



U.S. Food and Drug Administration



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Prior Notice of Imported Foods

October 2004

Sending Food through International Mail

Selected Excerpts from the Prior Notice Interim Final Rule, Guidance Documents, and Fact Sheets

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OVERVIEW: Food imported or offered import into the United States for human or animals is subject to prior notice requirements regardless of the mode of transportation. However, the Prior Notice Interim Final Rule treats imported food arriving by international mail somewhat differently than other modes of transportation. *The Interim Final Rule defines **International mail** to mean foreign national mail services. International mail does not include express carriers, express consignment operators, or other private delivery services. See [Interim Final Rule §1.276\(b\)\(7\)](#).*

The timeframe requirements for food arriving by international mail are different, too. If food is arriving by international mail, the prior notice may be submitted more than 5 calendar days before the anticipated date of arrival; however, the prior notice must be submitted before the food is sent to the U.S. In addition, the Prior Notice Confirmation Number must accompany the article of food and must appear on the Customs Declaration that accompanies the package.

When the prior notice submission has been validated, the transmitter will receive a message showing that the prior notice has been received by the Food and Drug Administration (FDA) for review and accepted as facially complete. This message will include a unique Prior Notice Confirmation Number as well as the date and time of the submission and confirmation. The message will confirm that the prior notice is facially complete and has been received by the FDA for review. The Prior Notice Confirmation Number that appears in this message must appear on the Customs Declaration that accompanies the package. The transmitter can print a hard copy of the prior notice submission which also can be used as confirmation for prior notice submission, if necessary. See [Interim Final Rule §1.279](#), and [Interim Final Rule 68 FR 58975 Pages 58999-59000](#).

HOME-MADE FOODS arriving by International Mail: Home-made food is not subject to

prior notice requirements if 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; see *Interim Final Rule § 1.277*.

GIFTS of FOOD no longer in its natural state arriving by International Mail: If the food is sent by an individual as a personal gift (i.e., for non-business reasons) to an individual in the United States, the name and address of the firm that appears on the label under 21 CFR 101.5 may be submitted instead of the name, address, and registration number of the manufacturer. See *Interim Final Rule § 1.281*.

Compliance Policy Guide and Enforcement Discretion: In the preamble to the interim final rule, FDA stated that it planned to provide guidance to its staff regarding the agency's enforcement policies. Accordingly, a Compliance Policy Guide (CPG) was issued which establishes policies regarding the enforcement of the prior notice requirements, including the requirement to provide a required registration number. This guidance document represents the FDA's and Customs and Border Protection's (CBP) current thinking regarding enforcement of prior notice requirements. It does not create or confer any rights for or on any person and does not operate to bind FDA, CBP, or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

The CPG discusses several situations which impact food shipments arriving by international mail for which we can exercise enforcement discretion:

COMMERCIAL SHIPMENTS arriving by International Mail: Commercial shipments of food arriving in the United States by international mail are subject to prior notice requirements. Since December 2003, the agencies have been exercising enforcement discretion for a period of time before full enforcement. For minor or inadvertent prior notice violations, the action FDA and CBP staff typically should consider taking is education and communication. However, if the violation reflects a history of repeated conduct of a similar nature by a person who had been notified of such violations, then the action FDA and CBP staff typically should consider taking is assessment of CBP Civil Monetary Penalties. See *Compliance Policy Guide, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002*.

NON-COMMERCIAL SHIPMENTS arriving by International Mail: Non-commercial shipments of food arriving in the United States by international mail are generally subject to prior notice requirements. However, since June 2004, the agencies have been exercising enforcement discretion. FDA and CBP should typically consider not taking any regulatory action when an article of food is imported or offered for import for non-commercial purposes with a non-commercial shipper. Generally, a non-commercial purpose is when the food is purchased or otherwise acquired by an individual for non-business purposes and the shipper is an individual (e.g., the individual delivers the food to a post office or common carrier for delivery to self, family member, or friend for non-business purposes, i.e., not for sale, resale, barter, business use, or commercial use.) Examples of foods imported or offered for import that may be covered by this non-commercial category are:

- food in household goods, including military, civilian, governmental agency, and diplomatic transfers;
- food purchased by a traveler and mailed or shipped to the traveler's U.S. address by the traveler;
- gifts purchased at a commercial establishment and shipped by the purchaser, not the commercial establishment.

The shipper and the carrier are different entities, and the carrier is likely to be a commercial entity even when the shipper is an individual. Thus, the food for non-commercial purposes may arrive by international mail or any other mode of transportation, but must be shipped by one individual to another individual (self, family member, or friend) to be considered for non-commercial purposes. For example, when an individual purchases food at Store A and sends that food to an individual by mail, the individual is the shipper and the carrier is the mail service. However, if Store A ships the food, Store A is the shipper. Since Store A is not an individual, this last example is not covered by the criteria because the food was not imported or offered for import with a non-commercial shipper. (While a "person" sometimes can be an individual, partnership, corporation, or association, see 21 U.S.C. 321(e), by "individual" we mean a human being, not a partnership, corporation, or association.) *see Compliance Policy Guide, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.*

SAMPLES arriving by International Mail: Certain samples of food are generally subject to prior notice requirements.

Food samples not considered articles of food: If the samples are items that are in such early stages of research and development that they cannot yet be considered food for the purposes of prior notice, then they would not be subject to prior notice requirements (Q&A, Section C., Question 1.3). In addition, if the sample is in a form that is not an article of food, such as a slurry of lettuce for pesticide analysis or a sterile sample container filled with juice for heavy metal analysis, then prior notice would not apply (Q&A, Section C., Question 17.2). *See Interim Final Rule 68 FR 58975 Page 58993. See Guidance for Industry, Prior Notice of Imported Food Questions and Answers (Edition 2).*

Food samples for quality assurance, research or analysis: If food is imported or offered for import for quality assurance, research or analysis purposes only, not for human or animal consumption and not for resale and if the prior notice submission does not include the registration number assigned to the manufacturing facility that is associated with the article of food, FDA and CBP should typically consider not taking any regulatory action.

Samples of food are considered to be for quality assurance, research or analysis purposes when they are imported in small quantities (i.e., quantities consistent with the quality assurance, research, or analysis purposes) and the entire sample is used up by the analysis or is destroyed after analysis or a reasonable retention period after analysis. The analysis may include sensory analysis or evaluations such as those organoleptic analyses for testing the quality of tea or for testing for histamines. Evidence that an article of food is imported for quality assurance, research, or analysis purposes only might include, among other evidence, that the food and shipment documents are marked accordingly. The enforcement discretion does not apply to samples intended for test marketing, such as tasting at trade shows or product promotional tasting events. *See Compliance Policy Guide, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.*

Additional Selected Excerpts from the Prior Notice Interim Final Rule, Guidance Documents, and Fact Sheets

Who is authorized to submit prior notice? A prior notice for an article of food may be submitted by any person with knowledge of the required information. This person is the submitter. The submitter also may use another person to transmit the required information on his/her behalf. The person who transmits the information is the transmitter. The submitter and

transmitter may be the same person. See *Interim Final Rule § 1.278*.

What is the definition of "shipper"? The interim final rule defines "shipper" as "the owner or exporter of the article of food who consigns and ships the article from a foreign country or **the person** who sends an article of food by international mail to the United States." See *Interim Final Rule § 1.276(b)(12)*.

For an abbreviated version of this information, see Abbreviated Information on Requirements for Submission of Prior Notice for Foods Arriving by International Mail below.

For more information see:

- [Prior Notice System Interface \(Overview and Background\)](#)
 - [Prior Notice for Food Articles sent by International Mail Step-by-Step Web System Instructions](#)
 - [Fact Sheet on FDA's New Food Bioterrorism Regulation: Interim Final Rule -- Prior Notice of Imported Food Shipments](#)
 - [Guidance for Industry: Prior Notice Questions and Answers \(Edition 2\)](#)
 - [Index of Help Pages for the Prior Notice System Interface](#)
 - [FDA Industry Systems Help Desk](#)
 - [Compliance Policy Guide: Guidance for FDA and CBP Staff](#)
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Abbreviated Information
on Requirements for Submission of Prior Notice
for Foods Arriving by International Mail

Refer to Prior Notice of Imported Foods particularly, Sending Food Gifts Through International Mail and Prior Notice for Food Articles sent by International Mail Step-by-Step Web System Instructions for additional information. For enforcement policies, refer to the Compliance Policy Guide (CPG).

Abbreviated Information

Article	Prior Notice Required	Generally Enforced
Home-made foods: 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 United States.	No	Not applicable
Non-Commercial Shipments: Food imported or offered for import for non-commercial purposes with a non-commercial shipper. A non-commercial purpose is when the food is purchased or otherwise acquired by an individual for non-business purposes and the shipper is an individual (e.g., the individual delivers the food to a post office or common carrier for delivery to self, family member, or friend for non-business purposes, i.e., not for sale, resale, barter, business use, or commercial use.) This includes food purchased by a traveler and mailed or shipped to the traveler's U.S. address by the traveler; gifts purchased at a commercial establishment and shipped by the purchaser, not the commercial establishment.	Yes	No, refer to CPG
Gifts of Food that is no longer in its natural state: Generally, the prior notice should include the identity of the manufacturing facility and the registration number of the manufacturing facility (§ 1.281(a)(6)). Here, the manufactured food is sent by an individual as a personal gift (i.e., for non-business reasons) to an individual in the U.S.	Yes	Yes, however, the name and address of the firm listed on the label may be provided in lieu of the registration number (§ 1.281a)(6))
Samples of Food 1: The samples are items that are in such early stages of research and development that they cannot yet be considered food, or the sample is in a form that is not an article of food, such as a slurry of lettuce for pesticide analysis or a sterile	No	Not applicable

sample container filled with juice for heavy metal analysis.		
Samples of Food 2: Food imported or offered for import for quality assurance, research or analysis purposes only, not for human or animal consumption and not for resale.	Yes	Yes , except for the registration number of the manufacturing facility; refer to CPG

Information in Prior Notice Submission of Food Arriving by International Mail

Information	Prior Notice Required	Generally Enforced
Submitter	Yes	Yes
Transmitter	Yes	Yes
Entry Types (always mail)	Yes	Yes
Entry Identifier (provided by PNSI)	Yes	Yes
FDA Product Code	Yes	Yes
Common, usual, or market name	Yes	Yes
Estimated Quantity	Yes	Yes
Lot/Code Number, if applicable	Yes	Yes
Manufacturer of food no longer in its natural state	Yes	Yes
Manufacturer Registration #	Yes	No
Grower, if known	Yes	Yes
FDA Country of Production	Yes	Yes
Shipper	Yes	Yes
Shipper Registration, if applicable	Yes	No
Country from which the food is Shipped	Yes	Yes
Date of Shipment	Yes	Yes
U.S. Recipient	Yes	Yes

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