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Report Name: New USA-Based Registration Applications Under Decree 248

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Report Highlights:

New export establishment registration applications that have been submitted in the U.S. FDA Export Listing Module (ELM) and GACC Bureau of Import Export Food Safety (BIEFS) China Import Food Enterprises Registration (CIFER) system since January 2022 are now being processed to allow U.S. exporters to register their manufacturing, processing, and storage facilities subject to Decree 248.

NOTE: The following text does not apply to U.S. exporters of meat, poultry, dairy, and seafood products. Exporters of those products should continue following procedures for exporting to China as outlined by relevant U.S. food safety regulators: FSIS and FDA.

The General Administration of Customs of the People's Republic of China (GACC) Bureau of Import Export Food Safety (BIEFS) requires establishments exporting specific categories of food products to the People's Republic of China (PRC) to register with GACC in the China Import Food Enterprises Registration (CIFER) system prior to shipping under Decree 248. As the competent authority for the categories of products not listed in the note above and subject to Decree 248, the U.S. Food and Drug Administration (FDA) operates the Export Listing Module (ELM) to review and approve requests for establishment listing.

Please see the latest USDA GAIN Report from May 2024 updating the list of products subject to Decree 248 (Decree 248 Product List Update - May 2024 | CH2024-0064.

GACC has moved some products originally under Decree 248 to management under the Department of Animal and Plant Quarantine (DAPQ) so please consult the latest list of products rather than the original Decree 248. Exporters are also encouraged to use the "Product Type Query" module in the CIFER system to search by HS Code to determine if your exported products require registration and whether they can be self-registered or need assistance from a competent authority.

In December 2021, FDA sent lists of exporting establishments from their ELM system under a "fast track" process and GACC has only allowed imports from these establishments. Since January 2022, GACC has required new registration applications to be made by establishments directly in the CIFER system. None of these new applications have been approved, while the U.S. government worked to understand GACC's procedures and implement a workable registration process for new applicants under Decree 248.

This report notifies affected industry that new export establishment registration applications that have been submitted in the ELM and CIFER systems since January 2022 are now being reviewed, processed, and transmitted. This report clarifies the application process that exporting establishments need to follow in both the FDA ELM and GACC CIFER systems in order to be registered to export their products to China. Please direct any specific question to cfsanexportcertification@fda.hhs.gov (ELM) or Decree248Inquiry@usda.gov (CIFER).

REGISTRATION GUIDANCE

FDA Export Listing Module

In order for U.S. establishments to export products subject to Decree 248, your establishment must first apply for listing for export to China with FDA in the Export Listing Module under specific product categories. Applications in the ELM system allows FDA to review and verify the regulatory history of your establishment. The ELM system is organized by product category, so please ensure that your establishment has submitted an application in the ELM system for every category of products that you wish to export. You will submit a 10-digit HS code in the ELM system for each product that your establishment intends to export to China.

The ELM and CIFER systems are not linked and do not transmit any data between each other. Therefore, exporting establishments must also submit an application for registration in the GACC CIFER System (please see section below). **Please note that FDA will NOT review and process your application in the ELM system until your establishment has submitted an application in the CIFER system. Applications in both systems must be submitted before action will be taken.**

More details and instructions for FDA's Export Listing Module can be found on FDA's website: Online Applications for Export Lists | FDA. For assistance with the FDA ELM system please contact: cfsanexportcertification@fda.hhs.gov.

GACC CIFER System

The first step to apply in the CIFER system is to create an account – please ensure that you enter the FDA Establishment Identifier (FEI) number for your establishment in the "Registration Number" field. Establishments may look up their FEI number on the FDA FEI Search Portal at: FEI Search Portal (fda.gov). Please note this is NOT your establishment's FDA Food Facility Registration number, which must be kept confidential by FDA under U.S. law. Please also ensure that FDA is indicated as the competent authority associated with your establishment. Once an account is created, the registration number associated with it cannot be changed in the CIFER system. If your establishment has previously created an account using a number different than your establishment's FEI number, it is recommended that you delete your current account and create a new one using your establishment's FDA FEI number.

The next step is for the U.S. government to authenticate your account in the CIFER system. Please send an email to Decree248Inquiry@usda.gov with the subject line "Request CIFER Authentication." This email should include your establishment name, registration number (i.e. FDA FEI number), and address. Your account will be authenticated within a few days by

checking against FDA registration records, so please ensure that your establishment name, registration number, and address match your FDA FEI records found in the FEI Search Portal.

Once you receive an email reply from USDA that your establishment's account has been authenticated, establishments should submit an application under the "Application for Registration" module within the CIFER system. This module can be accessed via the left-hand menu once logged into the CIFER website. Establishments will need to enter establishment address and contact information, product and manufacturing process information, and upload required documentation including a signed and stamped establishment declaration. All fields with a red asterisk or a "Yes" indication in the document checklist must be completed before your application can be approved. Please note your establishment will need to submit both a 10-digit, China assigned, HS code and 3-digit CIQ code for each product you intend to export. These CIQ codes can be found in the spreadsheet attachment within the USDA GAIN Report titled "Decree 248 Product List Update" (weblink below). Once complete, you will click "submit" to transmit the application to the U.S. government CIFER account where it will be reviewed and either transmitted to GACC or returned for correction by your establishment.

Once submitted to GACC, please note that the review process within GACC can take several weeks. We encourage establishment to check their CIFER accounts periodically to determine the status of their application with GACC. In the experience of the U.S. government, GACC will not respond to inquiries on application status. Once approved, your establishment will receive a GACC registration number that is different from the FEI number used to create your CIFER account. Your establishment will need this GACC registration number upon import so **it is important that your establishment does not export product without having first received a GACC registration number**.

More details and the current version of instructions for GACC's CIFER System can be found within the "Operation Manual" module of the CIFER system. For assistance with the GACC CIFER system please contact: Decree248Inquiry@usda.gov.

Warning Regarding Fake Websites

While companies may allow a third party to submit a registration for them, companies are encouraged to conduct due diligence on any party offering to assist with the registration process. Before registering, companies should verify the authenticity of the registration system they are using. Establishments can only be registered with GACC through the official CIFER establishment registration portal: https://cifer.singlewindow.cn. There is no charge for registration in this CIFER system although third parties may charge fees to do so. For additional information, please see the latest GAIN report on this matter: Guidance on Unofficial Facility Registration Websites for Food and Ag Exports | CH2024-0066

HELPFUL RESOURCES FOR U.S. EXPORTERS

Decree 248

GACC Official Website
Decree 248 Original Announcement
Decree 248 Translation
CIFER Site for Registration
CIFER Site for Verification of Registered Companies

USDA Foreign Agricultural Service GAIN Reports

Introduction to Facility Registration Under Decree 248
Decree 248 Product List Update - May 2024 | CH2024-0064
Decree 248 Changes and the June 30 Deadline
Information for Industry Regarding Decree 248 and CIFER
Notice on Fake Registration Portals - Decree 248
Decree 248 Unofficial Self-Registration Guide for Overseas Food Facilities

Food and Drug Administration

FDA Notice on Decree 248
Food Export Lists
Online Applications for Export Lists
FDA FEI Search Portal
Video on ELM Process

Attachments:

No Attachments.