

The FDA and Customs Revise Requirements for Prior Notice of Food Importations

On October 31, 2008, The Federal Drug Administration (FDA) and Customs and Border Protection (Customs) announced revisions to a 2003 interim rule requiring food importers to provide “prior notice” to the FDA when importing into the United States. The FDA and Customs simultaneously published a draft “Compliance Policy Guide” (CPG) to help importers interpret these updates.

The FDA and Customs enacted the rule to implement the requirements of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, as part of the FDA’s efforts to protect the nation’s food supply against terrorism and other food-related emergencies.

Definitions Revised

The rule adds a definition for “manufacturer,” defining it as the last facility that manufactured/processed the food. A facility is the “last facility” if the food does not undergo more than a *de minimis* amount of further manufacturing/processing (e.g., adding a label). It also revises many definitions in the interim rule, including “country from which the article is shipped,” “food,” “international mail,” “port of arrival,” “registration number,” and “shipper.”

The Submission Requirement

Previously, the FDA required importers to submit “prior notice” within five days of a shipment’s arrival. Now, importers may either submit “prior notice” electronically via Custom’s Automated Broker Interface (ABI) of the Automated Commercial System (ACS) (no

earlier than 30 calendar days before the shipment’s anticipated arrival) or submit it via the FDA Prior Notice System Interface (FDA PNSI) (no earlier than 15 calendar days before the anticipated arrival). If the importers cannot submit prior notice through the ABI or ACS system, they must submit it under the FDA PNSI system until the FDA and Customs determines that the ACS can accommodate these transactions.

The amount of time required for the FDA to confirm electronically that the submission is complete remains the same—no less than 8 hours for food arriving by water, 4 hours for food arriving by air or via rail, and 2 hours for food arriving via road.

The rule exempts food in diplomatic pouches from the prior notice requirement.

What the Submission Must Include

Previously, the FDA required importers to submit both the manufacturer’s name and registration number (in most circumstances). The FDA now requires the registration number and the manufacturer’s name in all circumstances. When the manufacturer’s registration number is unknown, however, it allows importers to submit the name of the manufacturer and either the registration number of the facility associated with the article of food or both the full address of the site-specific facility and reason the importer did not provide the registration. When an importer does not provide the manufacturer registration number, the FDA will accept the following reasons for the omission:

- The facility is out of business
- The facility is a private residence, a restaurant that qualifies for the restaurant exemption, a retail food establishment that qualifies for the retail food estab-

ishment exemption, a non-processing fishing vessel, or a non-bottled drinking water collection and distribution establishment

- The manufacturer satisfies the definition of “farm” in 21 C.F.R. § 1.227(b)(3), and qualifies for the farm exemption in 21 C.F.R. § 1.226(b)
- The submitter is unable to determine the registration number of the manufacturer, but the full address of the manufacturer has been provided.

It also now allows for the submission of the express consignment operator or carrier tracking number instead of the previously required anticipated arrival information,” flight number and Bill of Lading or Airway Bill number.

What Happens When Food is Refused

If, after an importer has submitted prior notice, the FDA refuses the food, the rule requires the food to be moved under appropriate custodial bond unless it is immediately exported under Customs supervision. If the food is to be held at the port or secured facility outside the port, the FDA must be informed of the location where the food is held at that port or secured facility before the food is moved there.

The Compliance Policy Guide

The updated CPG describes FDA’s enforcement discretion, stating that it generally will not require prior notice for non-commercial shipments, gift packs with a single prior notice submission, imported food arriving from or exiting to the same country, seeds for cultivation, certain U.S. Government shipments, and foreign-to-foreign mail and courier shipments to individuals.

Implementation

The rule will take effect May 6, 2009. Additionally, the agencies anticipate finalizing the CPG on that day. Customs and the FDA have invited those concerned to submit comments about the rule until May 6, 2009 and comments about the final CPG until December 8, 2008.

KELLEY DRYE & WARREN LLP

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