



U.S. Department of Health and Human Services

# Food and Drug Administration

Center for Food Safety and Applied Nutrition

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## FACT SHEET ON FDA'S FOOD BIOTERRORISM REGULATION: FINAL RULE—PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS

The U.S. Food and Drug Administration (FDA) and the U.S. Customs and Border Protection (CBP) recently published the "Prior Notice of Imported Food Final Rule" and a draft compliance policy guide (CPG) that outlines the agencies' enforcement policies regarding the final rule (*73 Federal Register* 66294 (final rule) and *73 Federal Register* 66411 (CPG); November 7, 2008). The final rule amends the existing Prior Notice Interim Final Rule (PN IFR) contained in 21 CFR Part 1, Subpart I, which has been in effect since December 12, 2003. The final rule implements section 308 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (21 U.S.C. 381), which requires that FDA receive prior notice of food imported into the United States. The final rule takes effect on May 6, 2009, and revises the IFR in only a few key areas.

Prior notice can be submitted by using CBP's Automated Broker Interface of the Automated Commercial System (ABI/ACS) or FDA's Prior Notice System Interface (PNSI). Most of the prior notice information required by the final rule is data usually provided at entry by importers or brokers to CBP after the food arrives in the United States. The Bioterrorism Act requires that this information also be provided to FDA in advance of an imported food's arrival to the United States. FDA uses this information in advance of the arrival to review, evaluate, and assess the information, and determine whether to inspect the imported food.

***What food is subject to the requirement for submitting prior notice?*** Prior notice applies to food for humans and other animals that is imported or offered for import into the United States. For purposes of the final rule, "food" is defined by reference to section 201(f) of the Federal Food, Drug, and Cosmetic Act; it does not include food contact substances or pesticides. Section 201(f) defines "food" as articles used for food or drink for man or other animals, chewing gum, and articles used for components of any such articles.

Examples of "food" include:

- Dietary supplements and dietary ingredients
- Infant formula
- Beverages (including alcoholic beverages and bottled water)
- Fruits and vegetables
- Fish and seafood
- Dairy products and shell eggs
- Raw agricultural commodities for use as food or components of food
- Canned and frozen foods
- Bakery goods, snack food, and candy (including chewing gum)
- Live food animals
- Animal feeds and pet food

***What foods are excluded from the prior notice requirement?*** Foods that are excluded from the prior notice requirement are: (1) food carried by or otherwise accompanying an individual arriving in the United States for that individual's personal use (i.e., for consumption by themselves, family, or friends, and not for sale or other distribution); (2) food that is exported without leaving the port of arrival until export; (3) meat food products, poultry products and egg products that are subject to the

exclusive jurisdiction of the U.S. Department of Agriculture (USDA) at the time of importation under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act; (4) food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e., for non-business reasons) to an individual in the United States; and (5) food in diplomatic bags/pouches based on the authority in Art. 27(3) of The Vienna Convention on Diplomatic Relations (1961).

**When must prior notice be submitted?** Except in the case of food arriving by international mail, FDA must receive and confirm a prior notice: 1) no more than 30 days before a shipment's anticipated arrival, if prior notice is submitted via ABI/ACS; or 2) no more than 15 days before a shipment's anticipated arrival, if prior notice is submitted via FDA's PNSI. In addition, the minimum time frames for submitting prior notice, as specified by the mode of transportation below, are no fewer than:

- 1) 2 hours before arrival by land by road
- 2) 4 hours before arrival by air or by land by rail
- 3) 8 hours before arrival by water
- 4) The time consistent with the timeframe established for the mode of transportation for an article of food carried by or otherwise accompanying an individual if it is subject to prior notice (the food must also be accompanied by the FDA confirmation.)

In addition, prior notice must be received and confirmed electronically by FDA before food is mailed by international mail. (The parcel must be accompanied by confirmation of FDA receipt of prior notice.)

**How must the prior notice be submitted?** Prior notice must be submitted electronically using CBP's ABI/ACS or FDA's PNSI. Both the CBP and FDA systems for prior notice are available 24 hours a day, 7 days a week for information submission. **For technical and computer-related questions about submitting prior notice using PNSI, contact the FDA Industry Systems Help Desk:**

- For the United States, call 1-800-216-7331 or 301-575-0156
- From all other countries and locations, call 301-575-0156
- Send a fax to 866-573-2804 or 301-436-2804

This technical assistance will be available on business days from 7:30 AM until 11 PM U.S. Eastern Time. Requests for assistance also may be emailed by completing the form at <http://www.cfsan.fda.gov/~furls/helpf2.html>. For assistance with ABI/ACS transmission, contact your CBP client representative.

If the ABI/ACS is not working, then prior notice must be submitted using the PNSI. If PNSI is not working, FDA will post prominent notification and instructions from the System Status link that can be accessed from the Prior Notice of Imports link at <http://www.fda.gov/>. FDA will accept prior notice submissions in the format it deems appropriate during the system outage.

**Who must submit prior notice?** Any individual with knowledge of the required information may submit the prior notice, including, but not limited to, individuals, brokers, importers, and U.S. agents.

**Will FDA provide confirmation of receipt of prior notice?** Yes. FDA will issue a confirmation of prior notice to the transmitter upon successful receipt of the prior notice information.

**What information must be included in the prior notice?** The prior notice must be submitted electronically and contain the following information:

- Identification of the submitter, including name, business address, telephone number, email address, and firm name and address (if applicable)
- Identification of the transmitter (if different from the submitter), including name, business address, telephone number, email address, and firm name and address (if applicable)
- Entry type and CBP identifier
- Identification of the article of food, including:
  - a. FDA product code,
  - b. Common or usual name or market name,
  - c. Estimated quantity described from the smallest package size to the largest container, and
  - d. Lot, code number, or other identifier (if applicable)
- Identification of the manufacturer: manufacturer's name 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 (reasons listed in the Compliance Policy Guide for Prior Notice of Imported Food)
- Identification of the grower, if known
- FDA Country of Production
- Identification of the shipper: name and full address of the shipper
- Country from which the article of food is shipped or, if the food is imported by international mail, the anticipated date of mailing and country from which the food is mailed
- Anticipated arrival information (location, date, and time) or, if the food is imported by international mail, the U.S. recipient (name and address)
- Identification of the importer, owner, and ultimate consignee (except for food imported by international mail or transshipped through the United States): name and full address
- Identification of the carrier and mode of transportation, (except for food imported by international mail)
- Planned shipment information (except for food imported by international mail)

***Does the carrier need the prior notice confirmation upon arrival?*** If prior notice is submitted through PNSI, the carrier must have the prior notice confirmation number accompany the food. In other cases, it is prudent to have the confirmation. For a prior notice that is submitted through the ABI/ACS interface, the prior notice confirmation number together with a "PN received" message will be made available to the filer through the ACS/ABI interface. If prior notice is submitted through PNSI, then the transmitter will receive a confirmation online that the submission is confirmed. To make it easier for the carrier or individual at the port, the carrier should have a copy of the confirmation, which includes a prior notice confirmation number in his/her possession. For international mail packages, the Prior Notice Confirmation Number must accompany the package. For food carried by or otherwise accompanying an individual arriving in the United States, the Prior Notice Confirmation Number must accompany the food.

***Can an incomplete prior notice be corrected?*** Yes. If the transmission fails the validation, it will be rejected and the transmitter will have an opportunity to make corrections.

PNSI has help features and interactive feedback to assist the submitter and minimize spelling mistakes and omissions. See also "How to get help with Prior Notice?" at the end of this document.

Confirmation means the information has been received and is facially complete. Subsequent system and manual review by FDA staff may result in inspection of the imported food upon arrival.

***What must be done if information changes after prior notice confirmation has been received?***  
If any of the following required information changes after confirmation, then a new prior notice must be submitted:

- Identification of the submitter, including name, telephone number, email address, and firm name and address
- Identification of the transmitter (if different from the submitter), including name, telephone number, email address, and firm name and address
- Entry type and CBP identifier (if identifier is available)
- Identification of the article of food, except the estimated quantity
- Identification of the manufacturer
- Identification of the grower, if known
- FDA Country of Production
- Identification of the shipper
- Country from which the article of food is shipped
- U.S. recipient (name and address) if the food is imported by international mail
- Identification of the importer, owner, and consignee
- Identification of the carrier and mode of transportation

***Does food that has been refused for inadequate prior notice require any additional information in prior notice?*** Yes. The prior notice for food that has been refused for inadequate prior notice also must include the port of arrival, actual quantity, the location where the refused food is being held or will be held, the date it arrived or will arrive at that location, and the identification of the contact person at that location.

***What are the consequences of failing to submit adequate prior notice information of an imported food shipment?*** Food that is imported or offered for import with inadequate prior notice is subject to refusal and holding at the port or in secure storage. FDA has provided its staff with guidance containing the Agency's policies on enforcing the prior notice requirements, including policies on injunctions, prosecution, debarment, refusals, and holds. FDA's guidance documents can be found through links found at <http://www.fda.gov>.

***How to get help with Prior Notice?*** For more details and information on the specific requirements of this final rule, please refer to the final rule itself. The final rule is available through links found at <http://www.cfsan.fda.gov/>. In addition, FDA has two systems for assistance with Prior Notice:

<b>FDA Industry Systems Help Desk</b> answers technical and computer-related questions about the Prior Notice System Interface
Hours: 7:30 AM – 11 PM U.S. Eastern Time
Phone: 1-800-216-7331 or 301-575-0156
FAX: 1-866-573-2804 or 301-436-2804
Email: <a href="http://www.cfsan.fda.gov/~furls/helpf2.html">http://www.cfsan.fda.gov/~furls/helpf2.html</a> and complete the form

<b>FDA Prior Notice Center</b> answers questions about Prior Notice policies, procedures and interpretations
Hours: 24 hours per day, 7 days per week
Phone: 1-866-521-2297