



U.S. Food and Drug
Administration

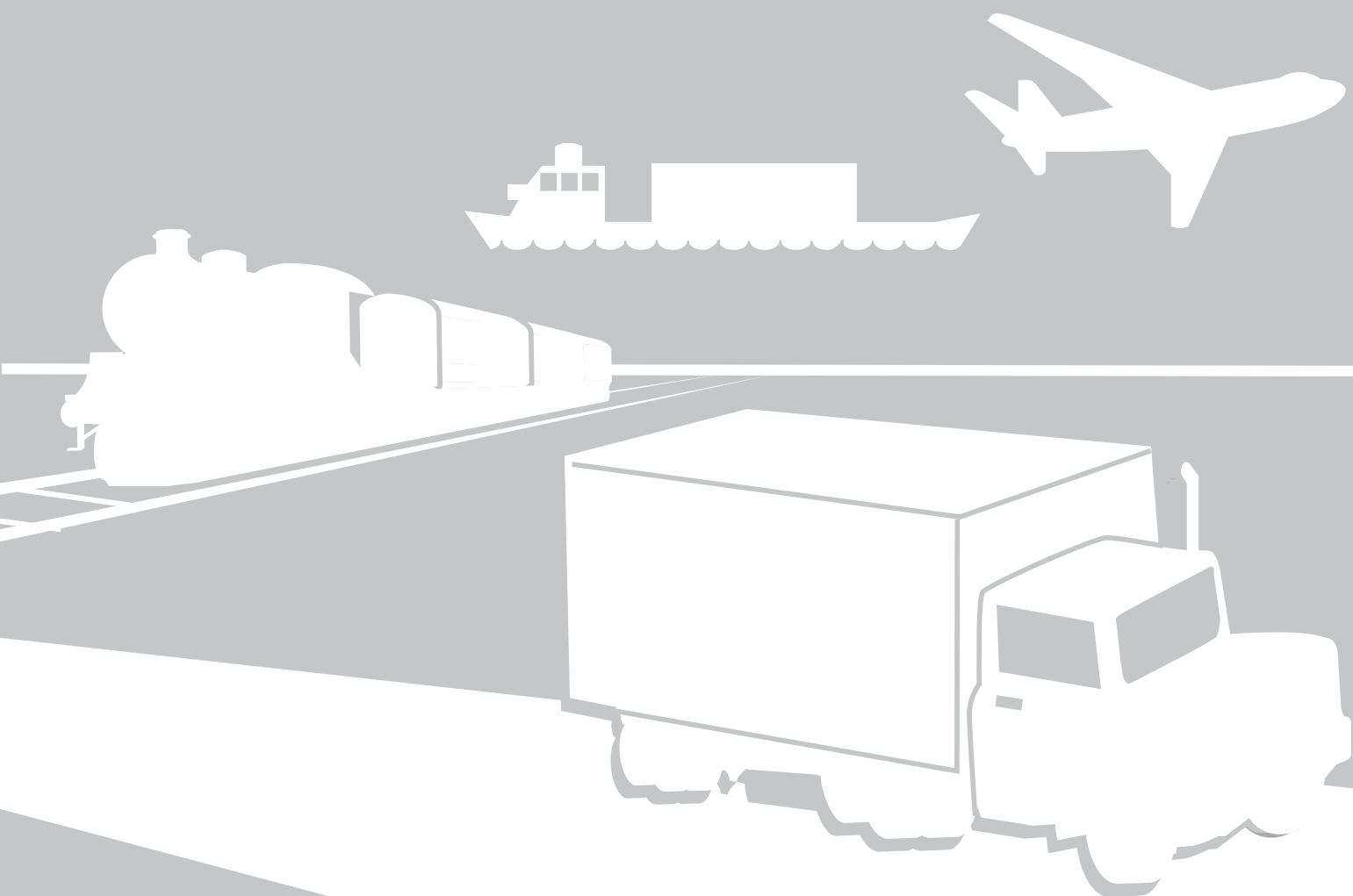
Protecting the U.S. Food Supply



U.S. Department of Health
and Human Services

What You Need to Know About **PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS**

A Small Entity Compliance Guide



The Public Health Security and Bioterrorism
Preparedness and Response Act of 2002

April 2009



U.S. Food and Drug
Administration



U.S. Department of Health
and Human Services

This guidance document is a restatement of the Food and Drug Administration's (FDA's) current requirements for prior notice of food presented in simplified format and language. As guidance, it is not binding on either FDA or the public. FDA notes, however, that the regulation that is the basis for this pamphlet establishes requirements for all covered activities. For this reason, FDA strongly recommends that affected parties consult the regulation at 21 CFR Part 1, Subpart I, in addition to reading this pamphlet.

The Food and Drug Administration has prepared this guidance to restate the legal requirements set forth in 21 CFR 1.276 through 1.285 concerning prior notice of imported food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. This guide is intended to help any entity, regardless of size, to comply with the regulations that require the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the United States. This document also serves as FDA's Small Entity Compliance Guide (SECG), in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121).

INTRODUCTION

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) directs the Food and Drug Administration (FDA), as the food regulatory agency of the Department of Health and Human Services, to take additional steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply or other food-related emergencies.

To carry out the provisions of the Bioterrorism Act, FDA has issued a final regulation amending the existing requirements in 21 CFR Part 1, Subpart I, which requires that FDA be given advance notice on shipments of imported food.

The amended regulations go into effect on **May 6, 2009**.

Purpose of this Booklet

This booklet was created to inform food transporters, food importers and exporters, foreign manufacturers and growers, and food filers and brokers about the prior notice requirements, as amended. It contains important information that may affect your food imports.

The information in this booklet also appears online at <http://www.fda.gov> through the Prior Notice of Imports link.

ABOUT PRIOR NOTICE

Prior Notice Requirement

As of December 12, 2003, FDA must be notified in advance of any shipments of food for humans and other animals that are imported into the U.S., unless the food is excluded from Prior Notice.

Why Prior Notice Is Required

Prior Notice of imported food shipments will give FDA time to:

- Review and evaluate information before a food product arrives in the U.S.
- Better deploy resources to conduct inspections
- Help intercept contaminated products

HIGHLIGHTS OF THE FINAL RULE

On October 10, 2003, the Secretaries of the Departments of Health and Human Services (HHS) and Homeland Security (DHS) jointly published an interim final rule (IFR) to implement prior notice. The IFR took effect on December 12, 2003, as required by the Bioterrorism Act; however, FDA and the U.S. Customs and Border Protection (CBP) gave interested persons 165 days to comment on the provisions of the IFR that we would consider as we developed the final rule.

The final rule, which takes effect on May 6, 2009, retains the majority of the requirements found in the IFR and includes revisions in a few key areas.

Highlights of the final rule:

- The final rule retains the minimum timeframes for submitting prior notice that are in the IFR.
- To assist importers, the final rule now permits prior notice submissions to be submitted no more than 15 calendar days before the anticipated date of arrival for submissions made through FDA's Prior Notice System Interface (PNSI) and no more than 30 calendar days before the anticipated date of arrival for submission made through CBP's Automated Broker Interface of the Automated Commercial System (ABI/ACS), instead of the 5 calendar days required in the IFR.
- The final rule adds a definition for "manufacturer" as the last facility, as that word is defined in 21 CFR 1.227(b)(2), that manufactured/processed the food and provides an alternative for identifying the manufacturer when the registration number is not provided such as when it is not known.
- The final rule exempts from prior notice food in diplomatic bags/pouches based on the authority in Art. 27(3) of The Vienna Convention on Diplomatic Relations (1961), which states: "The diplomatic bag shall not be opened or detained."
- The final rule allows, when certain conditions are met, for the submission of the express consignment operator or carrier tracking number in lieu of the anticipated arrival information, Bill of Lading, or Airway Bill number and flight number, which the IFR required.

Which Industry Sectors Are Affected by Prior Notice

If you export, transport, or import food into/through the United States, FDA must be given Prior Notice of imported food shipments.

Industry Sectors Affected

- Domestic and foreign cross-border transporters (rail, truck, ship, air)
- Domestic and foreign importers
- Domestic and foreign exporters
- Domestic and foreign filers and brokers
- Domestic and foreign manufacturers and growers

How “Food” Is Defined for Prior Notice

For purposes of Prior Notice, “food” is defined as:

- Articles used for food or drink for man or other animals
- Chewing gum
- Articles used for components of items listed in the 1st and 2nd bullets

Note: “Food” does not include food contact substances or pesticides.

Examples of “Food”

- Fruits
- Vegetables
- Fish and seafood
- Dairy products
- Eggs
- Raw agricultural commodities for use as food or as components of food
- Animal feed (including pet food)
- Food and feed ingredients
- Food and feed additives
- Dietary supplements and dietary ingredients
- Infant formula
- Beverages (including alcoholic beverages and bottled water)
- Live food animals
- Bakery goods
- Snack foods
- Candy
- Canned foods

Which Food Imports Require Prior Notice

Prior Notice is required for imports of all foods that are subject to the regulation. However, certain exclusions apply.

The following chart lists food imports that require Prior Notice. If the food you are importing falls under one of these requirements, be sure to review the Exclusions box (below) to see whether any exclusions apply.

Food Imports Requiring Prior Notice (Unless Exclusions Apply)

- Food imported for use, storage, or distribution in the U.S. (including gifts and trade and quality assurance/quality control and market research samples)
- Food transshipped through the U.S. to another country
- Food imported for future export, or food for use in a Foreign Trade Zone, unless it is on the list of exclusions on the following page

The following chart lists exclusions from the Prior Notice rule. If any of these exclusions apply to a food shipment you are importing, you do NOT have to submit Prior Notice for that shipment.

Exclusions

- Food carried by or otherwise accompanying (e.g., baggage) an individual arriving in the U.S. for that individual's personal use (i.e., for consumption by themselves, family, or friends, and not for sale or other distribution)
- Food 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 U.S.
- Food that is imported then exported without leaving the port of arrival until export
- Meat food products, poultry products, and egg products that at the time of importation are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act
- Food in diplomatic bags/pouches based on the authority in Art. 27(3) of The Vienna Convention on Diplomatic Relations (1961)

Who Can Give Prior Notice

Any individual with knowledge of the required information can submit Prior Notice. This includes individuals, manufacturers, exporters, brokers, importers, and U.S. agents.

What If You Fail to Give Adequate Prior Notice

Food that is imported or offered for import with inadequate Prior Notice is subject to refusal and, if refused, must be held at the port of entry unless directed to another location. The importing or offering for import into the U.S. of an article of food in violation of Prior Notice requirements is a "Prohibited Act" under the laws FDA administers. FDA has provided its staff with enforcement guidance containing the agency's policies on refusals, holds, injunctions, prosecution, and debarment related to failure to provide timely and accurate Prior Notice or otherwise comply with FDA Prior Notice regulations.

Note: Prior Notice guidance documents are available to the public and posted on FDA's website. FDA will continue to update these as appropriate.

GIVING PRIOR NOTICE OF AN IMPORTED FOOD SHIPMENT

How to Give Prior Notice

Prior Notice must be submitted electronically through either of the following systems:

- ACS of the Customs and Border Protection Service (CBP)
- FDA PNSI (<http://www.access.fda.gov>)

The FDA Prior Notice System Interface is available 24 hours a day, 7 days a week. FDA's and CBP's computer systems enable you to submit Prior Notice as part of the entry process. This will avoid duplication of information.

If a broker's or filer's system or ACS is not operating, Prior Notice must be submitted through the FDA Prior Notice System Interface.

If the FDA Prior Notice System Interface is not operating, or if the Operational and Administrative System for Import Support (OASIS) is not operating, 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(s) outage.

When to Give Prior Notice of a Shipment

FDA must electronically receive and confirm Prior Notice before a food shipment arrives at the first port in the United States (port of arrival). The deadline for submitting Prior Notice depends on the mode of transportation used for shipment.

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 arrives, if Prior Notice is submitted via ABI/ACS; or 2) no more than 15 days before a shipment arrives, if Prior Notice is submitted via FDA's PNSI.

In addition:

For Shipments Arriving:	Prior Notice Must Be Submitted:
By land via road	No less than 2 hours before arriving at the port of arrival
By land via rail	No less than 4 hours before arriving at the port of arrival
By air	No less than 4 hours before arriving at the port of arrival
By water	No less than 8 hours before arriving at the port of arrival
By international mail	Before the food is sent
Carried by or otherwise accompanying an individual	Within the timeframe for the applicable mode of transportation

If...	Then...
Prior Notice is submitted to the FDA PNSI	The Prior Notice confirmation number must accompany the food and be provided upon arrival.
An article of food arrives by international mail	The parcel must bear the Prior Notice confirmation number.
An article of food is carried by or otherwise accompanies an individual	The food must be accompanied by Prior Notice confirmation.

Note: Unless the Prior Notice is for food arriving by international mail or is carried by or otherwise accompanies an individual, Prior Notice submitted by ABI/ACS does not require additional documentation (although it may be prudent for the carrier to have a copy of Prior Notice confirmation or the number in his/her possession when arriving at the port of arrival).

Getting Help With Prior Notice

FDA offers an online tutorial on how to use the FDA Prior Notice System Interface at <http://www.access.fda.gov>. The FDA Prior Notice System Interface has Help features and interactive feedback to assist the submitter and minimize spelling mistakes and omissions. In addition FDA has two systems for assistance with Prior Notice:

FDA Industry Systems Help Desk 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: <http://www.cfsan.fda.gov/~furl/helpf2.html> and complete the form

FDA Prior Notice Center answers questions about Prior Notice policies, procedures and interpretations

Hours: 24 hours per day, 7 days per week

Phone: 1-866-521-2297

For assistance with ACS transmissions, contact your Customs and Border Protection Service client representative.

Information Required for Prior Notice

Importers or brokers already provide most of the information required for Prior Notice to the Bureau of Customs and Border Protection when goods arrive in the U.S. Now, according to the Bioterrorism Act, FDA must receive the information before a shipment of food arrives.


Required Information

- Name, business address, telephone, and email of the individual submitting Prior Notice, as well as firm name and address (if applicable)
- Name, firm name (if applicable) and business address, telephone, and email of the individual transmitting Prior Notice (if someone else is transmitting Prior Notice on behalf of the submitter)
- Entry type and CBP identifier (if identifier is available)
- Identification for each article of food in the shipment:
 - a. FDA product code
 - b. Common product name or market name
 - c. Estimated quantity (from smallest package size to largest container)
 - d. Lot, code number or other identifier (if food is required to have one)¹
- If the food is no longer in its natural state: 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)
- If the food is in its natural state: name of grower and growing location, if known
- FDA Country of Production
- Shipper's (sender's, if food is mailed) name and full address
- Country from which food is shipped; or, if food is imported by international mail, the anticipated date of mailing and country from which food is mailed
- Anticipated arrival information (location, date, and time); or, if food is imported by international mail, the U.S. recipient's name and address
- Name and full address of importer, owner, and consignee, unless the shipment is imported or offered for import for transshipment through the U.S. under a transportation and exportation (T&E) entry; or, if food is imported by international mail, the U.S. recipient's name and address
- Carrier and mode of transportation (except for food imported by international mail)
- Planned shipment information (except for food imported by international mail)


¹ Currently, low acid canned foods, acidified foods, and infant formula are required to bear lot codes or other identifiers [see 21 CFR 113.60(c) (low-acid canned foods); 21 CFR 114.80(b) (acidified foods); and 21 CFR 106.90 (infant formula low-acid canned foods)].

Prior Notice Screen

Here is a sample screen from the FDA Prior Notice System Interface:



**PRIOR NOTICE
SYSTEM INTERFACE**
UNITED STATES FOOD AND DRUG ADMINISTRATION



FDA

[Home](#) | [Contact Us](#) | [Help](#) | [Logoff](#)

CFSAN Tester, CFSAN Test Center

Welcome to the Prior Notice System Interface

The Prior Notice System Interface enables you to submit Prior Notices for Imported Food Articles to the Food and Drug Administration (FDA).

Get Started	▶ Overview of how to submit a Prior Notice for Food Importation.
Learn New Features	▶ Overview of New Features available in this version of the Prior Notice System Interface.
Create New Web Entry	▶ Creating a Web Entry is the first step in creating Prior Notices. A Web Entry contains information that one or more food articles you intend to import share (e.g., arrival information). After Creating a Web Entry, create, review, and submit Prior Notices. Prior Notices include information about the Product, its Quantity and Packaging, and other related information, such as the Manufacturer or Grower/Consolidator and the Shipper. You must complete the Web Entry after you have submitted all Prior Notices that you are planning to submit as part of this Web Entry. This will allow U.S. Customs and Border Protection to receive the Prior Notice review decisions in time from the U.S. Food and Drug Administration (FDA) for all articles in the Web Entry. The system automatically "Completes" Web Entries with submitted Prior Notices when the Prior Notice submission timeframe elapses (see the "Complete Web Entry" Help topic).
Find Existing Web Entry	▶ Use this feature to find Web Entries that you have already created.
Find Existing Prior Notice	▶ Use this feature to find Prior Notices that you have already created. To submit Holding Facility information for a Prior Notice submitted via PNSI by this account or another account within the same company, search for the Prior Notice and click the Submit Holding Facility button.
View/Submit Holding Facility	▶ To submit Holding Facility information for a Prior Notice that has been submitted via the U.S. Customs' and Border Protection (CBP) Automated Commercial System (ACS) or by another PNSI user of a different company click on the View/Submit Holding Facility button.
Manage Favorites	▶ Use this feature to maintain Favorite Facilities that you have already created.

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Prior Notice v1.10.00, December 10, 2008
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Correcting Errors During Submission

Both ACS and the FDA Prior Notice System Interface review the Prior Notice information you submit and provide feedback to help minimize errors. During submission, if information is missing or appears to be incorrect, or if there appear to be typographical errors, the system will give you an opportunity to make corrections electronically.

How Prior Notice Is Acknowledged

Once you submit all of the required Prior Notice information, you will receive confirmation, including a confirmation number, from FDA directly or from FDA through CBP's ACS.

Note: This confirmation means that FDA has deemed your Prior Notice facially complete. The confirmation does NOT mean that FDA has determined your Prior Notice is accurate, that FDA has approved the shipment, or that FDA has determined that the shipment may proceed without further FDA action. Subsequent system review and review by FDA staff may result in inspection of the imported food shipment upon arrival, or other action.

Presenting Prior Notice Confirmation on Shipment Arrival

FDA recommends that Prior Notice confirmation accompanies any shipment of imported food.

If a Shipment Arrives...	
By commercial carrier	If Prior Notice was submitted through the FDA Prior Notice System Interface, the carrier must have the Prior Notice confirmation number. In other cases, it is prudent for the carrier to have a copy of Prior Notice confirmation or the confirmation number in his/her possession when arriving at the port of arrival.
By international mail	The package must bear the Prior Notice confirmation number.
Carried by or otherwise accompanying an individual arriving in the U.S.	The individual must have a copy of Prior Notice confirmation.

What to Do If Information Changes After Confirmation

FDA must have adequate time to receive, review, and respond to each Prior Notice submission. Therefore, you cannot amend or change Prior Notice information once FDA has confirmed it. Instead, if any of the information in the table on page 12 changes, you must submit a new Prior Notice.

Note: FDA suggests that you cancel the previous Prior Notice before submitting a new one.

Information Changes Requiring New Prior Notice

- Name, business address, telephone, and email of the individual submitting Prior Notice, as well as firm name and address (if applicable)
- Name, firm name (if applicable) and business address, telephone, and email of the individual transmitting Prior Notice (if someone else is transmitting Prior Notice on behalf of the submitter)
- Entry type and CBP identifier (if identifier is available)
- Identification for each article of food in the shipment:
 - a. FDA product code
 - b. Common product name or market name
 - c. Estimated quantity (from smallest package size to largest container)
 - d. Lot, code number or other identifier (if food is required to have one)¹
- If the food is no longer in its natural state: 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 they registration number is not provided (reasons listed in the Compliance Policy Guide for Prior Notice of Imported Food)
- If the food is in its natural state: name of grower and growing location, if known
- FDA Country of Production
- Shipper's (sender's, if food is mailed) name and full address
- Country from which food is shipped; or, if food is imported by international mail, the anticipated date of mailing and country from which food is mailed
- U.S. recipient's name and address, if food is shipped; or, for food imported by international mail, the anticipated date of mailing
- Name and full address of importer, owner, and consignee, unless the shipment is imported or offered for import for transshipment through the U.S. under a T&E entry; or, if food is imported by international mail, the U.S. recipient's name and address
- Carrier and mode of transportation (except for food imported by international mail)

Note: Changes in estimated quantity, anticipated arrival, and planned shipment information do NOT require a new Prior Notice.

Note: The Prior Notice "clock" starts again when Prior Notice with the correct information is confirmed by FDA.

Submitting Prior Notice for Food That Has Been Refused Due to Inadequate Prior Notice

Prior Notice for food that was previously refused for inadequate Prior Notice must include:

- Port of arrival
- Actual quantity
- Location where the refused food is being, or will be, held
- Date it arrived, or will arrive, at that location
- Identification of the contact person at that location

¹ Currently, low acid canned foods, acidified foods, and infant formula are required to bear lot codes or other identifiers [see 21 CFR 113.60(c) (low-acid canned foods); 21 CFR 114.80(b) (acidified foods); and 21 CFR 106.90 (infant formula low-acid canned foods)].



FIND OUT MORE

How to Get More Information

Information on FDA's actions involving the Bioterrorism Act is available online at <http://www.cfsan.fda.gov/~dms/fsbtact.html>.

WHAT It Is: As of December 12, 2003, FDA must be notified in advance of any shipments of food for humans and other animals that are imported into the U.S., unless the food is excluded from Prior Notice.

WHY It's Required: To give FDA time to:

- Review and evaluate information before a food product arrives in the U.S.
- Better deploy resources to conduct inspections; and
- Help intercept contaminated products.

WHICH Industry Sectors Are Affected

- Domestic and foreign cross-border transporters (rail, truck, ship, air)
- Domestic and foreign importers of food
- Domestic and foreign exporters of food
- Domestic and foreign filers and brokers
- Domestic and foreign manufactures and growers

HOW "Food" Is Defined for Prior Notice: For purposes of Prior Notice, "food" is defined as: Articles used for food or drink for man or other animals; chewing gum; and articles used for components of any such articles (excluding food contact substances and pesticides).

Required Information

- Name, address, telephone, and email of the individual submitting Prior Notice, as well as the firm name and address, if applicable
- Name, firm name (if applicable) and business address, telephone, and email of the individual transmitting Prior Notice (if someone else is transmitting Prior Notice on behalf of the submitter)
- Entry type and CBP identifier (if identifier is available)
- Identification for each article of food in the shipment:
 - a) FDA product code
 - b) Common product name or market name
 - c) Estimated quantity (from smallest package size to largest container)
 - d) Lot, code number or other identifier (if the food is required to have one)¹
- If the food is no longer in its natural state: 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)
- If the food is in its natural state: name of grower and growing location, if known
- FDA Country of Production
- Shipper's (sender's, if food is mailed) name and full address
- Country from which the 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's name and address
- Name and full address of importer, owner, and consignee, unless the shipment is imported or offered for import for transshipment through the U.S. under a T&E entry; or, if the food is imported by international mail, the U.S. recipient's name and address)
- Carrier and mode of transportation (except for food imported by international mail)
- Planned shipment information (except for food imported by international mail)

¹ Currently, low acid canned foods, acidified foods, and infant formula are required to bear lot codes or other identifiers [see 21 CFR 113.60(c) (low-acid canned foods); 21 CFR 114.80(b) (acidified foods); and 21 CFR 106.90 (infant formula low-acid canned foods)].

Exclusions from the Prior Notice Rule

- Food carried by or otherwise accompanying (e.g., baggage) an individual arriving in the U.S. for that individual's personal use (i.e., for consumption by themselves, family, or friends, and not for sale or other distribution)
- Food 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 U.S.
- Food that is imported then exported without leaving the port of arrival until export
- Meat food products, poultry products, and egg products that at the time of importation are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act
- Food in diplomatic bags/pouches based on the authority in Art. 27(3) of The Vienna Convention on Diplomatic Relations (1961)

WHO Can Give Prior Notice: Any individual with knowledge of the required information — including individuals, manufacturers, exporters, brokers, importers, and U.S. agents.

HOW to Give Prior Notice: Submit electronically through CBP's ACS or the FDA Prior Notice System Interface.

WHEN to Give Prior Notice: 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 arrives, if Prior Notice is submitted via ABI/ACS; or 2) no more than 15 days before a shipment arrives, if Prior Notice is submitted via FDA's PNSI.

For Shipments Arriving:	Prior Notice Must Be Submitted:
By land via road	No less than 2 hours before arriving at the port of arrival
By land via rail	No less than 4 hours before arriving at the port of arrival
By air	No less than 4 hours before arriving at the port of arrival
By water	No less than 8 hours before arriving at the port of arrival
By international mail	Before the food is sent
Carried by or otherwise accompanying an individual	Within the timeframe for the applicable mode of transportation

Getting HELP:

- *ACS Transmission:* Contact your CBP client representative.
- *PNSI Transmission:* FDA offers an online tutorial on how to use the FDA Prior Notice System Interface at <http://www.access.fda.gov>. The FDA Prior Notice System Interface has Help features and interactive feedback to assist the submitter and minimize spelling mistakes and omissions. In addition FDA has two systems for assistance with Prior Notice:

<p>FDA Industry Systems Help Desk answers technical and computer-related questions about the Prior Notice System Interface</p> <p>Hours: 7:30 AM – 11 PM U.S Eastern Time</p> <p>Phone: 1-800-216-7331 or 301-575-0156</p> <p>FAX: 1-866-573-2804 or 301-436-2804</p> <p>Email: http://www.cfsan.fda.gov/~furls/helpf2.html and complete the form</p>	<p>FDA Prior Notice Center answers questions about Prior Notice policies, procedures and interpretations</p> <p>Hours: 24 hours per day, 7 days per week</p> <p>Phone: 1-866-521-2297</p>
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For more information, go to
<http://www.fda.gov/oc/bioterrorism/bioact.html>



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