Expeditors

FDA Bioterrorism Regulations

Summary of Bioterrorism Act of 2002 and its Effect on U.S. Imports

U.S. Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act"). The purpose of the Bioterrorism Act is to allow the Food and Drug Administration (FDA) and other authorities to quickly determine the source and cause of any deliberate or accidental contamination of food. This Act allows FDA to identify these sources through information provided by registered food facilities prior to entry of food and beverages for human and animal consumption, including alcoholic beverages and chewing gum, into the U.S. Depending on the mode of transportation, parties involved with importing these products are required to submit a prior notice to FDA anywhere from 2-8 hours before arrival in the U.S. beginning December 12, 2003. Registration information will also enable the FDA to quickly notify the facilities that might be impacted by an outbreak.

There are four major components of the Act:

Section 303 focuses on administrative detention;
Section 305 on food facility registration;
Section 306 on recordkeeping;
Section 307 focuses on prior notice.

Sections 305 and 307 are expected to have the greatest impact on parties involved with importing food products into the U.S.

Section 305: Registration of Food Facilities

Key points of this section include:

The owner, operator, or agent in charge of a domestic or foreign food facility must register that facility with FDA and provide necessary information as requested.

Registration is required for domestic facilities whether or not food from the facility enters interstate commerce. Foreign facilities are also required to provide emergency contact information.

Except for specific exemptions, the registration requirements apply to all facilities that manufacture, process, pack or hold food regulated by FDA, including animal feed, dietary supplements, infant formula, beverages (including alcoholic beverages) and food additives.

Registration will not be required for private residences of individuals or by those facilities that are regulated exclusively by the U.S. Department of Agriculture. Also exempt are foreign facilities if the food is to undergo further processing or packaging by another facility before it is exported to the U.S. (except for de minimis processing), farms, restaurants, manufacturers of food contact substances and pesticides regulated by EPA, nonprofit food establishments, non-processing fishing vessels, and certain food transport vehicles.

Registrations may be submitted electronically, via the Internet, or by paper through mail or by fax. Registrations may also be submitted on CD-ROM by mail. The FDA began accepting electronic registration beginning October 16, 2003.

A registering facility will receive confirmation of electronic registration and its registration number instantaneously once all the required fields on the registration screen are completed. There is no fee associated with registration. Registration is required only once.

Registration information is not made public.

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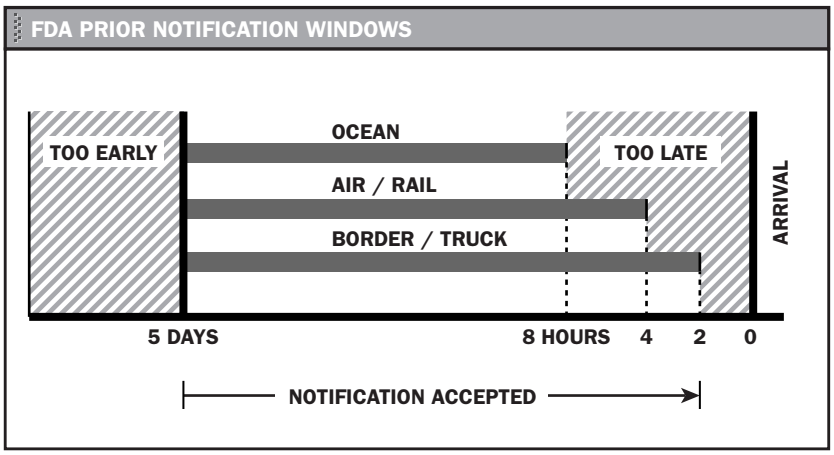
The Food Facility Registration Module is available online at: http://www.cfsan.fda.gov/~furls/ovffreg.html. Product detentions for non-compliance technically begin when the regulations take effect on December 12, 2003. However, FDA has stated that the agency will phase in enforcement over the first several months that registration is required, and that the FDA will focus on outreach and education of facility owners during that time.

Failure of a domestic or foreign facility to register, update required elements, or cancel its registration in accordance with this regulation is a prohibited act under the Federal Food, Drug, and Cosmetic Act. A facility that fails to register with FDA faces the possibility of having their goods seized by CBP and/or fines levied against them. FDA plans to issue enforcement guidance regarding the agency's policies regarding refusals of imported food.

Section 307: Prior Notice of Imported Food Shipments

Key points of this section include:

Prior notice of imported foods must be received and confirmed electronically by FDA no more than five days before arrival and no fewer than: two hours before arrival by land via road; four hours before arrival by air or by land via rail; or eight hours before arrival by water.



Exempted are products exclusively regulated by USDA, such as meat food products, poultry products, and egg products.

The advance notice to FDA may be submitted in most circumstances electronically via the following systems:

CBP's existing ABI/ACS (Automated Broker Interface/ Automated Commercial System) systems as part of the customs entry transmission.

The FDA's new Internet Prior Notice System Interface that can receive such notifications.

If the Prior Notice System is not working, then a printed version of the system's screen must be delivered in person, by fax, or by email.

After prior notice has been submitted, FDA will provide a Prior Notice (PN) Confirmation Number. The PN Confirmation Number does **not** indicate that the food article has been formally reviewed by FDA, only that the information has been successfully transmitted. Once transmitted, FDA will review the information submitted and determine whether the cargo must be examined. If the review concludes that no further action is necessary, a customs entry may be processed for that importation. NOTE: The requirement for Prior Notice is in addition to the existing admissibility screening performed on FDA-regulated products.

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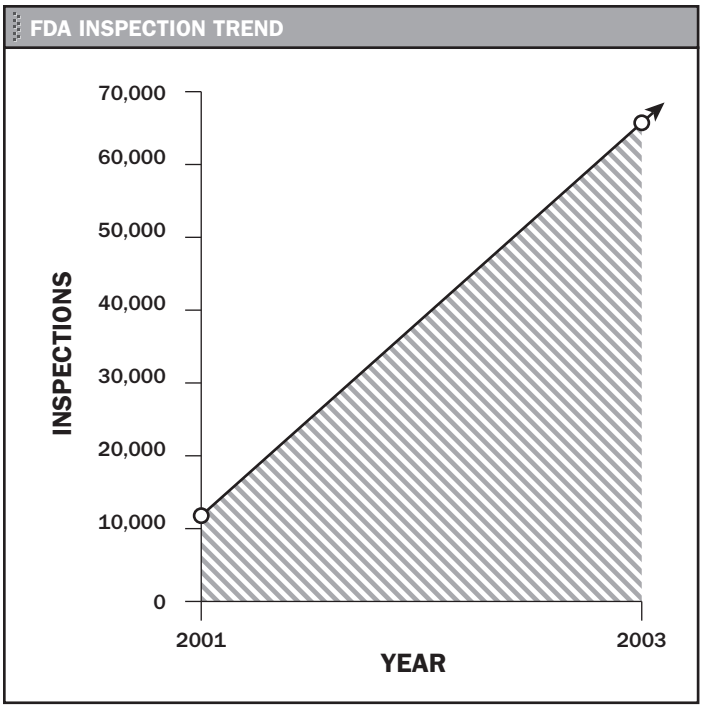
Specific information must be provided to FDA for **each** food article in an entry. Examples of such information include identification of the submitter of the prior notice, the manufacturer, country of origin, shipper, anticipated arrival time and date, arrival location, consignee, carrier, and FDA information.

Under the new Interim Rule, no amendments are allowed due to the shortened time frames for notifying FDA. If changes are required for essential information, such as manufacturer, type of food article, country of origin, etc., the original Prior Notice must be canceled and a new one submitted. Cancellation will not be required for changes to arrival information, planned shipment information or estimated quantities originally transmitted with the Prior Notice.

To date in 2003, FDA has quintupled the number of imported food examinations it conducted compared to those conducted in fiscal year 2001- 62,000 inspections so far this year compared with 12,000 in all of fiscal year 2001.



* **SOURCE:** *U.S. Food and Drug Administration*

For further information and any questions you may have, please contact your local Expeditors representative, or visit http://www.fda.gov/oc/bioterrorism/bioact.html.

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