

MEMORANDUM

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Date: August 24, 2017

Re: **A Primer on Dairy Exports to China**

U.S. exporters of dairy products to China are subject to importing country listing requirements for manufacturers or processors as a precondition of market access. Recently, the U.S. Food and Drug Administration (FDA) has signed a Memorandum of Understanding (MOU) with the Certification and Accreditation Administration of the People's Republic of China (CNCA), formally establishing a registration process for U.S. food manufacturers who export certain foods to China. ^{1/} FDA also issued guidance for industry on how to establish and maintain a list of U.S. milk and milk products, infant formula, and formulas for young children manufacturers or processors. ^{2/}

This memorandum summarizes the key legal requirements for exporting dairy products to China.

FDA Guidance

For background, China's State General Administration of the People's Republic of China for Quality Supervision and Inspection and Quarantine (AQSIQ) Decree 145 requires that CNCA receive certification of compliance with the relevant standards, laws, and regulations of China for the milk and milk products, infant formula, and/or formula for young children. For the U.S. food products, CNCA expects all eligible exporters to provide the FDA with information concerning the third-party certification by a firm approved by China.

Under this arrangement, FDA is also in charge of evaluating and providing CNCA with information about whether relevant U.S. establishments are in good standing with the FDA. FDA provides the following guidance regarding the criteria FDA will evaluate in determining whether to add establishments to the applicable list of establishments with interest in exporting to China:

- Expressing interest in exporting products to China

1/ "FDA Signs MOU with China to Outline Certification Process for Certain Exports," *available at*: <https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm562834.htm>.

2/ Guidance for Industry: Establishing and Maintaining a List of U.S. Milk and Milk Product, Seafood, Infant Formula, and Formula for Young Children Manufacturers/Processors with Interest in Exporting to China (June 2017), *available at*: <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm378777.htm>.

- Evaluating good regulatory standing with FDA, including substantial compliance with applicable FDA regulations
- Third-party certification

In the guidance, the agency further clarifies that “good regulatory standing” means that the establishment is not the subject of a pending judicial enforcement action (e.g., an injunction or seizure) or a pending administrative action (e.g., warning letter).

Dairy Exports to China

Establishing compliance with the FDA guidance is only part of the process before a company can export dairy products to China. Generally speaking, to sell imported milk and dairy products in China, there are three steps to be followed for a foreign company: (i) the registration in China of foreign manufacturers; (ii) the record-filing in China of exporter/exporter's agent and importer; and (iii) the imported goods inspection by Chinese authorities, if applicable. We discuss each of these requirements in more detail below:

I. The Registration of Foreign Manufacturers

Under the *Regulations on Administration of Registration of Overseas Manufacturers of Imported Foods* (the "Imported Food Regulations") issued by the AQSIQ and effective as of 1 May 2012, foreign manufacturers of certain categories of food products, before importing the food products into China, must register themselves with the CNCA.

In the *Implementing Catalogue of Imported Food Manufacturers that are Subject to Registration*, as amended and updated by the CNCA from time to time, the manufacturers of colostrum, lactogenesis and dairy products are subject to such registration process. More specifically, colostrum, lactogenesis and dairy products include pasteurized milk, fermented dairy products, milk powders, milk cream, concentrated milk, cheese, whey powder, milk-based infant and young children formula foods, as well as other milk and dairy products.

a. Threshold Requirements for Registration

- All following items should be determined qualified upon evaluation by the CNCA: veterinary service systems, plant protection systems, public health administration systems and other registration-related systems of countries (regions) where the manufacturers are located ;
- Animal and plant materials of food products exported to PRC should not originate from areas where epidemics are present; for food exported to PRC that has the potential risk of spreading animal and plant diseases capable of reaching an epidemic scale, competent authorities of countries (regions) where such manufacturers are located (the "Home Country Authority") must provide supporting documents and relevant scientific materials that prove the risk has been eliminated or is controllable; and
- Such manufacturers must be approved and subject to effective supervision by the Home Country Authority, and their sanitary conditions must conform to relevant provisions of PRC legislation and standards.

b. Registration Process of the Manufacturers

A complete manufacturer registration process includes the following steps:

File application to the Home Country Authority for verification and recommendation.

The CNCA is a supervising authority in China to handle manufacturer registration applications. However, it does not accept any application submitted directly to it by foreign manufacturers, instead, the CNCA only accepts applications based on official recommendations. That is, the applications can only be submitted by the Home Country Authority for the manufacturers. Therefore, we expect that manufacturers in different countries (regions) may be subject to a first round review and examination in their home jurisdictions, which may vary from other jurisdictions.

Manufacturers who are interested in selling milk and dairy products in China should first consult with their Home Country Authority for detailed inspection and review procedures.

The Home Country Authority submits application to the CNCA

After manufacturers have passed a domestic review or examination process (or equivalent process), the Home Country Authority must submit the following applications for the manufacturers to the CNCA in Chinese or English:

- Relevant laws and regulations of countries (regions) where such manufacturers are located regarding animal and plant epidemics, veterinary hygiene, public health, plant protection, pesticide and veterinary drug residue, food manufacturer registration administration and hygienic requirements, and written data on organization structuring and staffing of competent authorities of countries (regions) where such manufacturers are located, and implementation of laws and regulations;
- List of overseas food manufacturers that apply for registration;
- Evaluation papers of the Home Country Authority on facts and figures detailing quarantine and sanitary control of the manufacturers recommended;
- Statements of the Home Country Authority that the manufacturers recommended conform to Chinese laws and regulations; and
- Written applications for manufacturer registration, as well as plans of plants, workshops, refrigeration storage, and process flow charts, etc. when necessary.

Technical Review by the CNCA – Document Review

Upon the acceptance of applications, the CNCA will organize expert teams to review the application materials and decide whether or not an on-site inspection would be necessary. The process generally takes 30 working days.

Technical Review by the CNCA – On-site inspection

If the CNCA experts conclude that an on-site inspection is necessary, the CNCA will organize a team consisting of two or more experts to perform on-site inspections of applicants. After the on-site inspections, the expert team will deliver draft evaluation reports to the CNCA. This process generally takes another 30 working days.

Administration review by the CNCA

After the receipt of draft evaluation reports, the CNCA will conduct necessary communications with the Home Country Authority and finalize the evaluation report.

The CNCA will, based on the finalized evaluation reports, decide whether or not to approve the registration applications and inform the Home Country Authority of their decision in writing. This process generally takes 20 working days.

A registration is valid for a term of four years. Where foreign manufacturers wish to renew the registration, renewal applications must be filed one year before the expiration of the registration.

II. The Record-Filing of Food Exporter and Importer

Under the *Administrative Regulations on the Record-filing of Exporter and Importer of Imported Foods* issued by the AQSIQ and effective as of 1 October 2012, imported food exporters/exporting agents and Chinese consignees (i.e. importers) must perform record-filings at the AQSIQ.

For foreign exporters/exporting agents of foods, they must disclose the following information to the AQSIQ: the name, address, contact information of the exporters/exporting agents, the categories of food in which they operate, and information of the person who performs the filing.

For food importers, relatively more complicated procedures must be carried out. They need to file the same information as provided in the above paragraph, and in addition, they must submit the following information to the local offices of the AQSIQ:

- Filing application form;
- Business license, copies of the identity certificate of the legal representative, foreign trading record-filing certificate;
- Copies of the quality safety management system;
- Introduction of departments and positions in charge of food safety within the company;
- Categories of foods proposed to be operated and storage site;
- Illustration of foods imported, processed and sold in the past two years (if any); and
- Copies of the inspection declaration certificate, if the importer proposes to declare the import inspection on its own.

III. Imported Goods/Foods Inspections and Quarantines

Under Chinese law, specified subsets of dairy products may be subject to extra import product inspection. These import product inspections include import goods inspection, import animal/plant product quarantine, import food products sanitary inspections. For instance, formula milk powder for infants and young children (contains 5% or less non-fat cocoa paste by weight) (HS Code: 1901109000) is subject to only import food products sanitary inspection. Non- concentrated milk and cream containing 1% or less fat (HS Code: 0401100000) is subject to both import animal/plant product quarantine and import food products sanitary inspections. Solid milk and cream containing

more than 1.5% of fat (HS Code: 0402210000) is subject to import goods inspection, import animal/plant product quarantine, and import food products sanitary inspections.

Please note that the above regulatory requirements for importing foreign goods may be subject to changes from time to time. Such changes will be reflected in the *Catalogue of Goods subject to Inspection and Quarantine* (the "Catalogue") issued and updated by the AQSIQ. It is thus advisable that foreign manufacturers should keep track of the revisions to keep fully aware of regulatory requirements of imported products.

As Chinese food safety concerns have increased in recent years, Chinese authorities such as the China Food and Drug Administration, the AQSIQ etc. have tightened their control over food products from the perspective of food products labeling, sales record-keeping, food quality complaint and consumer rights protection, etc. We are therefore happy to provide further guidance on other food related issues and food compliance strategies in China.

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We will continue to closely monitor all developments related to exporting dairy products to China. If you have any questions, or if we can be of any assistance, please do not hesitate to contact us.