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Voluntary _ Public

Date: 4/6/2012

GAIN Report Number: 20020

China - Peoples Republic of

Post: Beijing

Registration of Overseas Manufacturers of Imported Food (Final)

Report Categories:

FAIRS Subject Report

Approved By: Scott Sindelar

Prepared By:

Melinda Meador and Wu Bugang

Report Highlights:

AQSIQ, China's quarantine authority, published the Administrative Measures for Registration of Overseas Manufacturers of Imported Food effective on May 1, 2012. China notified the WTO of the draft Measures on August 19, 2011 to solicit comments from trade partners. Compared with the draft, the final regulation no longer requires that the exporting country be located within a disease-free area but requires that the exporting country provide documents and scientific evidence indicating that the risks have been eliminated or are under control. Another major change is that, in general, overseas food manufacturers will not have to provide documents such as a factory floor plan or production process, but may be required to do so on a case-by-case basis. This report contains an unofficial translation of the Measures.

General Information:

BEGIN TRANSLATION

Administrative Measures for Registration of Overseas Manufacturers of Imported Food

Chapter I General Principles

Article 1 To strengthen the supervision and management of overseas manufacturers of imported food, these Measures are formulated according to the *Food* Safety *Law of the People's Republic of China* and t implementing regulations, the *Law of the People's Republic of China on Import and Export Commodity Inspection* and its implementing regulations.

Article 2 These Measures shall apply to overseas manufacturers of food production, processing, and storage (hereinafter referred to as "overseas manufactures of imported food), that export food to China.

Article 3 The State General Administration of the People's Republic of China for Quality Supervision and Inspection and Quarantine (hereinafter referred to as "AQSIQ") centralizes the administration of the registration of overseas manufacturers of imported food. The Certification and Accreditation Administration of People's Republic of China (hereinafter referred to as "CNCA") organizes and carries out the supervision and administration of the registration of overseas manufacturers of imported foods.

Article 4 Directory of the Implementation of the Registration of Overseas Manufacturers of Imported Food (hereinafter referred to as "Directory") shall be formulated and adjusted by CNCA, and shall be issued by AQSIQ. The registration evaluation procedures and technical requirements of different product types within the Directory shall be separately formulated and promulgated by CNCA.

Article 5 The food products of an overseas manufacturer within the Directory shall not be imported before such manufacturer is registered.

Chapter II Conditions and procedures for registration

Article 6 Conditions of registration for overseas manufacturers of imported food:

- 1. The veterinary service system, plant protection system and public sanitary management system of the country (region) where the manufacturer is located, in connection with the registration, has been evaluated for qualification;
- 2. The animal and plant raw materials used in the food exported to China shall come from a non-disease area; when exporting foods with possible risks of spreading animal or plant diseases to China, the competent authorities of the country (region) where the manufacturer is located shall provide certification documents and relevant scientific evidence indicating that the risks have been eliminated or are under control.
- 3. The manufacturer shall be approved by relevant competent authorities of the country (region) where the manufacturer is located, and under the effective control and surveillance of such authorities; the sanitary conditions of the manufacturer shall meet relevant provisions of the laws and regulations, standards and codes of China.

Article 7 When an overseas manufacturer of imported food applies for registration, it shall be recommended by the competent authorities of the country (region) where the manufacturer is located or in other form as required by CNCA, where the documents in evidence meet the conditions as prescribed in Article 6 under this Provision, and shall submit the following materials, in Chinese or in English:

- 1. Laws and regulations regarding the animal and plant epidemics, veterinary sanitation, public sanitation, plant protection, pesticide and veterinary drug residues, the registration management of the manufacturers of food and the sanitary requirements of the country (region) where the manufacturer is located, and the written materials with regard to the structural establishment, staff configuration and enforcement of laws and regulations of the competent authorities of the country (region) where the manufacturer is located;
- 2. Name list of overseas manufacturers of imported food applying for registration;
- 3. The evaluation questionnaire regarding the actual situations in connection with quarantine and sanitation control of the manufacturers recommended by the competent authorities of the country (region) where the manufacturer is located;
- 4. The statement made by the competent authorities of the country (region) where the manufacturer is located that the recommended manufacturer is in compliance with the requirements as defined by the laws and regulations of China;
- 5. The application for registration of the manufacturer and, if necessary, the topographical plan of the factory area, workshop and refrigeration facilities, as well as technology flow chart.

Article 8 CNCA shall organize relevant experts or designate the institutions to review the materials submitted by the competent authorities of the country (region) where the overseas manufacturer of imported food is located or materials in other forms as stipulated, and establish a review panel to conduct on-site review according to the actual job demands, where the members of such a panel shall include more than two people.

The personnel who engage in the review must pass an examination and be qualified by CNCA.

Article 9 The review panel shall follow the review procedures and requirements of different product types in the Directory and then submit a review report to CNCA.

CNCA shall evaluate the review report according to working procedures to decide whether the applicant can be registered. If approved, the applicant shall be registered by written notice to the competent authorities of the country (region) where the overseas manufacturer of imported food is located; if the registration is not approved, a written notice, with reasons, shall be sent to the competent authorities of the country (region) where the overseas manufacturer of imported food is located.

CNCA shall regularly and uniformly publish the list of the overseas manufacturers that have been registered and submit the name list to AQSIQ.

Article 10 The registration will be valid for four years.

For renewal of registration, the overseas manufacturer of imported food shall submit its application for renewal of registration to CNCA through the competent authorities of the country (region) where the overseas manufacturer of imported food is located or in other forms as defined, one year before the period of validity of the registration expires.

If no application for renewal of registration is proposed before the time limit expires, CNCA shall cancel the registration and issue a public notice of the cancelation.

Article 11 If registration items are altered, the overseas manufacturer of imported food that has been registered shall immediately inform CNCA of such alterations through the competent authorities of the country (region) where the overseas manufacturer of imported food is located or in other forms; and CNCA shall handle it accordingly based on the specific alterations and report to AQSIQ.

Article 12 The overseas manufacturer of imported food that has been registered shall mark the registration number, according to the facts, on the package of the food that is exported into China. It is prohibited to imitate or transfer the registration number.

Chapter III Registration administration

Article 13 CNCA shall supervise and manage according to law the overseas manufacturers of imported food within the Directory and shall organize relevant experts or designate the institutions to conduct reexaminations, if necessary.

Article 14 If an overseas manufacturer of imported food that has been registered is discovered, during the re-examination, to have failed to continuously satisfy the registration requirements, CNCA shall suspend its qualification of registration and request AQSIQ to suspend the import of relevant products; at the same time, CNCA will give notice to the competent authorities of the country (region) where the overseas manufacturer of imported food is located and make an announcement.

The competent authorities of the country (region) where the overseas manufacturer of imported food is located shall monitor the manufacturer that it is required to rectify and to accomplish the rectification within the time limit as stipulated, and submit to CNCA a written rectification report and a written statement in compliance with Chinese laws and regulations. No food shall be exported to China before it is deemed qualified by CNCA.

Article 15 If an overseas manufacturer of imported food that has been registered falls under any of the following circumstances, CNCA shall cancel the registration and report to AQSIQ; at the same time, CNCA will give notice to the competent authorities of the country (region) where the overseas manufacturer of imported food is located:

Where a major food safety accident occurs in relevant imported food caused by an overseas manufacturer of imported food;

When nonconformity is detected in relevant products during entry and exit inspection and quarantine and the circumstance is serious;

Where major problems are found after investigation in the management of food safety and sanitation, without guarantee of safety and sanitation of the products;

When the manufacturer still fails to meet the requirements for registration after rectification; Intentionally providing <u>false</u> testimonial or concealing facts;

Leasing, lending, transfer, altering, or reselling the registration number.

Article 16 When the imported food enters the country, the entry and exit inspection and quarantine institutions shall inspect whether the overseas manufacturer is registered, and whether its registration number is true; if it fails to meet statutory requirements through inspection, this case shall be handled according to relevant laws and administrative regulations, such as the Law of the People's Republic of China on Import and Export Commodity.

Article 17 When an entity imports the food produced by an overseas manufacturer of imported food that is subject to the registration administration of the Sate, but fails to be registered, the entry and exit inspection and quarantine institutions shall instruct such entity to stop the import, confiscate illegal gains and impose a penalty more than 10% but less than 50% of the value of products to such entity according to Article 52 in the Regulations for the Implementation of the Law of the People's Republic of China on Import and Export Commodity

Chapter IV Supplementary Articles

Article 18 During relevant periods when an international organization or competent authorities of the country (region) whose manufacturers export food to China publish a Report of Epidemic Situation or when an epidemic situation is detected in the products during the entry and exit inspection and quarantine, or when severe problems occur, such as the public health sanitation is out of control in the country (region) where such products are produced, and AQSIQ makes an announcement to suspend the import of the food produced in such country (region), CNCA shall refuse to accept the registration of relevant manufacturers of imported food recommended by the competent authorities of such country (region).

Article 19 The competent authorities of the country (region) where the overseas manufacturer of imported food is located shall assist the review panel sent by CNCA to accomplish the on-site evaluation and the re-examination.

Article 20 The registration administration for the producing, processing and storing manufacturers of Hong Kong Special Administrative Region and Macao Special Administrative Region and Taiwan area, which export the food within the Directory, shall be treated by reference to these Measures.

Article 21 The competent authorities of such country (region) where the overseas manufacturers of imported food referred to in this Regulation shall include the official departments, officially authorized organizations and the trade organizations that are responsible for the safety and sanitation of relevant foods of the country (region) where the overseas manufacturer of imported food is located.

Article 22 AQSIQ shall be <u>responsible</u> for the interpretation of this Provision.

Article 23 These Measures shall be implemented on May 1, 2012. The previous measures on the Administration of the Registration of Foreign Manufacturers of Imported Food issued by AQSIQ on March 14, 2002 shall be invalidated as of the same date.

END TRANSLATION