

## Guidance for Industry

# Prior Notice of Imported Food Questions and Answers (Edition 2)\*

Comments and suggestions regarding this document may be submitted at any time. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the Docket Number 2004D-0065.

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**U.S. Department of Health and Human Services  
Food and Drug Administration  
Office of Regulatory Affairs  
Center for Food Safety and Applied Nutrition  
Center for Veterinary Medicine  
Revised May 2004**

**This is a revision of the first edition of the FDA guidance "[Prior Notice of Imported Food Questions and Answers](#)," which FDA issued in December 2003. Revisions/ additions are noted by date. The question numbering system and Table of Contents have been revised for clarity.**

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## Guidance for Industry

# Prior Notice of Imported Food Questions and Answers (Edition 2)

This guidance document represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternate approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, please contact: Domenic Veneziano, Office of Regulatory Affairs, Office of Regional Operations, FDA, 5600 Fishers Lane, Rockville, MD 20857, Phone: 866-521-2297

## I. INTRODUCTION

On October 10, 2003, the Food and Drug Administration (FDA) published an interim final rule in the **Federal Register** requiring submission to FDA of prior notice of food, including food for animals, that is imported or offered for import into the United States (68 FR 58974). The Prior Notice Interim Final Rule (Prior Notice IFR) implements section 801(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381(m)), which was added by section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Public Law 107-188), and requires that FDA receive prior notice of food imported into the United States.

This guidance document provides a list of questions that frequently have been asked about the requirements of the prior notice regulation, and the answers to those questions. This document is being issued to help the food industry and others comply with the legal requirements established by the Prior Notice IFR.

We intend to issue additional guidance as new questions arise. FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidances means that something is suggested or recommended, but not

required.

[Added April 2004] This is the second edition of this document. The first edition was issued on December 16, 2003 and revisions and additions are noted by date.

## II. PRIOR NOTICE QUESTIONS AND ANSWERS

### A. BACKGROUND

#### 1.

#### General:

#### 1.1 What is prior notice?

[Response updated April 2004] Prior notice is notification to the FDA that an article of food, including animal feed or pet food, is being imported or offered for import into the United States in advance of the arrival of the article of food at the U.S. border. (68 FR 58974; October 10, 2003).

Additional information on the prior notice regulation may be found on FDA's web site at <http://www.fda.gov/>, select Bioterrorism Act. For additional information on the U.S. Bureau of Customs and Border Protection's (CBP's) procedures for prior notice, you may want to consult the CBP website at <http://www.cpb.gov/>.

#### 1.2 Why is prior notice required to be submitted to FDA?

Prior notice is required by new section 801(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 801(m)). Section 801(m) requires advance notification to FDA prior to the arrival of food imported or offered for import into the United States.

#### 1.3 When does prior notice go into effect?

[Response updated April 2004] The Prior Notice IFR took effect on December 12, 2003, in accordance with the Bioterrorism Act. To assure that the Prior Notice IFR can be implemented efficiently and with minimal disruption, FDA is exercising broad enforcement discretion until August 12, 2004. During this initial transition period, we will focus our efforts on educating importers about how they can comply with the regulations, and will work with trade associations and foreign governments to make sure all importers are well informed of the new requirements.

Specific details regarding that transition period are provided in an FDA Compliance Policy Guide. The Compliance Policy Guide is available on FDA's website at [http://www.fda.gov/ora/compliance\\_ref/cpg/default.htm](http://www.fda.gov/ora/compliance_ref/cpg/default.htm).

#### 1.4 [Question/response added April 2004] How do I comment on the interim final rule?

The prior notice regulation issued as an interim final rule (IFR) on October 10, 2003, and FDA provided a 75-day comment period which ended on December 24, 2003. No comments

submitted on the IFR after the comment period closed will be considered by the Agency. However, 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, FDA intends to reopen the comment period for an additional 30 days in March 2004. When the comment period reopens, there will be an announcement in the Federal Register as well as in the updated information at <http://www.cfsan.fda.gov/~pn/pnoview.html>.

**1.5 [Question/response added April 2004] What if I have a question about or need clarification on the interim final rule?**

You may wish to review the preamble to the interim final rule, which answers many of the questions that we have received regarding these new requirements. The rule may be found at <http://www.cfsan.fda.gov/~pn/pnfr.html> and may be searched easily by topic (e.g., mail shipments). If you have further questions about prior notice, you can submit questions by using the form at <http://www.cfsan.fda.gov/~furls/helpf2.html>. We will likely answer the questions in guidance documents; you will likely not receive an individual response.

Due to the large number of inquiries that we have received and our limited resources, we plan to issue guidance documents periodically to answer those questions that are not directly addressed in the prior notice interim final rules or their preambles. Please check our website at <http://www.cfsan.fda.gov/~pn/pnoview.html> periodically to obtain a copy of these guidance documents.

2.

**Outreach:**

**2.1 How can the industry learn how to comply and submit prior notice through the U.S. Bureau of Customs and Border Protection (CBP) Automated Broker Interface of the Automated Commercial System (ABI/ACS) or FDA Prior Notice System Interface (PNSI)?**

[Response updated April 2004] Since publication of the Prior Notice and Registration IFRs on October 10, 2003, FDA has conducted extensive domestic and international outreach and education about the new rules. FDA and CBP held a satellite downlink public meeting on October 28, 2003, and a series of public meetings across the U.S. to discuss the prior notice and registration interim final rules. FDA officials also have held outreach meetings with foreign government officials and industry representatives either in person or via video-conference. Public meetings are announced on FDA's web site at <http://www.fda.gov/>. In addition, we have prepared several tools, such as tutorials, instructions, and question-and-answer documents, to help importers and other affected persons to submit prior notice either through ABI/ACS or PNSI. These are available on FDA's web site at <http://www.fda.gov/>. CBP continues to issue instructions to ABI/ACS filers and brokers on complying with the prior notice regulation.

**2.2 Where can I get more information about FDA's prior notice regulation?**

Information on the prior notice regulation may be found on FDA's web site at <http://www.fda.gov/>. Many of your questions can be answered by reading the Prior Notice IFR or by reviewing the tutorials, fact sheet, and other materials that are posted on the web site. If your questions are not answered by information on that web site, you can send an email by using the form at the following address: <http://www.cfsan.fda.gov/~furls/helpf2.html>. FDA plans to periodically issue guidance documents to answer those questions that are not directly addressed in the Prior Notice IFR or its preamble. Thus, you will not receive an individual response to your email. You should check our web site at <http://www.fda.gov/oc/bioterrorism/bioact.html> periodically to obtain a

copy of these guidance documents.

### **2.3 Where can I get more information about CBP's procedures under the Bioterrorism Act and the prior notice regulation?**

For additional information on the U.S. Customs and Border Protection's (CBP's) procedures for prior notice, consult the CBP website at <http://www.customs.treas.gov/>.

### **2.4 Is information about prior notice available in languages other than English?**

[Response updated April 2004] Yes. Information about prior notice to FDA is available in other languages. Translations available are indicated at the top of the English version of documents located on the Internet at <http://www.cfsan.fda.gov/~dms/fsbtact.html>. However, please note that the official binding version is the IFR as published in the Federal Register on October 10, 2003 (68 FR 58974).

For example, the Fact Sheet on FDA'S New Food Bioterrorism Regulation: Interim Final Rule -- Prior Notice of Imported Food Shipments is also available in Arabic, Chinese (GB), Hindi, Japanese, Malay, Portuguese, and Spanish.

### **2.5 [Question/response added April 2004] How do I arrange for a presentation by FDA on prior notice requirements to my trade group?**

All requests for presentations about prior notice are coordinated by FDA's Food Safety and Security Staff in the Center for Food Safety and Applied Nutrition. Requests should be in writing and should include the date, time, duration, and subject of the requested presentation (for example, January 5, 2004, 10:00 AM - 11:30 AM, on prior notice regulatory requirements), as well as the location, the identification of the group sponsoring the event or presentation, the targeted audience and expected number of attendees, and a contact name, address, phone number, fax number, and e-mail address. Your request should be directed to: Louis J. Carson, Deputy Director, Food Safety and Security Staff (HFS-32), 5100 Paint Branch Parkway, College Park, MD 20740 or faxed to Mr. Carson's attention at: 301-436-2605. The request should be made no later than 60 days before the date of the event.

While we will make every effort to assist, we may not be able to honor all requests for FDA presentations.

## **B. DEFINITIONS**

1.

### **Food - General:**

#### **1.1 For the purposes of the prior notice regulation, what is food?**

[Response updated April 2004] Food is defined in § 1.276 of the Prior Notice IFR by reference to section 201(f) of the FD&C Act, which 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 (21 U.S.C. 321(f)). However, for purposes of prior notice, the definition of food does not include food contact substances or pesticides (21 CFR 1.276(b)(5)(i)). Examples of food subject to prior notice include: fruits, vegetables, fish, including 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, and canned foods.

**1.2 [Question/response updated April 2004] Is a bulk commodity like raw cane sugar "food" subject to prior notice?**

A bulk commodity is subject to prior notice if it is food as defined in the IFR. This includes articles for use as food, including for use as a component of food. Raw agricultural commodities for use as food or as components of food such as raw cane sugar are food for prior notice purposes (21 CFR 1.276(b)(5)(ii)). FDA will consider an article as one that will be used for food if any of the persons involved in importing or offering the product for import (e.g., submitter, transmitter, manufacturer, grower, shipper, importer, owner, or ultimate consignee) reasonably believes that the substance is reasonably expected to be directed to a food use. For more discussion on this topic, please see the preamble to the IFR at 68 FR 58986-87.

2.

**Food - Chemicals and Food Additives**

**2.1 [Question/response updated April 2004] Are chemicals used to manufacture food additives food for prior notice purposes?**

Yes, chemicals that are used for food or drink or are used for components of any such articles are food and are subject to the prior notice rule. However, if the chemicals are used for food contact substances or pesticides or components of food contact substances or pesticides, prior notice is not required. (21 CFR 1.276(b)(5)). For more discussion on this topic, please see the preamble to the IFR at 68 FR 58986.

**2.2 What are some examples of food contact substances?**

Food packaging materials, empty food packages, ceramic dinnerware, brass drinking vessels, and corn husks to be used as tamale wrappers, are examples of food contact substances. Even though these foods are excluded from prior notice requirements in section 801(m) of the FD&C Act, they are still subject to other provisions of the FD&C Act, including section 801(a), and FDA will still make admissibility decisions about them.

**2.3 Are secondary direct additives, many of which are processing aids, exempt from prior notice as "food contact substances"?**

The term "secondary direct food additive" is not a defined term. Under 21 CFR 1.276(b)(5), "food" excludes "food contact substances" and "pesticides." Thus, if the "secondary direct food additive" is a food contact substance or a pesticide, it is not included in the definition of food, for purposes of prior notice, and prior notice is not required.

3.

**Food - Live Animals**

**3.1 Are live animals "food" for prior notice purposes?**

[Response updated April 2004] Live animals are food for purposes of prior notice (21 CFR 1.276(b)(5)(ii)) if any of the persons involved in importing or offering the live animal for import (e.g., the submitter, transmitter, manufacturer, grower, shipper, importer, owner, or ultimate consignee) reasonably believes that the live animal is reasonably expected to be directed to a food use (21 CFR 1.276(b)(5)). Note that live food animals are not excluded from prior notice under section 801(m)(3)(B) of the FD&C Act and 21 CFR 1.277(b)(4) or (5) because live food animals do not fall within the exclusive jurisdiction of USDA under the Federal Meat Inspection Act or Poultry Products Inspection Act.

Live animals are capable of multiple uses, such as food, pets, research, or letting them stay wild. In these situations, the question is whether "any of the persons involved in importing [the animal] reasonably believes that [it] is reasonably expected to be directed to a food use." Cows are almost always directed to a food use eventually, even if that is not the immediate use.

Some small animals (e.g. guinea pigs) that are imported end up as food. When this food use is not intended or reasonably expected at the time of import, such as when they are imported as pets, then prior notice would not be required.

Many horses are imported for a food use - slaughter and export as food. However, many are imported for non-food uses, such as shows, racing, and pets. When imported for a non-food use, a horse is not subject to prior notice requirements, unless any of the persons involved in importing the animal reasonably believes that it is reasonably expected to be directed to a food use.

**3.2 If USDA's Animal Plant and Health Inspection Service (APHIS) inspects the live animals when they are imported into the U.S., are the live animals "food" for prior notice purposes?**

[Response updated April 2004] Yes. Live food animals that are subject to border inspections by APHIS are also subject to FDA's prior notice requirements: FDA and APHIS may both have jurisdiction over live animals. Note that the requirement for prior notice to FDA for live food animals does not alter the role of APHIS in, or any APHIS requirements relating to, inspection of live animals imported into the U.S. As stated in the Prior Notice IFR, with respect to food co-regulated by USDA (including APHIS) and FDA, only food under the exclusive jurisdiction of USDA at the time of importation is excluded from prior notice. See 68 FR 58974 at page 58991.

**3.3 Are game animals "food" for which prior notice must be given?**

Yes, if any person involved in importing the animal reasonably believes the animal is reasonably expected to be directed to a food use, the animal is food for which prior notice is required. (21 CFR 1.276(b)(5)). So, for example, elk imported to stock a ranch where the elk are hunted and used for food would be food under the prior notice definition. By contrast, elk imported for repopulating a national park where hunting the elk is not permitted would not be food for which prior notice is required. Note that neither live food game animals nor the food products derived from them are excluded from prior notice under section 801(m)(3)(B) of the FD&C Act and 21 CFR 1.277(b)(4) or (5); neither these live food animals nor the products derived therefrom, fall within the exclusive jurisdiction of USDA under the Federal Meat Inspection Act or Poultry Products Inspection Act.

4.

**Seeds:**

**4.1 [Question/response added April 2004] Are seeds subject to prior notice requirements?**

Whether the seeds are subject to prior notice depends on whether the seeds meet the definition of food. FDA considers a seed to be food if it will be used for food or if any of the persons involved in importing or offering the product for import (e.g., the submitter, transmitter, manufacturer, grower, shipper, importer, owner, or ultimate consignee) reasonably believes that the substance is reasonably expected to be directed to a food use. So, for example, if the seed is for use in animal feed, the seed is food and prior notice is required (21 CFR 1.276(b)(5); 21 CFR 1.277(a)). Similarly, if the seed is to be used for human food, such as sesame seeds to be

used in baking or oilseeds for processing into edible oil, then prior notice must be submitted to FDA before the seed is imported or offered for import into the U.S. If the seed will be used for the production of edible sprouts, such as alfalfa seeds for production of alfalfa sprouts, then you must provide prior notice to FDA before the seeds are imported or offered for import. By contrast, if you or any other person importing or offering the seed for import reasonably believe that the seed will be used only for cultivation (even if it is used to grow a plant that may subsequently be consumed as food), then prior notice is not required.

5.

#### **FDA Country of Production:**

##### **5.1 What is the FDA Country of Production and how does it differ from CBP's Country of Origin?**

[Response updated April 2004] "FDA Country of Production" is defined in § 1.276(b)(4) of the Prior Notice IFR. For food that is in its natural state (21 CFR 1.276(b)(4)(i)), the FDA Country of Production is generally the country where the food was grown or collected, including harvested and readied for shipment to the U.S. Articles of food grown, including harvested or collected and readied for shipment, in U.S. territories are considered to be grown in the U.S. (21 CFR 1.276(b)(4)(i)). However, for wild fish, including seafood, that is caught or harvested outside U.S. waters by a vessel that is not registered in the U.S., the FDA Country of Production is the country in which the vessel is registered. (21 CFR 1.276(b)(4)(i)). For further discussion on this topic, please see the preamble to the IFR at 68 FR 58974 at page 59007.

For food that is no longer in its natural state, the FDA Country of Production is generally the country where the food was made or processed. However, if the article is made from wild fish aboard a vessel, the FDA Country of Production is the country in which the vessel is registered. If food that is no longer in its natural state was made in a Territory, the FDA Country of Production is the United States. (21 CFR 1.276(b)(4)(ii)).

The FDA Country of Production may be different from the CBP Country of Origin. For example, the CBP Country of Origin for beans that are grown and dried in the U.S., then rehydrated and canned in the Dominican Republic would be the U.S. The FDA Country of Production would be the Dominican Republic. However, for purposes of the prior notice provisions of the FD&C Act, the "article of food" is canned beans, not dried beans. From a food safety standpoint, FDA is most interested in knowing where the article of food was processed and canned. To avoid confusion between FDA's prior notice requirements and CBP requirements, the interim final rule uses the term "FDA Country of Production" instead of the term "originating country" or "country from which the article originates." "FDA Country of Production" is already familiar to customs brokers and self-filers using ABI/ACS interface with OASIS.

6.

#### **International Mail:**

##### **6.1 Are express carriers, such as Federal Express, considered "international mail"?**

[Response updated April 2004] As stated in 21 CFR 1.276(b)(7) of the IFR, the term "international mail" only covers foreign national mail services. Express carriers, such as Federal Express, as well as express consignment operators, or other private delivery services are not considered international mail under the prior notice rule. (21 CFR 1.276(b)(7)).

7.

#### **Port of Arrival/Port of Entry:**

### **7.1 What is the "port of arrival" and how does it differ from the "port of entry"?**

The port of arrival is the water, air, or land port at which the article of food is imported or offered for import into the U.S., i.e., the port where the article of food first arrives in the U.S. (21 CFR 1.276(b)(9)). Port of entry is given the same definition the CBP regulations use, which "refer[s] to any place designated by Executive order..., by order of the Secretary of the Treasury, or by Act of Congress, at which a Customs officer is authorized to accept entries of merchandise, to collect duties, and enforce the various provision of Customs and navigation laws..." (19 CFR 101.1)

### **7.2 Can the port of arrival differ from the port where entry is made?**

Yes. The port of arrival is the port where the articles first arrive in the U.S. A consumption or warehouse entry or foreign trade zone admission documentation may be presented to CBP at a different port than the port of arrival. This port is often referred to as the "port of entry" or "port where entry is made." Note that timeframes for submission of prior notice are tied to the time of arrival in the port of arrival, not arrival in the so-called port of entry.

8.

### **United States:**

#### **8.1 Is prior notice required for foods that are imported into Puerto Rico?**

Yes. The Prior Notice IFR defines the United States to be the 50 states, the District of Columbia, and the Commonwealth of Puerto Rico, but not the U.S. Territories (21 CFR 1.276(b)(13)). Therefore, prior notice is required for food that comes from outside the U.S. into Puerto Rico, but not for food shipped from Puerto Rico into the 50 states or the District of Columbia.

#### **8.2 Is prior notice required for foods that are imported into the U.S. Territories?**

No. The Prior Notice IFR defines the United States to be the 50 states, the District of Columbia, and the Commonwealth of Puerto Rico, but not the U.S. Territories (21 CFR 1.276(b)(13)). Therefore, prior notice is not required for food shipped into a U.S. Territory. However, prior notice is required for food coming from a U.S. Territory (e.g., Guam, the U.S. Virgin Islands, and the Northern Mariana Islands) into the 50 states, the District of Columbia or the Commonwealth of Puerto Rico.

#### **8.3 Is prior notice required for shipments originating in another NAFTA country?**

Yes. Because the "United States" is defined for purposes of prior notice to be the Customs territory of the United States (21 CFR 1.276(b)(13)), food that is imported into the 50 states, the District of Columbia, or the Commonwealth of Puerto Rico from a country that is a signatory to the North American Free Trade Agreement (other than the United States) is subject to prior notice.

### **C. SCOPE**

1.

#### **General:**

## **1.1 What is the scope of prior notice regulation? What shipments of food imported or offered for import into the United States require prior notice?**

If the article that is shipped to the United States is food within the meaning of 21 CFR 1.276(b)(5), then prior notice generally is required, even if the item is intended for further processing, is not intended for consumption in the United States, or is not intended for commercial distribution. Thus, prior notice is required for all food for humans and other animals that is imported or offered for import into the United States for use, storage, or distribution in the United States, including food for gifts and trade and quality assurance/quality control samples, food for transshipment through the United States to another country, food for future export, and food for use in a U.S. Foreign Trade Zone.

## **1.2 Are there any exceptions from the prior notice requirements?**

[Response updated April 2004] Yes. As stated in 21 CFR 1.277(b), prior notice is not required for:

- a. Food for an individual's personal use (i.e., for consumption by the individual, family, or friends, and not for sale or other distribution) when it is carried by or otherwise accompanies the individual when arriving in the United States;
- b. 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;
- c. Food that is imported then exported without leaving the port of arrival until export; and
- d. 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. (21 CFR 1.277(b)).

Prior notice also is not required under FDA requirements for food brought into the United States in a diplomatic pouch. The Vienna Convention on Diplomatic Relations (1961) provides: "The diplomatic bag shall not be opened or detained." Art. 27(3) Any baggage or cargo marked "diplomatic bag" or "diplomatic pouch" is immune from search, including by electronic devices, and thus its contents are not subject to FDA's prior notice requirements.

### **1.3 Are there exceptions from prior notice for any of the following:**

- a. **Food items of small value or quantity;**
- b. **Food samples for research and development or for testing purposes only and not for consumption; or**
- c. **Food samples for test marketing?**

There are no exemptions from prior notice requirements for:

- a. Food based on the size or value of the shipment (68 FR 58993);
- b. Samples of food, including animal feed, for research and development. (However, if the samples are items that are in such early stages of research and development that they cannot yet be considered food under 21 CFR 1.276(b)(5), they would not be subject to prior notice requirements. An example of such an item is a substance being tested for possible preservative qualities before being tested in any food); or
- c. Samples of food, including animal feed, for test marketing.

2.

### **Airline Food:**

#### **2.1 Is aircraft food exempt from prior notice, since any excess is incinerated at the U.S. airport? Is in-flight food, imported in bulk and moved in-bond to U.S. caterers, for use on export flights exempt?**

[Response updated April 2004] If the aircraft food is consumed on the international flight or discarded and is not entered into the U.S. for use, storage, or distribution, it is outside the scope of the regulation and prior notice is not required (21 CFR 1.277(a)). By contrast, prior notice is required for in-flight food that is moved to U.S. caterers for use on export flights or on domestic flights (21 CFR 1.277).

3.

### **Charities:**

#### **3.1 Is there an exemption for food imported for charity?**

No. Food intended for charity is not exempt from prior notice. Although the registration interim final rule exempts nonprofit food establishments in which food is prepared for, or served directly to, the consumer from the requirements to register their facilities, (21 CFR 1.266(e)), the Prior Notice IFR does not exempt food imported for use by those nonprofit food establishments. Thus, imported food that is imported for or by a U.S. charity is subject to prior notice. (21 CFR 1.277)

4.

### **Express Carriers or Express Consignment Operators:**

#### **4.1 Is an article of food that is shipped by an express carrier or express consignment operators like Fed Ex exempt from prior notice?**

No, imported food transported into the U.S. via express carriers or express consignment operators is not exempt from the requirements of the prior notice regulation. Articles imported via these private delivery services are subject to prior notice, which must be submitted within the timeframe for the applicable mode of transportation (21 CFR 1.279).

5.

### **Farms:**

#### **5.1 Is prior notice required for tomatoes from a foreign farm that packs and exports tomatoes to the U.S. since farms don't have to register?**

Yes. The requirement for prior notice is not based on whether registration is required. FDA registration requirements (21 CFR 1.266(b)) apply to **facilities** that manufacture/process, pack, or hold food for consumption in the United States. The prior notice requirements apply to **articles of food** imported or offered for import into the United States. Although registration of farms is not required, the articles of food grown, harvested, or collected on farms are not exempt from prior notice requirements. Thus, generally, the food that a foreign farm exports to the U.S. is subject to the prior notice requirements. (21 CFR 1.277)

6.

### **Food Not for Consumption in the U.S.:**

#### **6.1 [Question/response updated April 2004] If the food will not be consumed in the U.S., is prior notice required?**

Yes. Prior notice requirements apply even when the food will not be consumed in the United States. You must submit prior notice for food that is for transshipment, further processing and export, or storage and export. In contrast, the requirement to register facilities applies only to food facilities that manufacture/process, pack, or hold food for consumption in the U.S.

7.

#### **Foreign Trade Zones:**

**7.1 [Question/response updated April 2004] Will imported food being admitted into a Foreign Trade Zone (FTZ) need to have prior notice?**

Yes. Imported food for admission into a Foreign Trade Zone is subject to the requirements of the prior notice regulation (21 CFR 1.277). Prior notice is required before arrival in the United States and is, therefore, required prior to admission into a Foreign Trade Zone.

**7.2 [Question/response added April 2004] If I submit prior notice before a food is admitted into a FTZ, do I need to submit prior notice again before a food is withdrawn from the FTZ?**

No. Since prior notice must be submitted before arrival and admission into a FTZ, prior notice is not required when the food is withdrawn from the FTZ, either as an export or for use within the United States. However, if the food is withdrawn from the FTZ for consumption entry into the United States, FDA will be notified and make the admissibility decision about the consumption entry at that time.

8.

#### **Gifts:**

**8.1 [Question/response updated April 2004] Does prior notice apply to food sent as gifts from family living outside the U.S.?**

No. If the food 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, prior notice is not required (21 CFR 1.277(b)(2)). Other food products sent as gifts are subject to the prior notice requirement (21 CFR 1.277). FDA recognizes that in these circumstances, the sender who purchased the food as a gift may not have the manufacturer/producer registration number. Thus, the sender can provide the name and address of the firm that appears on the label instead of the registration number of the manufacturer (21 CFR 1.281(a)(6)).

**8.2 [Question/response added April 2004] Does prior notice apply to food in its natural state, grown by an individual, and sent to an individual in the U.S. as a gift?**

No. Homegrown food sent by one individual to another as a gift is not subject to prior notice.

**8.3 [Question/response added April 2004] Is prior notice required if an individual purchases a food product, made by a third party, and sends it to an individual in the U.S. as a gift?**

Yes. Other food products sent as gifts are subject to the prior notice requirement (21 CFR 1.277). FDA recognizes that in these circumstances, the sender who purchased the food as a gift may not have the manufacturer/producer registration number. Thus, the sender can provide the name and address of the firm that appears on the label instead of the registration number of the

manufacturer (21 CFR 1.281(a)(6)).

9.

**Household Goods:**

**9.1 Are foods included with my household goods subject to prior notice when I move to the U.S.?**

[Response updated April 2004] Yes. The Prior Notice IFR does not exclude household goods of individuals moving to the United States (21 CFR 1.277).

**9.2 [Question/response added April 2004] Are foods included with my household goods subject to prior notice even if the move is covered by the military?**

Yes. The Prior Notice IFR does not exclude household goods of military personnel moving back to the United States (21 CFR 1.277).

10.

**International Mail:**

**10.1 Is food imported into the U.S. by international mail exempt from prior notice?**

[Response updated April 2004] No, food sent to the U.S. via international mail is not exempt from the requirements of the prior notice regulation. Articles imported via international mail are subject to prior notice, which must be submitted before the article is sent to the U.S. (21 CFR 1.279(c)). See "Sending Food Gifts Through International Mail - Selected Excerpts from the Prior Notice Interim Final Rule, Guidance Documents, and Fact Sheets" at

<http://www.cfsan.fda.gov/~pn/pngift.html>.

11.

**In-Transit Shipments:**

**Is prior notice required for food transiting the U.S. for exportation to another country, e.g., for a Transportation and Exportation (T&E) entry?**

Yes. Prior notice is required for food for transshipment through the U.S. to another country and food for future export (21 CFR 1.277(a)).

12.

**Meat:**

**12.1 [Question updated April 2004] Is prior notice required for meat, poultry, or egg products that are under the jurisdiction of the U.S. Department of Agriculture (USDA)?**

If, at the time the food is imported or offered for import, the food is subject to the exclusive jurisdiction of the USDA's Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), the food is not subject to the requirements of prior notice. (21 CFR 1.277(b) (4)-(b)(6)). These acts are enforced by USDA's Food Safety and Inspection Service (FSIS).

**12.2 [Question/response added April 2004] Is prior notice required for meat intended for animal feed or pet food?**

Yes. Meat intended for animal feed, such as that fed to zoo animals or meat products intended to be incorporated into animal feed, is not under the jurisdiction of USDA/FSIS and is subject to the prior notice requirements. These meats include meat derived from cattle, swine, goats, sheep, horse, and mules that are destined for animal food or feed.

13.

[Reserved]

14.

**Produce**

**14.1** [Question/response added April 2004] **Is produce that is inspected by the Animal and Plant Health Inspection Service's Plant Protection and Quarantine (PPQ) or graded by USDA's Agricultural Marketing Service subject to FDA's prior notice requirements?**

Yes. Such produce is not under the exclusive jurisdiction of the USDA. Only imported food that is regulated exclusively by USDA is exempt from the prior notice requirements.

15.

**Personal Baggage:**

**15.1 I am bringing food from a foreign country in my luggage and for my personal use. Do I need to submit prior notice to FDA?**

No. Prior notice is not required for food that is carried by or otherwise accompanies an individual entering the United States (e.g., is in his or her carry-on or checked baggage) when the food is for that individual's personal use (21 CFR 1.277(b)(1)). Personal use means that the food is for consumption by the individual or by the individual's family and friends and is not for sale or other distribution.

**15.2** [Question/response added April 2004] **I plan to drive back to the U.S. from Canada with my trunk full of food I purchased there to serve at a family picnic. Is prior notice required?**

No. Prior notice is not required for food that is carried by or otherwise accompanies an individual entering the United States (e.g., is in his or her automobile) when the food is for that individual's personal use (21 CFR 1.277(b)(1)). Personal use means that the food is for consumption by the individual or by the individual's family and friends and is not for sale or other distribution.

**15.3** [Question/response added April 2004] **I plan to drive back to the U.S. from Mexico with my trunk full of shellfish that I plan to sell at a flea market on the U.S. side of the border. Is prior notice required?**

Yes. Prior notice is required for food that is imported or offered for import into the U.S. for use, storage, or distribution in the U.S. Prior notice is not required for food that is carried by or otherwise accompanies an individual entering the United States (e.g., is in his or her automobile) when the food is for that individual's personal use (21 CFR 1.277(b)(1)). Here, the shellfish are to be sold and are not for personal use.

**15.4** [Question/response added April 2004] **I plan to drive back to the U.S. from Canada with my trunk full of samples of finished packaged foods for testing. Is prior notice required?**

Yes. Prior notice is required for food that is imported or offered for import into the U.S. for use, storage, or distribution in the U.S. Prior notice is not required for food that is carried by or otherwise accompanies an individual entering the United States (e.g., is in his or her automobile)

when the food is for that individual's personal use (21 CFR 1.277(b)(1)). Here, the samples of finished packaged food are to be used for testing and not for personal use.

16.

**Personal Shipments:**

**16.1 [Question/response updated April 2004] Is prior notice required for food for personal use that I ship to myself while overseas and, therefore, does not accompany me when I return to the U.S.?**

Yes. Under the IFR, food purchased abroad and sent to the U.S. (i.e., does not accompany the individual when arriving in the U.S.) is subject to prior notice (21 CFR 1.277).

**16.2 [Question updated April 2004] I have ordered food for my personal use that is being shipped to me through international mail. Is prior notice required?**

Yes, under the IFR, prior notice must be provided. Under the IFR, the exception for food for "personal use" applies only when the food is carried by or otherwise accompanies an individual when arriving in the U.S. (21 CFR 1.277(b)(1)). This exception does not apply when the food is shipped to the U.S.

Although you or any other person with knowledge of the required information may submit prior notice (21 CFR 1.278), it would make sense for the foreign shipper to provide prior notice because the PN Confirmation Number, which indicates that FDA has received and confirmed the prior notice for review, must accompany an article of food that is sent to the U.S. via international mail (21 CFR 1.279(e)).

**16.3 What if my order is shipped by an express carrier or express consignment operators like Fed Ex?**

Under the IFR, prior notice is required. Food transported to the U.S. via express carriers or express consignment operators is not exempt from the requirements of the IFR. Articles of food imported via these private delivery services are subject to prior notice, which must be submitted within the timeframe for the applicable mode of transportation (21 CFR 1.279).

17.

**Samples:**

**17.1 Is food that is a trade sample and that I carry with me into the United States exempt from prior notice?**

No. The exclusion for good carried by an individual applies when the food is for the individual's personal use when it is carried by or otherwise accompanies the individual when arriving in the United States. (21 CFR 1.277(b)(1)) However, trade samples are imported or offered for import to generate sales, which is a commercial, not personal, use.

**17.2 [Question/response added April 2004] Are samples of food that are intended for analytical testing for contaminants exempt from prior notice?**

If the samples are articles of food, such as a head of lettuce or a can of juice, then prior notice is required. However, 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.

18.

**U.S. Goods Returned:**

**18.1 Is prior notice required for "reimported" food product that was produced in the U.S., shipped to a foreign country, and then shipped back to the U.S. without further processing?**

Yes. FDA has determined that, for the purposes of section 801(m) of the FD&C Act, the phrase "imported or offered for import into the United States" applies to articles of food of U.S. origin that are "reimported" back into the U.S. (68 FR 58990; 21 CFR 1.277). These reimportations are most often referred to as American Goods Returned or U.S. Goods Returned.

**D. REQUIREMENTS TO SUBMIT PRIOR NOTICE OF IMPORTED FOOD**

1.

**Submitters and Transmitters:**

**1.1 Who may submit prior notice to FDA?**

Any person with knowledge of the required information may submit prior notice for an article of food. This person is the submitter. The submitter may also use another person to transmit the required information on his or her behalf. The person who transmits the information is the transmitter. The submitter and transmitter may be the same person (21 CFR 1.278).

**1.2 May I submit a prior notice on behalf of another person?**

Yes. Note that if you transmit the required information on behalf of a submitter, you are the transmitter.

**1.3 Is it possible for the submitter to have his/her legal residence in the country of origin and for the transmitter to have his/her legal residence in the U.S.?**

Yes. There are no geographic restrictions on the location of the submitter or the transmitter. (21 CFR 1.278)

2.

**Deadlines for Prior Notice:**

**2.1 When must prior notice be submitted?**

[Response updated April 2004] Except for food being sent by international mail, prior notice must be submitted and the submission must be confirmed by FDA no more than 5 calendar days before the anticipated date of arrival, and no less than:

- \_ 2 hours before arrival, if the food is arriving by land by road;
- \_ 4 hours before arrival, if the food is arriving by land by rail
- \_ 4 hours before arrival, if the food is arriving by air; and
- \_ 8 hours before arrival, if the food is arriving by water. (21 CFR 1.279(a) and (b))

For an article of food sent by international mail, prior notice must be submitted and confirmed by FDA before the food is sent (21 CFR 1.279(c)). The Prior Notice (PN) Confirmation Number must appear on the Customs Declaration that accompanies the package. (21 CFR 1.279(e))

If you are carrying an article of food or if it otherwise accompanies you (i.e., the food is in your checked baggage or in the trunk of your car), and the food is not for personal use, you must submit prior notice according to the timeframe established for the mode of transportation you are using. You must receive confirmation from FDA and provide a copy of the confirmation, including the PN Confirmation Number, to CBP or FDA when arriving in the U.S. (21 CFR 1.279(f)).

**2.2 [Question/response added April 2004] What is the deadline if the food is transported by truck, but the truck arrives via ferry due to a water crossing?**

In this case, the deadline is 2 hours prior to arrival.

**2.3 [Question/response added April 2004] What is the deadline if the food walks across the border, such as livestock that are driven across?**

If cattle are driven across the border, then the food is arriving by land via road and the deadline is 2 hours prior to arrival.

3.

**Submitting Prior Notice:**

### **3.1 How is prior notice submitted to FDA?**

[Response updated April 2004] You must submit prior notice to FDA electronically either through the U.S. Customs and Border Protection's (CBP's) Automated Broker Interface of the Automated Commercial System (ABI/ACS) or FDA's Prior Notice System Interface

— CBP's ABI/ACS allows prior notice to be submitted to FDA through the existing ABI/ACS interface (21 CFR 1.280(a)(1)); and

— FDA's Prior Notice System Interface (PNSI) is available through FDA's website at <http://www.access.fda.gov/> (21 CFR 1.280(a)(2)).

Both ABI/ACS and the FDA PNSI are available 24 hours a day, 7 days a week for information submission.

You must be authorized in order to use CBP's ABI/ACS interface (19 CFR 143.1), but anyone can use PNSI. If you are an authorized user of the ABI/ACS, you can provide prior notice as part of your CBP entry.

**3.2 Do I have to submit prior notice information to both FDA and CBP?**

[Response updated April 2004] No. Prior notice must be submitted to FDA. If you are an authorized user of CBP's ABI/ACS, you may submit prior notice to FDA through the ABI/ACS interface or through FDA's Prior Notice System Interface (PNSI) at <http://www.access.fda.gov/>. If you are not an authorized user of CBP's ABI/ACS, you may arrange for the prior notice submission by an authorized user or you may submit prior notice through PNSI. However, prior notice must be submitted through FDA's PNSI for the following:

— Articles of food shipped through international mail;

— Transaction types that cannot be transmitted through ABI/ACS; and

— Articles of food that have been refused admission under section 801(m)(1) of the FD&C Act. (21 CFR 1.280(a)(2))

**3.3 I am an authorized user of CBP's ABI/ACS. Can I use FDA's Prior Notice System**

## **Interface (PNSI) to submit prior notice?**

Yes. You may submit prior notice through either system.

### **3.4 I am shipping food by international mail. How do I provide Prior Notice?**

[Response updated April 2004] You must provide prior notice to FDA through the FDA Prior Notice System Interface (PNSI) (21 CFR 1.280(a)(2)). Prior notice must be submitted and confirmed by FDA before the food is sent (21 CFR 1.279(c)). The Prior Notice (PN) Confirmation Number must appear on the Customs Declaration that accompanies the package (21 CFR 1.279(e)).

### **3.5 What happens if the CBP or FDA system is not working?**

If CBP's ABI/ACS is not available or if your broker's or your self-filing system is not working, you must submit prior notice through the FDA Prior Notice System Interface at <http://www.access.fda.gov/>. (21 CFR 1.280(b))

If we determine that our Prior Notice System Interface is not working, we will issue notification on our website (<http://www.fda.gov/>) and on the Prior Notice System Interface, as well as through messages in ABI/ACS. If you do not use ABI/ACS, and the PNSI is down, you must submit prior notice by e-mail or fax to FDA.

If FDA determines that its automated import system (OASIS) is not working, FDA will issue notification on our website (<http://www.fda.gov/>) and on the Prior Notice System Interface and all prior notices must be submitted to FDA by e-mail or by fax. The e-mail address and fax number, as well as more information on how to submit prior notice if FDA or CBP systems are not working, will be available at <http://www.fda.gov/>.

### **3.6 What happens if my computer system is not functioning or I don't have electricity for a period of time?**

If your computer is not functioning or there is no electricity to operate your computer but the Prior Notice System Interface and ABI/ACS are functioning, you must make arrangements to use a functioning computer to submit the required prior notice.

### **3.7 If I have problems submitting prior notice through the Prior Notice System Interface (PNSI), how can I get help?**

[Response updated April 2004] Tutorials on use of PNSI are available on FDA's website at <http://www.fda.gov/>. . If you are already familiar with how to use PNSI and you are having problems with an online submission through PNSI, you can gain assistance through the following means:

- \_ Phone: In the U.S call toll-free 1-800-216-7331. From elsewhere, call 301-575-0156.
- \_ Facsimile: You may send a fax to 301-210-0247.
- \_ Email: Requests for assistance also may be emailed to <http://www.cfsan.fda.gov/~furls/helpf2.html>.

This technical assistance is available on business days from 7 AM until 11 PM U.S. Eastern Time. For assistance with ABI/ACS transmission, contact your CBP client representative.

Both the CBP and FDA systems for prior notice are available 24 hours a day, 7 days a week for submitting prior notice.

### **3.8 Can I submit the prior notice to the Prior Notice System Interface in a language other than English?**

You must submit all prior notice information in the English language, except that an individual's name, the name of a company, and the name of a street may be submitted in a foreign language. All information, including these items, must be submitted using the Latin (Roman) alphabet (21 CFR 1.280(a)).

If you are not comfortable with English, you may choose to use a transmitter to enter the information for you.

### **3.9 Can anyone submit prior notice through ACS/ABI?**

[Response updated April 2004] No. CBP allows submissions through ABI/ACS only by authorized participants (19 CFR 143.1). Individuals can contract with a broker to transmit prior notice for them. In this case, the submitter is the person responsible for providing the information, but the broker is the transmitter.

Brokers are licensed private individuals or companies that are regulated by CBP and who aid importers and exporters to move merchandise through CBP, including often filing entry of the merchandise with CBP. Brokers provide the proper paperwork and payments to CBP for clients and charge a fee for this service. Before brokers apply for a license, they must pass the Customs broker examination.

See:[http://www.customs.gov/xp/cgov/import/broker\\_management/brokers.xml](http://www.customs.gov/xp/cgov/import/broker_management/brokers.xml)

Filers are required to submit a written request to CBP port personnel for a filer code, which is subsequently assigned by CBP headquarters. See: Chapter 10 pp. 73-76,  
[http://www.cbp.gov/ImageCache/cgov/content/import/brokers/broker\\_5fhandbook\\_2epdf/v1/broker\\_5fhandbook.pdf](http://www.cbp.gov/ImageCache/cgov/content/import/brokers/broker_5fhandbook_2epdf/v1/broker_5fhandbook.pdf)

Individuals who choose not to use a broker or who choose not to become recognized by CBP as a filer can submit their prior notice only through the FDA Prior Notice System Interface (PNSI).

### **3.10 Do I have to submit prior notice if I do not have to file a consumption entry with CBP?**

Yes. The requirement to submit prior notice to FDA is different from the requirement to file a consumption entry with CBP. Some foods arriving in the United States do not require a CBP consumption entry at the time of arrival, such as entries that move under bond (in-bonds) from the port of arrival to an inland port and shipments into a Foreign Trade Zone. However, any article of food imported or offered for import into the United States requires prior notice, unless the food is specifically excluded from the requirement to submit prior notice (21 CFR 1.277).

### **3.11 Can I submit any CBP entry or admission for food without prior notice?**

No, not if the entry or admission contains food subject to the prior notice requirements. You can not submit a CBP import entry or admission if you have not submitted prior notice to FDA for an article of food that requires prior notice, because the Harmonized Tariff Schedule (HTS) codes have been flagged to indicate foods that require or may require prior notice. You must submit prior notice either through the Automated Broker Interface of the Automated Commercial System (ABI/ACS) (along with the CBP entry information) or through the FDA Prior Notice System Interface at <http://www.access.fda.gov/> (21 CFR 1.280(a)).

When you submit prior notice through the FDA Prior Notice System Interface, you will receive a Prior Notice (PN) Confirmation Number (21 CFR 1.279(d)). If you subsequently submit import entry or admission information through the Automated Broker Interface of the Automated Commercial System (ABI/ACS), you must enter the PN Confirmation Number for that submission as an Affirmation of Compliance when the CBP entry or admission is filed. The PN Confirmation Number will allow CBP to confirm that prior notice was submitted to FDA.

**3.12 I cannot or do not want to use CBP's ABI/ACS. What other way can I submit prior notice?**

If you cannot or do not want to use ABI/ACS, you must submit prior notice through the FDA Prior Notice System Interface at <http://www.access.fda.gov/>. (21 CFR 1.280(a)) You will receive a confirmation number when you complete the prior notice through the Prior Notice System Interface. (21 CFR 1.279(d)) The PN Confirmation Number must accompany the food when the article arrives in the U.S. (21 CFR 1.279(g))

**3.13 How do I submit prior notice for foods that are covered by Immediate Transportation or Transportation and Exportation entries?**

The U.S. Customs and Border Protection (CBP) has modified the Automated Broker Interface of the Automated Commercial System (ABI/ACS) interface to allow for submission of prior notice to FDA for IT and T&E entries. Prior notice for such entries also may be made through FDA's Prior Notice System Interface.

**3.14 [Question/response updated April 2004] I ship the same food weekly to the United States in a truck under bond to St. Louis. When and how do I need to file prior notice? Can I file one prior notice to cover all of these repetitive shipments?**

The time frame for submitting prior notice is based on the mode of transportation and the port of arrival, i.e., the port where the food first arrives in the United States. This port may be different from the port where the entry documentation is presented to CBP. Prior notice for food arriving by truck (by land by road) must be confirmed by FDA for review at least 2 hours before the truck arrives at the port where it is crossing the border into the United States (21 CFR 1.279).

If you are entering under bond and want to file your CBP entry in St. Louis, you can file your prior notice either through FDA's Prior Notice System Interface or through CBP's ABI/ACS interface (21 CFR 1.280(a)). If you submit the prior notice through the FDA Prior Notice System Interface, you will receive a Prior Notice Confirmation Number (21 CFR 1.279(d)). This Prior Notice (PN) Confirmation Number must be made available to CBP when entering the United States, and must be entered as an Affirmation of Compliance when you file your CBP entry information (21 CFR 1.279(g)).

You may not file one prior notice to cover all the repetitive shipments. Each article of food requires prior notice (21 CFR 1.281). The Prior Notice IFR states that, except for food imported by international mail, you may not submit prior notice more than 5 calendar days before the anticipated date of arrival of the food at the anticipated port of arrival (21 CFR 1.279(b)). Therefore, you would need to submit a prior notice for each article of food contained in each of the weekly shipments.

**3.15 Is there a filing fee for prior notice?**

No. FDA does not charge a fee for filing prior notice or for using FDA's Prior Notice System

Interface. However, if you chose to use a broker to file the prior notice through the ABI/ACS interface, the broker may charge a fee for providing that service. The collection of duty by CBP is not affected by FDA's prior notice regulation.

4.

## **General Information Requirements:**

### **4.1 What information must be included in the prior notice?**

[Response updated April 2004] The information required for prior notice varies, based on the type of entry, mode of transportation for the entry, and whether the food is in its natural state. You should refer to the interim final rule (21 CFR 1.281) for details on the required information. The preamble to the interim final rule includes a chart that summarizes the information requirements (68 FR 58980). The interim final rule is available on FDA's web site <http://www.fda.gov/>. The chart (Table 1A) from the interim final rule is also located at <http://www.cfsan.fda.gov/~pn/pngift.html>. "Sending Food Gifts Through International Mail - Selected Excerpts from the Prior Notice Interim Final Rule, Guidance Documents, and Fact Sheets."

Tutorials on the FDA Prior Notice System Interface (PNSI) also are available on FDA's website to help guide you through the process for providing the required information when you submit prior notice through PNSI.

### **4.2 How does the information required for prior notice of imported food shipments differ from information submitted to the CBP before December 12, 2003?**

Most of the information required by 21 CFR 1.281 also is entry data required by CBP before December 12, 2003. The key differences are the information required about the identity of manufacturer, grower, owner, and submitter and the identification of the country from which the article is shipped.

### **4.3 What time do I enter for anticipated time of arrival?**

[Response updated April 2004] For prior notice, anticipated time of arrival relates to the local time of the anticipated port of arrival. (21 CFR 1.281(a)(11)(iii) and 68 FR 59009) For vessels, this would be when the vessel is expected to dock in the port where it first arrives in the United States. For planes, this would be when the plane is scheduled to land. For land vehicles, such as trucks, buses, and trains, this would be when the vehicle is expected to cross at the border.

5.

## **Registration Numbers**

### **5.1 [Question/response added April 2004] What food facility registration numbers must I provide as part of my prior notice submission?**

At most, you must provide two registration numbers to accompany a prior notice submission.

1. If the food is no longer in its natural state, you must provide the registration number assigned to the facility that manufactured the article of food.
2. If the shipper is required to register under 21 CFR part 1, subpart H, you also must provide the registration number assigned to the shipper's facility.

However, you do not need to provide either registration number if the article is imported or offered for import for transshipment, storage, and export, or further manipulation and export. In addition, if the article is sent by an individual as a personal gift to an individual in the U.S., you may provide the name and address of the firm as it appears on the label, instead of the manufacturer's name, address, and registration number (21 CFR 1.281(a)(6) and (a)(9) (Articles not arriving by international mail); 21 CFR 1.281(b)(5) and (b)(8) (Articles arriving by international mail)).

6.

## Grower Identity

### 6.1 [Question/response added April 2004] **If a food from a known grower is commingled with food from unknown growers, may the submitter still identify only the consolidator instead of the grower?**

No. Section 801(m)(1) of the FD&C Act requires grower information to be submitted if it is known. In the interim final rule, FDA emphasizes that the submitter may opt to provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations only when the submitter does not know the identity of any of the growers of the consolidated food. If the submitter knows the identity of any grower of a food that has been consolidated, a separate prior notice must be submitted for each article of food represented by a known grower. Therefore, in the situation in question, if the submitter knows the identity of a grower and the article of food associated with that grower, then one prior notice would be submitted for the article of food associated with the known grower and a second prior notice would be submitted for the remaining product. For the second prior notice, you could opt to identify the consolidator. (21 U.S.C. 381; 21 CFR 1.281(a)(7), (b)(6); 68 FR 59006).

### 6.2 [Question/response added April 2004] **Does a grower need to be identified if an article of food can no longer be associated with a particular grower? May growing location be used instead?**

No. If you do not know the identity of the grower associated with an article of food, you may opt to identify the consolidator or you may leave the data element empty. Section 801(m)(1) of the FD&C Act does not allow for growing location to be submitted in lieu of known grower information (21 U.S.C. 381; 21 CFR 1.281(a)(7), (b)(6)).

7.

## Product Identity

### 7.1 [Question/response added April 2004] **If my shipment consists of just one type of food in the same size container but under different brand names, do I have to submit a separate prior notice for food labeled with each brand name?**

The prior notice regulations do not require submission of the trade or brand name of the article; therefore, the fact that food is labeled under different brand names does not mean that each different label is a separate article of food for the purpose of submitting prior notice. However, a separate prior notice must be submitted for each article of food that has a different complete FDA product code, different package size, or different manufacturer or grower. (21 CFR 1.281(a); see also 68 FR 59003).

**7.2 [Question/response added April 2004] How many prior notice submissions are required and what is the estimated quantity of food shipped in each of the following four scenarios:**

**I sell fish to grocery stores in the US. The grocery stores will order the fish in bulk. The fish is packed shipped to the U.S. in one of the following manners:**

- a. Bulk tote with 1,000 pounds of whole salmon**
- b. 25--50 lb cardboard boxes containing 2-3 lb and 3-4 lb whole salmon (not individually wrapped); fish normally will be sold individually in a grocery market in a display case of ice**
- c. 15--50lb cardboard boxes containing salmon fillets of various weights (not individually wrapped)**
- d. Salmon fillets sold on styro-trays in a poly bag of various weights (typically 2-3 salmon fillets in a package); larger salmon may be cut and put in styro trays as well**

- a. You would be required to submit 1 prior notice. The estimated quantity would be 1,000 lbs of whole salmon.
- b. You would be required to submit 1 prior notice. The estimated quantity would be 25 boxes of 50 lbs whole salmon.
- c. You would be required to submit 1 prior notice. The estimated quantity would be 15 boxes of 50 lbs salmon fillets.
- d. If the trays are unlabeled and sold by bulk weight, then 1 prior notice submission is required and the estimated quantity would be the bulk weight of the shipment. If the trays are labeled for retail sale, 1 prior notice submission is required and the estimated quantity would be the number of trays and the average tray weight.

8.

**Changes to Prior Notice Submissions:**

**8.1 Which changes require me to resubmit prior notice and which changes don't?**

Changes in the estimated quantity, anticipated arrival information, or planned shipment information do not require resubmission of prior notice after FDA has confirmed your prior notice submission for review (21 CFR 1.282(a)(1)(i)-(iii)). For all other changes (e.g., if the identity of the manufacturer changes), you should cancel the prior notice and you must resubmit prior notice if you still intend to import or offer the food for import into the U.S. (21 CFR 1.282).

**8.2 Do I have to resubmit prior notice if the anticipated time of arrival changes?**

No. Prior notice does not need to be resubmitted if the anticipated arrival information changes (21 CFR 1.282(a)(2)(ii)). Although a new prior notice submission is not required, FDA staff may need time to respond to the changes in arrival information.

**8.3 What should I do if information changes after I submit prior notice?**

The interim final rule requires that if required information (except estimated quantity, anticipated arrival information, and planned shipment information) changes after FDA has confirmed prior notice for review, the prior notice must be resubmitted (21 CFR 1.282(a)(2)).

If the prior notice was submitted as part of a multi-line ABI/ACS entry, and information about one or more of the products changes, the entry must be deleted and resubmitted. Prior notice for the new product can be submitted as part of a new entry. If you submitted the prior notice via the FDA Prior Notice System Interface, you should cancel the prior notice via the FDA Prior Notice System Interface (21 CFR 1.282(b)).

9.

### **Changes to Shipments:**

#### **9.1 May I add another article of food to an existing prior notice after the prior notice has been submitted to FDA?**

No. Each article of food requires a separate prior notice (21 CFR 1.281(a)(5) and 1.281(b)(4)) and receives a unique confirmation number (21 CFR 1.279(d)). However, FDA is allowing prior notices to be grouped in an Automated Broker Interface of the Automated Commercial System (ABI/ACS) entry, or in an "envelope" for the FDA Prior Notice System Interface (PNSI) entries and In-Bonds submitted through ABI/ACS, in order to reduce data entry for transmitters and to simplify CBP review at the border. For submissions through PNSI, no articles of food can be added to an envelope after FDA has provided the Prior Notice Confirmation Number(s). For submissions through ABI/ACS, no additional lines may be added after the entry is accepted by ACS.

#### **9.2 What can I do if I want to add another article of food to a shipment after prior notice was submitted to the FDA?**

New articles of food cannot be added to an entry, or prior notice envelope, after it has been submitted to FDA (21 CFR 1.282). If a new article of food is being added to a shipment for which prior notice(s) has already been submitted and confirmed, a separate prior notice must be filed for that article under **a new entry/envelope** (21 CFR 1.281(a) and (b)). The submission time for the new prior notice will be different from that of the rest of the shipment, and this may have an effect on the ability of the shipment to enter the United States (21 CFR 1.279). For example, if you add another food to a truck at 9:00 am, that food is not covered by timely prior notice until 11:00 am. The rest of the food on that same truck may be covered by prior notices submitted at 8:00 am and deemed timely at 10:00 am. It is recommended that the time for arrival be anticipated on the last article of food submitted and confirmed by FDA for review.

#### **9.3 What can I do if I want to remove an article of food from the information provided for a shipment?**

If the prior notice was submitted through the Automated Broker Interface of the Automated Commercial System (ABI/ACS), you can delete the prior notice using the existing entry delete procedures. If you submitted the prior notice via the FDA Prior Notice System Interface, you should cancel the prior notice via the Prior Notice System Interface (21 CFR 1.282(b)).

10.

### **FDA Prior Notice System Interface (PNSI) and Automated Broker Interface of the Automated Commercial System (ABI/ACS) Features:**

#### **10.1 If I need to revise some information on a prior notice, will some of the fields be filled in by**

## **the computer automatically or will I need to start from the beginning?**

The answer depends on how the prior notice submission is being made. If submitting through the CPB Automated Broker Interface of the Automated Commercial System (ABI/ACS), the ability to pre-fill or otherwise support submission will depend on the functionality of the software used by the filer. The ABI/ACS interface is concerned with the validity of the information in the submission, not with how it was generated.

If submitting through FDA's Prior Notice System Interface, the answer varies with the status of the submission. The Prior Notice System Interface will allow a transmitter to pre-enter information and save the draft until the time of actual submission. Before the draft is submitted, changes can be made easily to the draft because information previously entered will be pre-filled.

After the prior notice has been submitted to FDA, no changes can be made unless requested by FDA to correct an error found during the review process before a Prior Notice (PN) Confirmation Number issues to the transmitter. (21 CFR 1.282)

### **10.2 [Question/response added April 2004] My food is being shipped in several different containers. Does PNSI accept multiple container numbers?**

Not at this time. Until PNSI can be reprogrammed to accept multiple container numbers for a single prior notice, you may include only one container number per prior notice.

11.

#### **Confirmation:**

### **11.1 Will I receive confirmation that FDA has received the prior notice I submitted?**

Yes. FDA will notify the transmitter that the prior notice has been confirmed for review with a reply message that contains a Prior Notice (PN) Confirmation Number. For prior notice submissions through the CPB ABI/ACS, the PN Confirmation Number together with the "PN received" message will be made available to the transmitter (broker or filer) through the ABI/ACS. For prior notice submissions through the FDA Prior Notice System Interface (PNSI), a PN Confirmation Number will be provided to the transmitter through PNSI as soon as FDA confirms your prior notice for review.

### **11.2 Is a copy of the prior notice required to accompany the food?**

[Response updated April 2004] To ensure that entry proceeds as smoothly as possible, the carrier or individual should consider having a copy of the reply message that contains a PN Confirmation Number in his/her possession upon arrival.

For food carried by or otherwise accompanying an individual that is not for personal use, the individual must provide a copy of the PN confirmation to FDA or CBP (21 CFR 1279(f)). Food covered by prior notice submitted through the FDA Prior Notice System Interface must be accompanied by a copy of the reply message that contains the PN Confirmation Number (21 CFR 1.279(g)).

For international mail packages, the confirmation number must accompany the package (21 CFR

1.279(e)).

**11.3 [Question/response updated April 2004] Does receipt of a PN Confirmation Number mean that the food will not be examined or sampled? Does meeting all the requirements of prior notice mean that the article of food will not be held or examined further?**

No. Receipt of a PN Confirmation Number is evidence only that a prior notice has been received for FDA review. Based on review of the prior notice, FDA may determine that an article of food should not be allowed to proceed into the United States without further inspection and sampling at the border. The food may be refused under the prior notice regulation and section 801(m) of the FD&C Act and held if the prior notice is inaccurate or if it is untimely and FDA has not had sufficient time to receive, review, and respond to the prior notice information.

Furthermore, the food must meet the requirements of all other applicable regulations. If FDA decides to take no prior notice action for an article of food under 21 CFR 1.283 or 1.285(a), this decision has no bearing on whether the article of food is admissible or will be granted admission under other provisions of the FD&C Act or other U.S. laws. Thus, for imported food or food offered for import, FDA will continue its normal investigative and enforcement activities for food safety and security concerns and for determining whether the food is subject to refusal under section 801(a) of the FD&C Act.

**11.4 If receipt of the Prior Notice (PN) confirmation number does not mean the FDA has determined that timely prior notice was submitted or that the information submitted is accurate, what is the value of the PN Confirmation Number?**

The Prior Notice (PN) Confirmation Number is FDA's notice to you that your prior notice was submitted and received for review by FDA. It is the signal to you that the time frame for prior notice for the food covered by that prior notice submission has started. In addition, the PN Confirmation Number provides a mechanism for prior notice data, submitted to FDA, to be matched with an entry submitted to CBP. The timeliness of prior notice can not be assessed until the food actually arrives in the United States and, often, the accuracy of the prior notice can not be fully determined until the food is examined upon arrival.

**11.5 [Question/response added April 2004] Do I need to submit samples to accompany my prior notice submission or to accompany the shipment?**

No. There is no need or opportunity to send samples to FDA with the prior notice submission (21 CFR 1.280(a)). FDA will use the information submitted for prior notice to determine whether to inspect or sample the article of food when it arrives in the U.S.

## **E. CONSEQUENCES**

### **1.**

#### **Inadequate prior notice:**

##### **1.1 What does FDA consider to be inadequate prior notice?**

[Response updated April 2004] Inadequate prior notice is when:

1. There is no prior notice submitted for an article of food imported or offered for import into the United States; and/or
2. The information submitted in the prior notice is inaccurate; and/or
3. The prior notice is not submitted in concurrence with the required timeframes.

FDA's enforcement policies on inadequate prior notice are stated in a separate guidance document. This Compliance Policy Guide was announced in the **Federal Register** on December 15, 2003 (68 FR 69708) and is available on FDA's website at [http://www.fda.gov/ora/compliance\\_ref/cpg/default.htm](http://www.fda.gov/ora/compliance_ref/cpg/default.htm) or <http://www.cfsan.fda.gov/~pn/cpgpn.html>.

### **1.2 What are some examples of inadequate prior notice?**

[Response updated April 2004] The following examples of inadequate prior notice are for five articles of food (foods A, B, C, D, & E) arriving at the border by truck:

1. Prior notice was submitted for only 4 of the 5 articles of food (foods A, B, C, & D). Inadequate prior notice, e.g., no prior notice, was provided for food E.
2. Prior notice for food A was submitted and confirmed for FDA review with PN Confirmation Number 999. Food B arrives associated with PN Confirmation Number 999. Inadequate prior notice, e.g., inaccurate prior notice, was provided for food B.
3. Prior notice for food A was submitted and confirmed for FDA review at 9:00am on February 2, 2005. Food A arrives at the port of arrival at 9:30 am on February 2, 2005, but CBP has not received an examination decision response from FDA. Inadequate prior notice, e.g., untimely prior notice, was provided for food A.

FDA's enforcement policies on inadequate prior notice are stated in a separate guidance document. This Compliance Policy Guide was announced in the **Federal Register** on December 15, 2003 (68 FR 69708) and is available on FDA's website at [http://www.fda.gov/ora/compliance\\_ref/cpg/default.htm](http://www.fda.gov/ora/compliance_ref/cpg/default.htm) or <http://www.cfsan.fda.gov/~pn/cpgpn.html>.

### **1.3 What happens to food that is imported or offered for import without adequate prior notice?**

[Response updated April 2004] Articles of food arriving with no prior notice, inaccurate or incomplete prior notice, or untimely prior notice may be refused admission and, other than food arriving by international mail or carried by or otherwise accompanying an individual, if refused, will be handled in one of the following ways:

1. Immediately exported, with CBP concurrence, from the port of arrival; or
2. Held within the port of entry, unless directed by CBP or FDA. (21 CFR 1.283(a)(1)(i)-(iii) and (b))

As stated in the IFR, refused food is considered general order merchandise under section 490(a) of the Tariff Act (19 U.S.C. 1490(a)) and may move only under appropriate custodial bond (21 CFR 1.283(a)(2)). If the refused article is moved, the submitter must notify FDA of the hold location within 24 hours of refusal. The refused food may not be delivered to the importer, owner, or ultimate consignee. (21 CFR 1.283(a)(2)(ii))

For food that is carried by or accompanies an individual arriving in the U.S. and the food is not for personal use, if adequate prior notice is not submitted or if the PN confirmation number cannot be provided to FDA or CBP, the food is subject to refusal. If before leaving the port, the individual does not arrange to have the food held at the port or exported, the article may be destroyed (21 CFR 1.283(b)).

For food arriving by international mail, if prior notice is inadequate or if the PN Confirmation Number is not affixed, the article will be held for FDA inspection and disposition. If refused and there is a return address, the parcel may be returned to sender. If there is no return address or the food in the shipment appears to present a hazard, FDA may dispose of or destroy the parcel at its expense. If FDA does not respond within 72 hours of the CBP hold, CBP may return the parcel back to the sender or, if there is no return address, destroy the parcel, at FDA expense.

FDA's enforcement policies on inadequate prior notice are stated in a separate guidance document. This Compliance Policy Guide was announced in the **Federal Register** on December 15, 2003 (68 FR 69708) and is available on FDA's website at [http://www.fda.gov/ora/compliance\\_ref/cpg/default.htm](http://www.fda.gov/ora/compliance_ref/cpg/default.htm) or <http://www.cfsan.fda.gov/~pn/cpgpn.html>.

#### **1.4 Will my food be held if it arrives earlier than the anticipated time of arrival I submitted?**

If arrival occurs before the anticipated arrival time, the food could be refused and held until the prior notice timeframe has elapsed (21 CFR 1.279) or until processing is complete, whichever ever comes first. However, if the prior notice has been fully processed by FDA, the food will not be refused because the anticipated arrival time has not yet come (21 CFR 1.283(a)(1)(ii)). However, if FDA plans to examine the food, it may be held to allow time for FDA staff to arrive.

#### **1.5 What does it mean if, after I receive a Prior Notice (PN) Confirmation Number, FDA later refuses the same article of food?**

The PN Confirmation Number only confirms that the submission is complete and facially valid. If FDA's review process determines that the prior notice is inaccurate after receipt of the prior notice is confirmed by issuance of the PN Confirmation Number, the article of food is still subject to refusal under 21 CFR 1.283(a)(1)(ii).

#### **1.6 Who will be notified if FDA determines that a food needs to be held for examination when it arrives at the border?**

FDA will communicate the decision to examine articles of food to CBP.

2.

### **Transition Period and Exercise of Enforcement Discretion:**

#### **2.1 Does FDA plan to provide a transition period for enforcing the prior notice regulation?**

[Response updated April 2004] FDA is providing an initial transition period during which we are emphasizing education regarding the requirements of prior notice to achieve compliance. Specific details regarding that transition period is provided in an FDA Compliance Policy Guide. The Compliance Policy Guide was announced in the Federal Register on December 15, 2003 (68 FR 69708) and is available on FDA's website at <http://www.cfsan.fda.gov/~pn/cpgpn.html> or

[http://www.fda.gov/ora/compliance\\_ref/cpg/default.htm](http://www.fda.gov/ora/compliance_ref/cpg/default.htm).

**2.2 Will import food shipments be held or refused admission for lack of prior notice if they are in route to the U.S. before December 12, 2003 but do not arrive until after the prior notice rule is in effect?**

Rather than hold or refuse admission of shipments that are in route before December 12, and arrive on or soon after December 12, FDA intends generally to provide information on the requirements of prior notice.

**2.3 [Question/response added April 2004] What enforcement discretion is described in FDA's Compliance Policy Guide "Guidance for FDA and CBP Staff/Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002?"**

The Compliance Policy Guide describes and provides guidance on FDA's and CBP's strategy for enforcing and otherwise achieving compliance with the Prior Notice IFR. The guidance does not establish legally enforceable responsibilities nor does it create or confer any rights for or on any person and does not operate to bind FDA, CBP, or the public. The document does provide a tiered approach to enforcement of the interim final rule. It describes the types of violations the agencies believe are best addressed by education and the types of violations best addressed by refusing a shipment or assessing civil monetary penalties. However, the guidance also provides that staff may take different or additional actions if they believe particular circumstances warrant them.

**2.4 [Question/response added April 2004] Does the enforcement discretion described in FDA's Compliance Policy Guide mean that registration of foreign food facilities is not required until August 2004?**

No. Exercise of enforcement discretion does not mean that the Agency will encourage a person to break the law. It means, in the case of failure to register a foreign food facility as required by section 801(l) of the Federal Food, Drug, and Cosmetic Act, that the suggested action by the Agency is to provide education regarding the failure to register, as opposed to assessing penalties against the violator or refusing the food. The guidance also suggests that the Agency should analyze data for compliance action. For example, if after the failure to register has been communicated to the person or persons who are responsible for registration of the facility additional shipments of food are imported or offered for import, the Agency may refuse that food rather than continue the educational process.

### **III. ELECTRONIC ACCESS**

Persons with access to the Internet may obtain this document "Prior Notice Questions and Answers" at <http://www.cfsan.fda.gov/~dms/guidance.html>.

### **IV. [Section added April 2004] WHERE TO GET ADDITIONAL INFORMATION**

## **A. PRIOR NOTICE HELP DESK**

- Phone: 800-216-7331 or 301-575-0156
- Fax: 301-210-0247
- E-mail: <http://www.cfsan.fda.gov/~furls/helpf2.html>

## **B. USEFUL WEBSITES**

FDA Home Page

<http://www.fda.gov/>

FDA website on the Bioterrorism Act

<http://www.fda.gov/oc/bioterrorism/bioact.html>

FDA's Prior Notice System Interface (PNSI)

<http://www.access.fda.gov/>

FDA's Prior Notice Compliance Policy Guide

<http://www.cfsan.fda.gov/~pn/cpgpn.html>

or

[http://www.fda.gov/ora/compliance\\_ref/cpg/default.htm](http://www.fda.gov/ora/compliance_ref/cpg/default.htm)

Prior Notice Interim Final Rule

<http://www.cfsan.fda.gov/~pn/pnfr.html>

FDA/CFSAN website on the Bioterrorism Act, including Prior Notice

<http://www.cfsan.fda.gov/~dms/fsbtact.html>

FDA/CFSAN main Prior Notice website

<http://www.cfsan.fda.gov/~pn/pnoview.html>

FDA/CFSAN website on Prior Notice and Sending Food Gifts Through International Mail

<http://www.cfsan.fda.gov/~pn/pngift.html>

FDA/CFSAN website that contains this Guidance Document

<http://www.cfsan.fda.gov/~dms/guidance.html>

FDA/CFSAN form for submitting questions on Prior Notice

<http://www.cfsan.fda.gov/~furls/helpf2.html>

CBP Home Page

<http://www.cbp.gov/>

CBP Broker Management Handbook

[http://www.cbp.gov/ImageCache/cgov/content/import/brokers/broker\\_5handbook\\_2epdf/v1/broker\\_5handbook.pdf](http://www.cbp.gov/ImageCache/cgov/content/import/brokers/broker_5handbook_2epdf/v1/broker_5handbook.pdf)

CBP website on Becoming a Broker

[http://www.cbp.gov/xp/cgov/import/broker\\_management/brokers.xml](http://www.cbp.gov/xp/cgov/import/broker_management/brokers.xml)

\* This is a revision of the FDA guidance "[Prior Notice of Imported Food Questions and Answers](#)," which FDA issued on December 12, 2004.

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