration Administration of Overseas Production Enterprises of Imported Foods

Chapter I General Rules

Article 1 For the purpose of strengthening registration administration of overseas production enterprises of imported foods, these Regulations are hereby formulated in accordance with the provisions of laws and administrative regulations such as the "Food Safety Law of the People's Republic of China" and its implementing regulations, "Law of the People's Republic of China on Import and Export Commodities Inspection" and its implementing regulations, "Law of the People's Republic of China on the Entry and Exit Animal and Plant Quarantine" and its implementing regulations, as well as "Special Provisions of the State Council on Strengthening the Supervision and Administration of the Safety of Food and Other Products", etc.

Article 2 These Regulations shall apply to the registration administration of overseas production, processing and storage enterprises that export foods to China (hereinafter referred to collectively as "overseas production enterprises of imported foods").

The overseas production enterprises of imported foods specified in the preceding paragraph do not include the production, processing and storage enterprises of food additives and food-related products.

Article 3 The General Administration of Customs shall be uniformly responsible for the registration administration of overseas production enterprises of imported foods.

Article 4 Overseas production enterprises of imported foods shall obtain the registration from the General Administration of Customs.

Chapter II Conditions and Procedures of Registration

Article 5 Registration conditions for overseas production enterprises of imported foods are as follows:

- (I) The food safety management system of the country (region) where the enterprise is located shall be subject to the equivalence evaluation and review of the General Administration of Customs;
- (II) The enterprise shall be approved by the competent authority in the country (region) where it is located and subject to its effective supervision and administration;
- (III) The enterprise shall establish an effective food safety and health management and protection system, legally produce and export in the country (region) where it is located, and ensure that the food exported to China meets relevant Chinese laws & regulations and national food safety standards;

(IV) The enterprise shall comply with the relevant inspection and quarantine requirements agreed upon by the General Administration of Customs and the competent authority in the country (region) where it is located.

Article 6 The registration methods for overseas production enterprises of imported foods include registration recommended by the competent authority in the country (region) where they are located and application for registration by the enterprises.

The General Administration of Customs shall, based on the analysis of factors such as food raw material sources, production and processing techniques, food safety historical data, consumer groups as well as consumption methods, *etc.*, and combined with the international practices, determine the corresponding registration methods and application materials.

Where the risk analysis or evidence shows that the risk of a certain type of food has changed, the General Administration of Customs may make adjustment of the registration method and application materials for the overseas production enterprises of corresponding food.

Article 7 The registration of overseas production enterprises of following foods shall be recommended by the competent authorities in the country (region) where they are located to the General Administration of Customs: meat and meat products, casings, aquatic products, dairy products, bird's nest and bird's nest products, bee products, eggs and egg products, edibles fats and oils, stuffed pasta, edible grains, grain milling industrial products and malt, fresh and dehydrated vegetables as well as dried beans, seasonings, nuts and seeds, dried fruits, unroasted coffee beans and cocoa beans, foods for special dietary uses, health food.

Article 8 The competent authorities in the country (region) where the enterprises are located shall perform review and inspection on the enterprises they recommended for registration and, after confirming their compliance with the registration requirements, recommend registration to the General Administration of Customs and submit the following application materials:

- (I) Recommendation letter from competent authority in the country (region) where the enterprise is located;
- (II) List of enterprises and enterprise's application for registration;
- (III) Enterprise identification documents, e.g. business licenses issued by the competent authority in the country (region) where the enterprise is located;
- (IV) A statement indicating that such recommended enterprise meets the requirements of these regulations;
- (V) Review and inspection report of the competent authority in the country (region) where the enterprise is located on relevant enterprise.

When necessary, the General Administration of Customs may request the enterprise food

safety, health and protection system documents, e.g. the floor plan of enterprise's plant area, workshop, and refrigeration house, as well as process flow charts and so on.

Article 9 The overseas production enterprises of foods other than those listed in Article 7 of these regulations shall apply for registration to the General Administration of Customs on their own or under entrusted agent and submit the following application materials:

- (I) Enterprise's application for registration;
- (II) Enterprise identification documents, e.g. business licenses issued by the competent authority in the country (region) where the enterprise is located;
- (III) A statement that the enterprise promises to meet the requirements of these regulations.

Article 10 The enterprise's application for registration shall include such contents as the name of enterprise, the country (region) where it is located, the address of the production site, the legal representative, contact person, contact information, the registration number approved by the competent authority in its country (region), the type of food applying for registration, production type, production capacity, *etc*.

Article 11 Registration application materials shall be submitted in Chinese or English. Where the relevant country (region) and China have agreed otherwise on the registration method and application materials, such agreement shall prevail.

Article 12 The competent authority in the country (region) where the enterprise is located or the overseas production enterprise of imported foods shall be responsible for the authenticity, completeness and legality of the submitted materials.

Article 13 The General Administration of Customs shall, on its own or by entrusting relevant agencies, organize a review team to conduct evaluation and review to overseas production enterprises of imported food applying for registration through written inspections, video inspections, on-site inspections, *etc.*, and combinations thereof. The review team shall be composed of more than 2 evaluation reviewers.

The overseas production enterprises of imported foods and the competent authorities in the country (region) where they are located shall assist in the above evaluation and review.

Article 14 The General Administration of Customs shall, based on the evaluation and review, approve the registration, offer registration number in China and notify the overseas production enterprise of imported foods or the competent authority in the country (region) where it is located in written form for those meeting the registration requirements; for those rejected for registration, the General Administration of Customs shall notify the overseas production enterprise of imported foods or the competent authority in the country (region) where it is located in written form.

Article 15 The enterprises that have been approved for registration shall label the registration number in China or the registration number approved by the competent authority in the country (region) where they are located on the inner and outer packaging of the foods exported to China.

Article 16 The registration of overseas production enterprises of imported foods is valid for 5 years.

The General Administration of Customs shall, upon approving the registration for overseas production enterprises of imported foods, confirm the start and end dates of the validity period of such registration.

Article 17 The General Administration of Customs shall uniformly publish the list of overseas production enterprises of imported foods approved for registration.

Chapter III Registration Administration

Article 18 The General Administration of Customs shall, on its own or by entrusting relevant agencies, organize a review team to re-examine if the overseas production enterprises of imported foods continue to meet the registration requirements. The review team shall be composed of more than 2 evaluation reviewers.

Article 19 During the validity period of the registration, where the overseas production enterprise of imported foods have change in registration information, it shall submit a change application to the General Administration of Customs through the registration application channel and submit the following materials:

- (I) A comparison table of registration item change information;
- (II) Proof materials related to the change information.

The General Administration of Customs shall approve such change if it deems feasible after assessment.

In the case of a relocation of production site, a change of legal representative, or a change of registration number granted by the country (region) where the enterprise is located, re-application for registration shall be made and the registration number in China shall automatically become invalid.

Article 20 Where a renewal of registration is needed, the overseas production enterprise of imported foods shall file an application to the General Administration of Customs through the registration application channel for the renewal of registration within 3-6 months before the expiry date of the registration.

Application materials for renewal of registration shall include:

- (I) Application for renewal of registration;
- (II) A statement that enterprise promises to continue to meet the registration requirements.

The General Administration of Customs shall approve the renewal of registration for enterprises that meet the registration requirements, and the validity period shall be extended for another 5 years.

Article 21 In case that an overseas production enterprise of imported foods approved for registration has any of the following circumstances, the General Administration of Customs shall cancel the registration, notify the competent authority in the country (region) where it is located or overseas production enterprise of imported foods, and make an announcement:

- (I) Failure to apply for renewal of registration as required;
- (II) Active application for cancellation thereof by the competent authority in the country (region) where the enterprise is located or an overseas production enterprise of imported foods:
- (III) Failure to meet the requirements of Item (2) of Article 5 of these regulations.

Article 22 The competent authority in the country (region) where the overseas production enterprises of imported foods are located shall implement effective supervision of the registered enterprises, and urge the registered enterprise to continue to meet the registration requirements. Where it finds non-conformity with the registration requirements, it shall immediately take control measures and suspend the relevant enterprises from exporting food to China until the rectification meets the registration requirements.

Where an overseas production enterprise of imported foods finds, on its own, non-conformity with the registration requirements, it shall proactively suspend the export of food to China and immediately take rectification measures until the rectification meets the registration requirements.

Article 23 Where the General Administration of Customs finds that an overseas production enterprise of imported foods that has been registered no longer meets the registration requirements, it shall order it to make rectification within the prescribed time limit and suspend the import of foods from relevant enterprises during the rectification.

Where a suspension of import from enterprises recommended for registration by the competent authority in the country (region) where they are located is made, such competent authority shall supervise the relevant enterprises to complete the rectification within the prescribed time limit, and submit a written rectification report and a written statement of compliance with registration requirements to the General Administration of Customs.

Where a suspension of import from enterprises applied for registration on their own or under

entrusted agents is made, the enterprises shall complete the rectification within the prescribed time limit, and submit a written rectification report and a written statement of compliance with registration requirements to the General Administration of Customs.

The General Administration of Customs shall review the rectification of enterprises, and if the review is qualified, the food imports from relevant enterprises shall be resumed.

- **Article 24** In case that an overseas production enterprise of imported foods approved for registration has any of the following circumstances, the General Administration of Customs shall withdraw the registration, and make an announcement:
- (I) where a major food safety accident occurs in the imported foods due to reasons of the enterprise itself;
- (II) where food safety problems are discovered during entry inspection and quarantine for food exported to China, and the circumstances are serious;
- (III) where an enterprise has major problems in its food safety and health management, and cannot guarantee that the food exported to China meets the safety and health requirements;
- (IV) where an enterprise fails to meet the registration requirements after rectification;
- (V) where false materials are provided or relevant situation is concealed;
- (VI) where an enterprise refuses to cooperate with the General Administration of Customs in performing re-examination and accident investigation;
- (VII) where the registration number is lent, leased, transferred, resold or illegally used.

Chapter IV Supplementary Provisions

Article 25 Where an international organization or the competent authority of country (region) exporting food to China issues an epidemic situation notice, or where serious problems such as epidemic situation and public health events are found during entry inspection and quarantine of relevant foods, the General Administration of Customs shall announce the suspension of import of related foods from such country (region), and the refusal to accept application for registration of related food production enterprises of such country (region).

Article 26 The competent authority in the country (region) in these Regulations refers to the official department responsible for the safety and health supervision of the food production enterprise in the country (region) where overseas production enterprises of imported foods are located.

Article 27 The General Administration of Customs shall be responsible for the interpretation of these Regulations.

Article 28 These Regulations shall come into force as of January 1, 2022. The "Regulations on Registration Administration of Overseas Production Enterprises of Imported Foods" as promulgated in former General Administration of Quality Supervision, Inspection and Quarantine Decree No. 145 on March 22, 2012 and as amended in accordance with Decree No. 243 of the General Administration of Customs on November 23, 2018 shall be repealed at the same time.