

Stringent New FDA Rules to Go into Effect December 12: Failure to Comply Can Lead to Penalties and Inability to Import Food

Since 9-11, government entities and private-sector organizations and companies have been taking steps to protect the public from threatened or actual terrorist attacks on the U.S. food supply. Two new requirements by the FDA should be of immediate concern to affected parties.

Registration of Food Facilities

As of December 12, 2003, the United States Food and Drug Administration ("FDA") will require facilities that manufacture, process, pack or hold food items for human or animal consumption to register with it in order to assist in the FDA's efforts to combat bioterrorism and improve U.S. homeland security. Timely, accurate, and complete registration under this new regulation is especially critical for food facilities outside of the United States as the failure to properly register a facility can result in the food products being refused entry into the United States, and the United States is not responsible for transportation, storage, or other expenses resulting from the refusal. Below are provisions of the registration that are of particular interest to foreign facilities:

▶ What Foreign Food Facilities Must Register

As of December 12, 2003, any facility that **manufactures, processes, packs, or holds** "food" as defined by FDA statutory authority and regulations must register its facility with the FDA. **EVERY** individual facility must register, not just the entity that manages multiple facilities. Failure to properly register all appropriate facilities can have serious consequences.

The next appropriate question is what constitutes "food" for the purposes of these regulations. "Food" is defined under applicable FDA law as articles used for food or drink for man or other animals, chewing gum, and components of such articles. There are over 70 categories of "Food" that are covered by the registration regulation and related FDA regulations. Included among those categories are beverages, fruits, fish, infant formula, candy, dietary supplements, vitamins, minerals, preservatives, as well as food additives and color additives. Items exempt from registration regulation requirements include certain facilities regulated exclusively by the United States Department of Agriculture, pesticides, food contact substances, and any other items exempted by U.S. statutes or regulations.

■ Contact Info

If you would like more information, please contact any of the McKenna Long & Aldridge attorneys with whom you regularly work. You may also contact:

Larry R. Pilot
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▶ What Is Needed to Register

In order to properly register, the following information must be provided to the FDA:

- Name, address, and phone number for facility and facility's parent corporation (if applicable);
- Name, address, and phone number for owner, operator, or agent in charge of facility;
- All trade names used by the facility;
- Categories of food products handled by the facility;
- For foreign facilities, name and contact information for U.S. agent and emergency contact information if emergency contact is not also U.S. agent;
- Other information as dictated by FDA.

▶ Important Considerations for Foreign Facilities

Registration **MUST** be completed by December 12, 2003. Meeting this deadline is critical, as the failure to properly register will result in food being **REFUSED ENTRY** into the United States. In addition, foreign facilities **MUST** designate a U.S. Agent for registration purposes. The purpose of such a requirement is to allow FDA officials to contact someone in the United States in case of an emergency.

Determining whether your facility must register and completing the necessary steps (including obtaining a U.S. Agent) is critical to preventing any interruption in your food production chain. For additional information regarding the preparations now required of foreign food facilities, please contact [Larry R. Pilot](#) at (202) 496-7561 or [Brian E. Finch](#) at (202) 496-7241 in the U.S.A. or [Ursula Schliessner](#) at 32.2.278.1224 in Brussels.

Prior Notice of Imported Food Shipments

On December 12, 2003, the United States Food and Drug Administration ("FDA"), as part of its efforts to bolster U.S. homeland security, will require that advance notice be provided to it of food shipments for humans or animals being sent into the United States. Complying with this new regulation is critical, as the failure to do so will result in the imported food being refused entry into the United States, and the United States will not take responsibility for any costs associated with the refusal. Listed below are some key points associated with the new regulation that foreign companies should be aware of.

▶ What Items Require Prior Notice

Prior Notice must be given for food or drink as defined under FDA statutory authority and regulations including food or drink for man or other animals, chewing gum, and component items thereof (unless otherwise exempted by U.S. statutes or regulations). "Food" items covered by FDA statutory authority and regulations include beverages, fruits, fish, infant formula, candy, dietary supplements, vitamins, minerals, preservatives, as well as food additives and color additives. Food carried by an individual for personal use, foods produced at home and intended as a personal gift, items imported and then exported without leaving the port of arrival until export, meat, poultry, and egg products subject to the exclusive jurisdiction of the United States Department of Agriculture at the time of export, and certain other products do **NOT** require Prior Notice.

▶ When Prior Notice Must Be Given

For Shipments Arriving

By land via **road**

By land via **rail**

By **air**

By **water**

By **international mail**

Carried by or otherwise accompanying an individual

Prior Notice Must Be Submitted

No less than **2 hours** before arriving at the port of arrival

No less than **4 hours** before arriving at the port of arrival

No less than **4 hours** before arriving at the port of arrival

No less than **8 hours** before arriving at the port of arrival

Before the food is sent

Within the timeframe for the applicable mode of transportation

In every instance, FDA must receive and confirm prior notice no more than 5 days before a shipment arrives (unless arriving by international mail).

▶ How Prior Notice Must Be Given

There are several ways to give Prior Notice. A covered entity may use either the Automated Commercial System from the Customs and Border Protection Service or the FDA Prior Notice Interface System. Detailed information on food import items must be provided, including (but not limited to):

- Contact information for individual submitting and transmitting Prior Notice;
- Anticipated arrival information;
- Contact information for importer, owner, and consignee;
- Carrier and mode of transportation;
- Planned shipment of information.

Once the proper information has been received by the FDA, it will provide in return confirmation information, including a confirmation number. If certain information in the Prior Notice changes (such as mode of transportation or country of production), a **NEW** Prior Notice is required.

▶ Critical Information for Foreign Entities

Starting on December 12, 2003, all "food" items as defined by FDA will require Prior Notice. Failure to provide Prior Notice will result in shipment being refused entry, and the United States will not be responsible for transportation, storage, or other expenses resulting from the refusal. The FDA will adhere strictly to its timing guidelines for Prior Notice, and changes in information will in most cases require a new filing of a Prior Notice.

Adhering to the Prior Notice regulations is critical to preventing any interruption in your food production chain. For additional information regarding understanding the Prior Notice regulation, the implementation of a Prior Notice system or responding to FDA refusal of "Food" for entry into the U.S.A., please contact Larry R. Pilot at (202) 496-7561 or Brian E. Finch at (202) 496-7241 in the U.S.A. or Ursula Schliessner at 32.2.278.1224 in Brussels.

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