



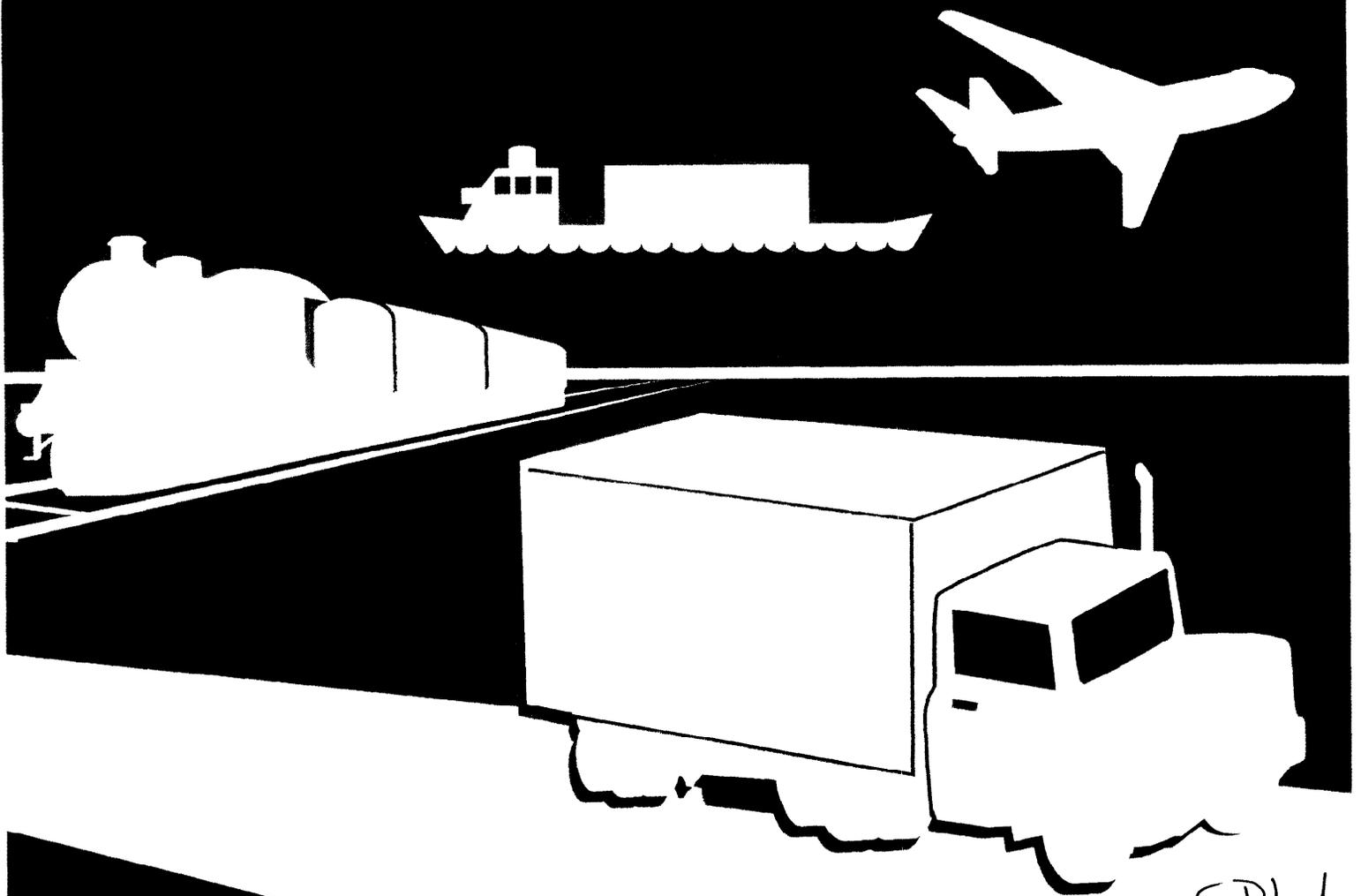
Protecting the U.S. Food Supply



U.S. Food and Drug
Administration

U.S. Department of Health
and Human Services

What You Need to Know About **PRIOR NOTICE OF**



GDL 1
The Public Health Security and Bioterrorism
Preparedness and Response Act of 2002

November 2003



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 for importation 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 H, 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 and other food-related emergencies.

To carry out certain provisions of the Bioterrorism Act, FDA has established new regulations requiring that:

- Food facilities are registered with FDA, and
- FDA be given advance notice on shipments of imported food.

These regulations go into effect on December 12, 2003.

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 new Prior Notice regulation. It contains important information that may affect your food imports.

The information in this booklet also appears online at <http://www.fda.gov/oc/bioterrorism/bioact.html>.

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; and
- Help intercept contaminated products.

HOW PRIOR NOTICE AFFECTS YOU

Which Industry Sectors Are Affected by Prior Notice

If you import, transport, or bring food into the United States, you should be aware that, beginning on December 12, 2003, FDA must be given Prior Notice of imported food shipments.

Groups Affected

- Domestic and foreign cross-border transporters (rail, truck, ship, air)
- Domestic and foreign importers of food to the U.S.
- Domestic and foreign exporters of food to the U.S.
- 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; and
- 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 (on the following page) 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
<ul style="list-style-type: none"> • 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 exported without leaving the port of arrival until export • Meat food products, poultry products, and egg products that 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

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.

FDA must receive and confirm Prior Notice no more than 5 days before a shipment arrives, unless it is arriving by international mail.

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 Prior Notice System Interface	The 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 the Automated Broker Interface/ Automated Commercial System (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).

Who Can Give Prior Notice

Any individual with knowledge of the required information can submit Prior Notice. This includes 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 arrival. Importing food with inadequate Prior Notice is also a "Prohibited Act" under the laws FDA administers. FDA will provide 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. FDA intends to include a transition period in this guidance, during which it will emphasize education to achieve Prior Notice compliance.

Note: Prior Notice guidance documents will be available to the public, and FDA will publish a notice of their availability in the Federal Register.

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 Prior Notice System Interface (<http://www.access.fda.gov>)

The FDA Prior Notice System Interface is available 24 hours a day, 7 days a week. FDA and CBP are upgrading and interfacing their computer systems to 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 and you do not submit Prior Notice through ABI/ACS, or if the Operational and Administrative System for Import Support (OASIS) is not operating:

1. Go to <http://www.access.fda.gov> to:
 - a. Find the fax number or email address where you must send your Prior Notice.
 - b. Be sure that you have all of the required Prior Notice information.
2. Fax or email the required information to the fax number or email address.

Note: FDA will activate the fax numbers and email addresses listed on the web site ONLY if the FDA Prior Notice System Interface or OASIS is not operating.

Note: The FDA Prior Notice System Interface and FDA web site operate independently of each other. Therefore, the FDA web site would still be accessible if the Prior Notice System Interface is down.

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>. After December 12, 2003, an Online Prior Notice Help Desk will also be available on business days, from 7:00 AM until 11:00 PM U.S. Eastern Standard Time, to help you with the system.

To Contact the Online Prior Notice Help Desk:

By phone	WITHIN THE U.S.: Call 1-800-216-7331 or 301-575-0156 OUTSIDE THE U.S.: Call 301-575-0156
By fax	Fax questions to 301-210-0247
By email	Go to http://www.cfsan.fda.gov/~furls/helpf2.html and complete the form

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 Customs and Border Protection Service 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, fax, 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, fax, 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 address, and registration number, if applicable²
- If the food is in its natural state: name of grower, if known, and growing location
- FDA Country of Production
- Shipper's (sender's, if food is mailed) name, address, and registration number²
- Country from which the 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 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)
- 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)].

² Registration number is NOT required when an article of food is imported for transshipment or other export.

Prior Notice Screen

Here are sample screens from the FDA Prior Notice System Interface:

The screenshot shows the top navigation bar with the logo for the Prior Notice System Interface, the FDA logo, and links for Home, Contact Us, Help, and a Log On button. Below the navigation bar is a dark banner with the text "Welcome to the Prior Notice System Interface". Underneath this banner is a paragraph explaining the system's purpose. A central box contains five links, each with a right-pointing arrow and a brief description of the feature. At the bottom of the page is a footer with copyright information.

PRIOR NOTICE SYSTEM INTERFACE
UNITED STATES FOOD AND DRUG ADMINISTRATION

FDA

Home | Contact Us | Help | **Log On**

John Doe, Our International

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).

- Home** ▶ Overview of how to submit a Prior Notice for Food Importation.
- Creating a New Web Entry** ▶ Creating a Web Entry is the first step in creating a Prior Notice. A Web Entry contains information that one or more food articles you intend to import share (e.g., arrival information).
- Creating a New Prior Notice** ▶ After Creating a Web Entry, create, review and submit a Prior Notice. A Prior Notice includes information about the Product, its Quantity and Packaging, and other related information, such as the Producer/Manufacturer and the Shipper.
- Find my existing Web Entry** ▶ Use this feature to find Web Entries that you have already created.
- Find my existing Prior Notice** ▶ Use this feature to find Prior Notices that you have already created.

Copyright © 2003 Prior Notice
PriorNotice v1.0 build-0.0.36, November 17, 2003

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 are typographical errors, the systems 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.

For Shipments Arriving:	
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 following table 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, fax, 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, fax, and email of the individual transmitting Prior Notice (if someone different 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 address, and registration number, if applicable²
- If the food is in its natural state: name of grower, if known, and growing location
- FDA Country of Production
- Shipper's (sender's, if food is mailed) name, address, and registration number²
- Country from which the 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 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)].

² Registration number is NOT required when an article of food is imported for transshipment or other export.

How to Comment on this Regulation

The Prior Notice regulation is currently an interim final rule. This means the regulation has the full force of law, but FDA is providing a 75-day comment period on the regulation through December 24, 2003. In addition, to ensure that those commenting on this interim final rule have had the benefit of FDA's outreach and educational efforts and have had experience with the systems, timeframes, and data elements of this interim final rule, the agency intends to reopen the comment period again in March 2004.

Note: You will find regularly updated information on the interim final rule and how to comment on it at <http://www.fda.gov/oc/bioterrorism/bioact.html>.

How to Get More Information

Information on FDA's actions involving the Bioterrorism Act is available online at <http://www.fda.gov/oc/bioterrorism/bioact.html>.

FDA'S PRIOR NOTICE REGULATION AT-A-GLANCE

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 Groups Are Affected

- Domestic and foreign cross-border transporters (rail, truck, ship, air)
- Domestic and foreign importers of food to the U.S.
- Domestic and foreign exporters of food to the U.S.
- 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; and articles used for components of any such articles (excluding food contact substances and pesticides).

Required Information

- Name, business address, telephone, fax, 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, fax, 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 address, and registration number, if applicable²
- If the food is in its natural state: name of grower, if known, and growing location
- FDA Country of Production
- Shipper's (sender's, if food is mailed) name, address, and registration number²
- Country from which the 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 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)
- 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)].

² Registration number is NOT required when an article of food is imported for transshipment or other export.

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 exported without leaving the port of arrival until export
- Meat food products, poultry products, and egg products that 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

WHEN to Give Prior Notice: FDA or the Customs and Border Protection Service (CBP) must receive and confirm Prior Notice no more than 5 days before a shipment arrives, unless arriving by international mail.

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

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

HOW to Give Prior Notice: Through CBP's ACS or the FDA Prior Notice System Interface

Getting HELP:

- *ACS Transmission:* Contact your CBP client representative.
- *FDA Prior Notice System Interface:* Contact the Online Prior Notice Help Desk, (available on business days, 7:00 AM to 11:00 PM U.S. Eastern Standard Time, beginning December 12, 2003).

To Contact the Online Prior Notice Help Desk:

By phone	WITHIN THE U.S.: Call 1-800-216-7331 or 301-575-0156 OUTSIDE THE U.S.: Call 301-575-0156
By fax	Fax questions to 301-210-0247
By email	Go to http://www.cfsan.fda.gov/~furls/helpf2.html and complete the form

[REDACTED]

[REDACTED]

[REDACTED]