

FDA Revises Regulations on Prior Notice for Food Imports FDA States That Final Rule Contains Significant Changes from Interim Rule

The Food and Drug Administration has issued a final rule that makes a number of changes to its regulations on the submission of prior notice for food that is imported or offered for import into the U.S. The **final rule will be effective May 6, 2009** (180 days after Nov. 7, the date on which the rule was published in the *Federal Register*) and replaces the Interim Final Rule.

OPERATIONAL CHANGES:

- Removes the requirement that the identity of the anticipated border crossing within the port of arrival be provided in the prior notice
 - Removes the requirement to provide the 6 digit Harmonized Tariff Schedule number in the prior notice
 - **Requires the registration number** of the manufacturer (or the full address of the manufacturer and a reason) in **all** circumstances
- In the interim final rule, a registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage, and export, or further manipulation and export. FDA has removed this from the final rule
- The final rule will require the PN to include the name and full address of the shipper, if the shipper is different from the manufacturer (in order to eliminate duplicative requirements). If the address of the shipper is a registered facility, the submitter may also submit the registration number of the shipper's registered facility

The final rule requires prior notice be submitted electronically via either the Automated Broker Interface (ABI) or the FDA's Prior Notice System Interface (PNSI). As is already the case, the information must be electronically submitted and confirmed as facially complete by the FDA for review

Effective May 6, 2009 Must be submitted at least	But not earlier than	Current – through May 5, 2009
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PNSI	ABI	PNSI	ABI
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8 hours prior to food arriving by vessel	15 days	30 days	5 days prior
4 hours prior to food arriving by air or rail	15 days	30 days	5 days prior
2 hours prior to food arriving by truck	15 days	30 days	5 days prior

The following are some of the more notable changes the FDA has made to the prior notice regulations (commercial shipments)

- Adds the term manufacturer and revises definitions for the following terms: country from which the article is shipped, food, international mail, no longer in its natural state, port of arrival, registration number and shipper
- Clarifies that prior notice must be submitted via PNSI for articles of food that have been refused under section 801(m)(1) of the BTA until such time as the Automated Commercial System or its successor system can accommodate such transactions
- Adds provisions stating that for food arriving by express consignment operator or carrier when neither is the submitter or transmitter and the prior notice is submitted via PNSI, the express consignment operator or carrier tracking number may be submitted in lieu of (a) the anticipated arrival information and (b) the bill of lading or the airway bill number and flight number
- Clarifies that refused food must be moved under appropriate custodial bond unless immediately exported under U.S. Customs and Border Protection supervision
- Clarifies that refused food may be held at the port or at a secure facility outside the port and revises the time frame for notifying the FDA of the hold location from within 24 hours of refusal to before the food is moved to the hold location
- Food that is imported or offered for import without adequate prior notice is subject to refusal and, if refused, must be held
- Identity of the manufacturer, for food no longer in its natural state . The final rule will revise the PN information requirements in 21 CFR 1.281(a)(6) for an article of food that is no longer in its natural state, to require the name of the manufacturer and either: (1) the registration number, city and country of the manufacturer or (2) both the full address of the manufacturer and the reason the registration number is not provided
- Arrival date for PN submissions for refused food articles. For PN submissions for refused articles, the actual date the article arrived at the port of arrival will be a required data element (so that FDA knows how long it has been since the refused food shipment arrived in the U.S. and how to connect the refused PN to the post-refusal PN submission for shipments for which a previously refused PN was filed)

New and Revised Definitions

The final rule will **add** the following definitions:

Full address - the facility's street name and number; suite/unit number, as appropriate; city; province or state as appropriate; mail code, as appropriate; and country.

Manufacturer - the last facility, as defined in 21 cfr 1.227(b)(2), that manufactured/processed the food. A facility is considered the last facility even if the food undergoes further manufacturing/processing that consists of adding labeling or any similar activity of a de

minimis nature. If the food undergoes further manufacturing/processing that exceeds an activity of a de minimis nature, then the subsequent facility that performed the additional manufacturing/processing is considered the manufacturer.

The final rule will **revise** several definitions, including (*partial list*):

International mail – to state that the term does not include express consignment operators or carriers or other private delivery services unless such service is operating under contract as an agent or extension of a foreign mail service

Port of arrival – to add specific sentences defining the port of arrival for articles of food arriving by water, air, or land. The definition is amended by deleting the phrase “i.e., the port where the article of food first arrives in the U.S.” and adding the following: “For an article of food arriving by water or air, this is port of unloading. For an article of food arriving by land, this is the port where the article of food first crosses the border into the U.S.”

Shipper – to include express consignment operators or carriers or other private delivery service to the U.S. (to clarify that a shipper is involved with various types of transactions, and not just international mail shipments)

Revisions to the information that must be provided in a PN (non commercial shipments)

- Identity of manufacturer if such food sent as a personal gift. The final rule will revise the PN information requirements for an article of food that is no longer in its natural state to remove the current option that allows the name and address that appears on the label under 21 CFR 101.5 to be submitted instead of the name, address, and registration number of the manufacturer for food sent by an individual as a personal gift (i.e., for nonbusiness reasons) to an individual in the U.S.
 1. The FDA notes, however, that under the enforcement policy proposed in the PN final rule draft Compliance Policy Guide, FDA and CBP should typically consider not taking any regulatory action when no PN is submitted for food articles imported or offered for import for noncommercial purposes with a noncommercial shipper, irrespective of the type of carrier
- Making the provisions in 21 CFR 1.281(a)(17)(i) and (c)(17)(i) for the Airway Bill number/Bill of Lading number and flight number as applicable, since this information is generally not available to individual submitters
- Removing the requirement for the license plate number (and state or province that issued the license) for an article of food that arrived by privately owned vehicle from the required planned shipment information to the required carrier information

SINGLE WEB SITE ADDRESS FOR PNSI, OASIS OUTAGE NOTIFICATION, ETC.

The final rule will also simplify the provisions in 21 CFR 1.280(b)-(e) pertaining to PNSI or the Operational and Administration System for Import Support (OASIS) system outages by providing outage notification at one Web address (<http://www.fda.gov>) and will state that FDA will accept PN submissions in the format it deems appropriate during the system(s) outage.

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