

Voluntary Report – Voluntary - Public Distribution

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Report Name: Health and Special Dietary Foods and Decrees 248 and 249

Country: China - People's Republic of

Post: Shanghai ATO

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Report Highlights:

GACC recently released an interpretation of Decrees 248 and 249 as they apply to health food and foods for special dietary purposes. This report provides an unofficial translation of the interpretation. The interpretation contains definitions of health food and foods for special dietary purposes, and an outline of the facility registration process for these two classes of products.

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AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT POLICY

SENSITIVE BUT UNCLASSIFIED

GACC recently released an interpretation of Decrees 248 and 249 as they apply to health food and foods for special dietary purposes. This report provides an unofficial translation of the interpretation. A list of FAS China reports on Decrees 248 and 249 is also included after the translation. Inquires on Decree 248 can be directed to Decree248inquiry@usda.gov.

BEGIN TRANSLATION

On April 13, 2021, the General Administration of Customs of China (GACC) announced the Regulations on the Registration and Administration of Overseas Producers of Imported Food as GACC Decree 248, and the Measures of the People's Republic of China for the Administration of Import and Export Food Safety as GACC Decree 249. The two regulations have entered into force since January 1, 2022.

1. Definition of Health Food

In accordance with 'National food safety GB standards: Health Food'(GB16740-2014), health food is food which claims to have specific healthcare functions or to be a supplement of vitamins and minerals for the human body. Health food is designed for specific group of people, aiming to benefit the functioning of human body whilst not to treat or cure any disease. Health food shall not bring acute or subacute or chronic harm to human body.

In China, all the domestic manufactured and imported health food are required to obtain a registration number through applying to the registration administrative authority and mark it on the label. The logo of health food is commonly known as 'blue-hat'. After 2004, the format of a registration number for domestic health food is Guo Shi Jian Zi (four Chinese characters), followed by the letter G, 4-digit year, and finally, 4-digit serial number. The format of a registration number for imported health food is Guo Shi Jian Zi (four Chinese characters), followed by the letter J, 4-digit year, and finally, 4-digit serial number. The only difference between domestic and imported registration number is the letter G representing domestic health food, and the letter J for imported one.

2. Definitions of Food for Special Dietary Purposes

In accordance with 'GB13432-2013 National Food Safety Standard Labeling of Prepackaged Foods for Special Dietary Uses', food for special dietary uses refer to the specially processed or formulated food to meet the special physical or physiological conditions and/or to meet the special dietary needs of diseases, disorders, etc. Different with general foods in China,

The nutrients and/or other nutrient contents are significantly different with the similar general foods.

The current categories of food for special dietary uses in China are as follows:

- a) Infant formula foods: 1) Infant formula; 2) Follow-up formulas for older babies or toddlers; 3) Infant formula for special medical purposes;
- b) Infant complementary foods: 1) cereal based complementary foods for infants and young children; 2) canned complementary foods for infants and young children;
- c) Foods for special medical purposes (FSMP) (categories of FSMP for infants are exclusive);
- d) Other foods for special purposes (including complementary nutritional supplements, sports nutrition food, and other foods for special purposes conforming to China GB standards).

New Regulations of Imported Food

1) In accordance with the Regulations on the Registration and Administration of Overseas Producers of Imported Food as GACC Decree 248, manufacturers, processors, and storage facilities of the following 18 specified product groups must be recommended by the countries/regions' competent authority for registration with GACC: meat and meat products, sausage casings, aquatic products, dairy products, bird nest products, bee products, eggs and egg products, edible oils and fats, oilseeds, stuffed wheaten products, edible grains, milled grain industry products and malt, fresh and dehydrated vegetables, dried beans, condiments, nuts and seeds, dried fruits, unroasted coffee and cocoa beans, **foods for special dietary purposes, and health foods.**

Registration Conditions and Procedures:

Step 1. Application

Overseas producers of Health Food and Food for Special Dietary Purposes shall be registered with GACC by initiating their applications at the competent authorities of their countries (regions). The competent authority of the country (region) shall examine and inspect the facility to be recommended for registration; after confirming that the facilities conform with the registration requirements, (the competent authority of the country or region) recommends the producers to GACC for registration and submit the application materials.

Step 2. Submission

The application for registration, modification, renewal, and cancellation of an overseas producer shall be submitted through The China Import Food Enterprise Registration System, unless the competent authority of the relevant country/region and GACC have a separate agreement on the registration method and application materials.

Step 3. Acceptance of application

GACC Bureau of Import and Export Food Safety shall, after receiving the application materials, proceed according to the following circumstances respectively:

- (1) Accept the application materials if they conform to the requirements.

(2) Notify the competent authority of the country (region) where the producer located or the overseas producer at one time of all necessary supplements and corrections within 20 working days of receipt of application materials if the application materials are incomplete or are not prepared in the statutory form.

(3) Notify the competent authority of the country (region) where the producer located or the overseas producer not to accept the application if the registration management is not required by Regulations of the People's Republic of China on the Registration and Administration of Overseas Manufacturers of Imported Food (GACC Decree 248).

(4) Notify the competent authority of the country (region) where the producer located or the overseas producer not to accept the application once identified the applicant to provide with fraudulent application materials; a registered overseas producer will be handled according to the relevant requirements of Article 24 of GACC Decree 248 once the enterprise is identified to provide with fraudulent application materials.

Step 4. Evaluation and Review

According to risk analysis and actual work demand, GACC Bureau of Import and Export Food Safety shall set up review teams to conduct evaluations and reviews of the overseas producers applying for registration. The evaluation is conducted in forms of document review, video inspection, and/or on-site inspection.

Step 5. Verification

GACC Bureau of Import and Export Food Safety shall verify the evaluation and review the report prepared by review teams.

Step 6. Approval

GACC shall register overseas producers that meet the requirements and grant them China registration numbers; (GACC) notifies the competent authority of the country/region or the overseas producers in writing (of the registration). GACC denies registration of overseas producers that do not meet the requirements and notifies the competent authority of the country/region or the overseas producers in writing (of the denial).

In addition, a registered producer shall mark the Chinese registration number or the registration number approved by the competent authority of the country (region) on the inner and outer packaging of the foods exported to China.

2) In accordance with the Measures of the People's Republic of China for the Administration of Import and Export (GACC Decree 249), the Chinese labels of imported health food and food for special dietary purposes must be printed on the minimum sales package and not affixed using a stick-on/adhesive label after January 1, 2022.

END TRANSLATION

Previous Reports on Decree 248 and 249

FAS China has published the following reports on Decrees 248 and 249 to inform and educate U.S. food and agricultural stakeholders.

- [Decree 248 March 4 Additions to Single Window List - March 15, 2022](#)
- [Decree 248 Clearing Detained Shipments Unofficial Guidance - March 14, 2022](#)
- [Decree 248 Additions to List of Items Subject to Decree 248 - February 28, 2022](#)
- [GACC Updates Decree 248 Product List - February 5, 2022](#)
- [Verifying Decree 248 Facility Registration Information - January 17, 2022](#)
- [Decree 248 Single Window Searchable Database and Jan 1 Shipment Information - December 23, 2021](#)
- [Decree 248 Single Window Operation Manuals and Tutorial – December 22, 2021](#)
- [Decrees 248 and 249 – January 1 Implementation \[Public Notice 103\] – December 14, 2021](#)
- [Decree 248 – FDA Constituent Update – December 8, 2021](#)
- [Decree 248 Single Window User Manual and Training – November 30, 2021](#)
- [Decree 248 HS Codes Published in GACC Single Window – November 30, 2021](#)
- [Informing Industry and Supporting Trade Facilitation as China Implements Decrees 248 and 249 – November 10, 2021](#)
- [Decree 248 Information Update – November 19, 2021](#)
- [GACC Issues Interpretation of Decree 248 - November 6, 2021](#)
- [Decree 248 Foreign Facilities Self-Registration Website Launched - November 3, 2021](#)
- [Decree 248 Unofficial Self-Registration Guide for Overseas Food Facilities - November 2, 2021](#)
- [Notes from Information Sessions on GACC Decrees 248 and 249 - October 22, 2021](#)
- [GACC Issues Explanatory Letter on Decree 248 - October 8, 2021](#)
- [Interpretative Guidance on Imported Food Labeling Requirements in Decree 249 - August 13, 2021](#)
- [Decrees 248 and 249 Status Update on Facilities Registration and Food Safety Measures - May 25, 2021](#)
- [Administrative Measures on Import and Export Food Safety - Decree 249 - May 7, 2021](#)
- [Overseas Facilities Registration Regulation - Decree 248 - April 20, 2021](#)
- [China Notified the Draft Administrative Measures on Import and Export Food Safety - December 11, 2020](#)
- [China Notifies Revised Overseas Facilities Registration Regulations as TBT 1522 - December 2, 2020](#)
- [China Released Draft Administrative Measures for Registration of Overseas Producers of Imported Foods - December 6, 2019](#)

Attachments:

No Attachments.