

Prior Notice of Imported Food Under The Bioterrorism Act

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The Food and Drug Administration (FDA) has published a proposed rule that FDA would receive notice of any food imported or offered for import into the United States. 68 Fed. Reg. 5428 (Feb. 3, 2003). Comments on this proposed rule must be submitted to FDA by **April 4, 2003**.[\[1\]](#)

This proposed rule, together with a [proposed rule that would require registration of food facilities](#), are the first two of four anticipated proposed rules implementing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act). The Bioterrorism Act was passed in response to the events of September 11, 2001, and Title III of the Bioterrorism Act includes provisions designed to protect the U.S. food supply from acts of bioterrorism or intentional contamination.

This memorandum summarizes the Prior Notice Proposed Rule. The Prior Notice Proposed Rule would affect the importation of food products, including dietary supplements, animal feed products, including pet food, live animals to be processed into food, and substances that migrate into food from contact material. The Proposed Rule would impose requirements that are quite different from the existing notification procedures importers now follow when reporting their food imports through FDA's Operational and Administrative System for Import Support (OASIS) system and the U.S. Customs Service's (Customs) Automated Broker Interface (ABI) of the Automated Commercial System (ACS). Essentially, the Prior Notice Proposed Rule would create a new, separate reporting system wholly independent of the Customs/FDA notification system currently applicable to imports. Comments on the Prior Notice Proposed Rule are due to FDA by **April 4, 2003**.

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FDA's Proposed Regulations:

[Sec. 307. Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 \(PDF Version\)](#)

Summary Of The Prior Notice Proposed Rule

The key features of the Prior Notice Proposed Rule are:

- The purchaser or importer of an article of food (or their agent) who resides or maintains a place of business in the United States generally would be responsible for submitting the notice.
- The notice would have to be submitted by noon of the calendar day before the day of import arrival.
- The notice would be submitted electronically through a Prior Notice System FDA will establish.
- The FDA Prior Notice System would provide an automatic electronic acknowledgment of receipt of a complete prior notice submission.
- The prior notice would have to contain information that identifies:
 - The individual and firm submitting the prior notice;
 - The entry type and Customs ACS entry number or other Customs identification number associated with the import;
 - If the article of food is under hold, the location where it is being held;
- The identity of the article of food being imported or offered for import, including:
 - The complete FDA product code;
 - The common or usual name or market name;
 - The trade or brand name, if different from the common or usual name;
 - The quantity described from smallest package size to largest container; and
 - The lot or code numbers or other identifier of the food if applicable;
 - All known growers;
 - The country from which the article originates;
 - The shipper;
 - The country from which the article of food was shipped;
 - The anticipated arrival information;
 - Information related to entry process;
 - The importer, owner, and consignee; and
 - The carrier.
- The notice could be amended only to update the anticipated port of entry, to change the anticipated time of arrival, or to make certain changes to the product identity.
- Amendments changing product identity would be allowed only if complete information about product identity did not exist by the deadline for prior notice for the planned shipment.
- Information regarding identity of the food could be amended only once;
- Any amendments or updates would have to be submitted no later than 2 hours prior to arrival.

Current Importation Practice And The Bioterrorism Act

When an FDA-regulated product is imported or offered for import, generally a broker submits entry information to Customs and to FDA. Under Customs laws and regulations, entry of the merchandise may be made up to 15 days after importation. Brokers report information about the import to Customs electronically via the ABI. If the import is an FDA-regulated food product, the broker submits, typically at the same time, information to FDA through the OASIS system.. As a result, there are times when FDA does not receive information about a food import until days after the food has arrived in the United States.

In section 307 of the Bioterrorism Act, Congress amended § 801 of the Federal Food, Drug and Cosmetic (FDC) Act (21 U.S.C. § 381(m)) to close this time gap. The requirements of the statute include the following:

- Requires prior notice of imported food shipments beginning on December 12, 2003;
- If adequate notice is not provided, requires that the food be refused admission and held until adequate notice is given;
- Amends the FDC Act to make it a prohibited act to import or offer for import an article of food in violation of the prior notice requirements; and
- Mandates that prior notice be submitted no less than 8 hours and not more than 5 days before it is imported or offered for import, if final rules are

not in effect on December 12, 2003.

What Food Is Subject To The Prior Notice Proposed Rule? (Proposed 21 C.F.R. § 1.276)

Prior notice requirements would apply to all food that is brought across United States borders (with the following four exceptions) **regardless of whether the food is intended for consumption in the United States**. Even food brought into the United States to be put into foreign trade zones, or for transshipment or immediate reexport, would be deemed imported or offered for import and thus would have to comply with the prior notice requirements.

Four categories of food would not be subject to the prior notice requirements:

- Food individual travelers carry in their personal baggage for their own personal enjoyment.[\[2\]](#)
- Imported foods subject to the Federal Meat Inspection Act;
- Imported foods subject to the Poultry Products Inspection Act; and
- Imported foods subject to the Egg Products Inspection Act.

What Definitions Apply To The Prior Notice Proposed Rule? (Proposed 21 C.F.R. § 1.277)

FDA seeks comment on several proposed definitions that bear upon the scope of the Prior Notice Proposed Rule.

The prior notice would be required to include the country from which the article of food was shipped. FDA is requesting comment on whether this term should include the countries of intermediate destination.

The Proposed Rule would define “food” consistently with the definition in section 201(f) of the FDC Act (21 U.S.C. § 321(f)). Examples of food imports that would be subject to the prior notice requirements include the following:

- fruits and vegetables;
- fish and shellfish;
- dairy products;
- eggs;[\[3\]](#)
- raw agricultural commodities for use as food or components of food;
- infant formula;
- alcoholic beverages;
- non-alcoholic beverages and bottled water;
- bakery goods, snack foods, candy, and canned foods;

- pet food;
- animal feed and feed ingredients;
- live food animals (such as hogs and elk);
- dietary supplements and dietary ingredients;
- food components; and
- substances that migrate into food from food packaging and any other articles that contact food.

FDA is proposing that the United States would be designated as the originating country for wild-caught fish or seafood that is: harvested in the waters of the United States; caught by a United States flagged vessel; or processed aboard a United States flagged vessel. Otherwise, the originating country would be the country under which the vessel is flagged. FDA recognizes that this proposed definition may differ from Customs' definition of "country of origin" and specifically seeks comment.

"Port of entry" would be defined as the port where food first arrives in the United States. Customs' statutes permit products to be imported into one port and then transported to another port under a custodial bond before a consumption entry is filed. FDA requests comments on this proposed distinction.

What Are The Consequences Of Failing To Submit Adequate Prior Notice? (Proposed 21 C.F.R. § 1.278)

If an food is imported or offered for import with no prior notice or inadequate prior notice, the food would be refused admission into the United States. If the food is refused admission, the Proposed Rule would require that the food be held at the port of entry unless FDA directs its removal to a secure facility. The carrier or the person who submitted the prior notice would have to arrange and pay for the transportation and storage of the food under appropriate custodial bond and promptly notify FDA of the storage location. FDA seeks comment on whether Congress intended that FDA or Customs take custody of food refused admission.

In the preamble to the Prior Notice Proposed Rule, FDA notes that Congress provided no kind of application, petition, or appeal of FDA's determination that an article be refused admission for failure to be in compliance with prior notice requirements. Consequently, FDA has proposed no provision for challenges to the agency's determinations (a possible area for comment).

Who Is Authorized To Submit Prior Notice For Food That Is Imported Or Offered For Import Into The United States? (Proposed 21 C.F.R. § 1.285)

If the food is imported for in-bond movement through the United States for export, the prior notice must be submitted by the arriving carrier or, if known, the in-bond carrier. The types of entries that cover these importations are known to FDA and Customs as Transportation for Exportation and Immediate Export.

FDA seeks comment on whether other persons should be authorized to provide prior notice.

When Must The Prior Notice Be Submitted To FDA? (Proposed 21 C.F.R. § 1.286)

FDA is proposing that the prior notice would have to be submitted to FDA no later than noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry. Prior notice could not be submitted more than 5 days before the anticipated date of arrival.

FDA states that it considered the potential effects of this deadline upon imported food. FDA believes that in most circumstances information

regarding imports is generated when the food to be imported is ordered or purchased, not when it is shipped to the United States, and that orders are normally placed a day or more prior to shipment. FDA invites comments on the proposed deadline.

Further, FDA recognizes that this proposed deadline will have the most impact on those who import food by truck and rail across United States land borders, and believes there will be less effect at airports, and almost no effect at water ports. However, even for imports via land, FDA believes that the information required in the prior notice will be, in most cases, sufficiently fixed by noon of the calendar day before arrival to allow for submission of prior notice that meets the proposed requirements.

FDA is proposing that prior notice may not be submitted until **all** of the information required by proposed 21 C.F.R. § 1.288 (discussed below) exists. Certain amendments and updates to a submitted prior notice would be permitted under very limited circumstances also described further below.

How Must The Prior Notice Be Submitted? (Proposed 21 C.F.R. § 1.287)

FDA is proposing that if its Prior Notice System is unable to receive a prior notice electronically, the prior notice, amendments, and updates would have to be submitted using a printed version of the Prior Notice Screen, delivered in person, by fax, or by E-mail to the FDA field office with responsibility over the geographical area in which the anticipated port of entry is located. FDA anticipates the system would provide a date and time stamped any electronic confirmation of the system's receipt of each prior notice, amendment, or update, which the system will send to the submitter automatically. FDA cautions that a confirmation through the Prior Notice System is **not** the agency's decision regarding the adequacy or timeliness of the prior notice.

What Information Must Be Submitted In A Prior Notice? (Proposed 21 C.F.R. § 1.288)

The Proposed Rule lists the information or "data elements" that would be required to be included in each prior notice. Some of these data elements are taken directly from the statute; others are information that FDA believes would be necessary for efficient enforcement. FDA is proposing that a prior notice that does not contain all requisite information would be considered inadequate. FDA solicits comments on this approach.

FDA emphasizes that a prior notice would have to be submitted for **each** article of food, **not** a whole shipment. Thus, any food product identified by a specific FDA product code and quantity description **produced by a single manufacturer (or grower, if fresh)** associated with a single entry line number (Customs entry number plus ACS line number plus OASIS/FDA line number) would have to be covered by a prior notice. In the example FDA gives in the preamble, assume a shipment consists of the following:

- 1,000 cases of 48/6 oz. cans each of Brand X tuna;
- 240 cases of 24/15.25 oz. cans each of yellow corn;
- 300 cases of 24/12 oz cans each of Brand X tuna, and
- 1,500 cases of 48/6 oz. cans each of Brand P tuna.

Under the example, FDA would require four separate prior notices. If one of the products, such as the corn, comes from two different manufacturers, an additional prior notice would be needed.

Generally, for **all firms** that the Proposed Rule would require be identified in a prior notice (including **the submitter, importer, owner, consignee, manufacturer, growers (if known), and shipper**), FDA is proposing that the prior notice include not only the firm's name, but also its **address, phone number, fax number, and E-mail address**, and if the firm is required to register a facility associated with the food, **the facility's registration number**.

FDA is proposing to require the following information in the prior notice:

- a. The submitter;

- b. The Customs entry type;
- c. The Customs ACS entry line number or other Customs identification number;
- d. The location where the food is being held, if applicable;
 - FDA is proposing to require that, if the food has been refused admission due to inadequate prior notice and thus being held at the port of entry or in a secure facility, the submitter would be required to inform FDA both that the food is under hold, and the location where the shipment is being held. Additionally, FDA is proposing to require the date that the article would arrive at that location, as well as the identification of a contact at that location.
- e. The product identity;
 - FDA is proposing the following data elements to identify the food being imported or offered for import:
- i. The complete FDA product code^[4];
- ii. The common or usual or market name;
- iii. The trade or brand name;
- iv. The quantity^[5]; and
- v. The lot or code numbers or other identifier.
- f. The manufacturer
- g. The grower(s), if known
 - Section 801(m)(1) of the FDC Act (21 U.S.C. § 381(m)(1) requires that a prior notice include the identity of all growers of each food, if known. Thus, in FDA's view, this information is not optional; if it is known, it must be submitted. If a product is sourced from more than one grower, the prior notice would have to provide the identification of all growers, if known.^[6]
 - The prior notice would have to include the growing location if it is different from the grower's business address, if known at the time of submission of the prior notice.
 - FDA solicits comments on two issues. First, FDA asks whether the statute gives FDA any flexibility to exempt or otherwise treat differently processed foods produced with products from more than one grower. Second, FDA asks whether the term "grower" includes **a harvester or collector of wild products, e.g., some fish and botanicals.**
- h. The originating country;
- i. The shipper;
- j. The country of shipping;
- k. Anticipated arrival information;

The Proposed Rule would require identification of the anticipated port of entry, the anticipated arrival date, and the anticipated time of arrival. FDA is proposing to require the prior notice be updated if any of the anticipated arrival information changes after submission of the prior notice.
- l. The port where Customs entry will be made;
 - The port where the food enters the United States may be different from the port where entry will be made for Customs purposes. The Proposed

Rule would require identification of both ports.

m. The anticipated date of Customs entry;

n. The importer, owner, and consignee;^[7] and

What Changes Are Allowed To A Prior Notice After It Has Been Submitted To FDA? (Proposed 21 C.F.R. § 1.289)

FDA would allow changes to a submitted prior notice under only two, very limited, circumstances. First, amendments would be appropriate when complete product identity will not exist by the deadline for the submission of a prior notice. FDA believes that these situations largely involve fresh produce and fish harvested in countries close to the United States, *e.g.*, Mexico and Canada. Second, a submitted prior notice could be updated to change arrival information.

For any other changes to the information in the prior notice, the submitter would have to cancel the initial prior notice and submit a new one.

Under What Circumstances Must You Submit A Product Identity Amendment To Your Prior Notice After You Have Submitted It To FDA? (Proposed 21 C.F.R. § 1.290)

FDA would permit **one** amendment to a previously submitted notice in order to make certain limited changes to the identity of the food. If all the information about the identity of the food does not exist by noon of the calendar day before the day of arrival, the submitter would have to indicate at the time the initial prior notice is submitted, his or her intention to amend the information. To accomplish this partial amendment to product identity, FDA is proposing that the last two digits of the FDA product code and other product identity information that provides the specific identity of the article could be amended. The submitter would **not** be able to change completely the identity of the article. FDA gives several examples of how this limitation would work.

- Prior notice is submitted for “lettuce” by noon the calendar day prior to arrival, but the specific variety of lettuce that will be shipped does not exist because the growers have not yet harvested their crops. At or before the time when the article is placed in the carrier for shipment, however, the complete identity of the article exists and the prior notice must be amended to identify the specific type of lettuce (*e.g.*, romaine or leaf).
- The prior notice identifying the food as lettuce may not be amended to identify a new food, such as pears. A new prior notice must be submitted (and by noon of the calendar day before arrival at the United States port).
- If a food is not covered by a specific FDA product code, *e.g.*, a root vegetable not more specifically described in the FDA product code builder, then the last two numbers of the product code may be provided as “99” - root vegetables, not elsewhere classified. This prior notice cannot be amended later to identify the product as carrots because, even though carrots are root vegetables, there is an FDA product code that is specific to carrots and thus it should have been used in the initial notice.

What Is The Deadline For Product Identity Amendments Under § 1.290? (Proposed 21 C.F.R. § 1.291)

FDA is proposing a 2-hour before arrival minimum deadline for product identity amendments. 68 Fed. Reg. at 5438; proposed 21 C.F.R. § 1.291. FDA recognizes that this limitation on amendments may affect the practice of “topping off a container” by filling unused space in the container or truck bed with last-minute shipments of other food products not covered by a prior notice. FDA solicits comment on how common “topping off” is and the quantities of food involved.

How Do You Submit A Product Identity Amendment Or An Arrival Update To A Prior Notice? (Proposed 21 C.F.R. § 1.292)

FDA is proposing that a product identity amendment or an arrival update to a prior notice could only be submitted electronically to FDA through the Prior Notice System.

What Are The Consequences If You Do Not Submit A Product Identity Amendment To Your Prior Notice? (Proposed 21 C.F.R. § 1.293)

FDA is proposing that if the importer, purchaser, or its United States agent, informed FDA in a prior notice that the submission would be amended, but subsequently does not amend it appropriately and within the applicable timeframe, then the prior notice would be inadequate. The food would be refused admission and held at the port of entry unless FDA directs its removal to a secure facility.

What Must You Do If The Anticipated Arrival Information Submitted In Your Prior Notice Changes? (Proposed 21 C.F.R. § 1.294)

FDA is proposing to require the submitter to update anticipated arrival information submitted in a prior notice, if the anticipated information changes after the submission. FDA is proposing that if the time of arrival is expected to be more than 1 hour earlier or more than 3 hours later than the anticipated time of arrival, would have to be updated.

Submitting Comments

The Prior Notice Proposed Rule would represent a dramatic departure from current import practices. Any entity importing food or products that come in contact with food would have to alter their import procedures. FDA devotes a significant part of the Proposed Rule to an analysis of these many impacts and burdens. The agency devotes additional analyses to the economic harm likely to result to those involved in the importation of fish, seafood, and produce. We do not summarize that economic analysis here, but it may be useful to review FDA's conclusions closely to determine the extent, if any, to which the agency has understated or overstated the costs of complying with the Prior Notice Proposed Rule.

[Submit Comments Electronically](#)

Submit Written Comments:

Submit written comments in duplicate [individuals may submit one copy] to: Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, Maryland 20852 ATTN: Docket No. 02N-0278

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[1] Comments on FDA's estimate of the cost of the proposed rule to industry must be submitted to the Office of Management and Budget's Office of Information and Regulatory Affairs by March 5, 2003.

[2] When travelers bring food into the United States in their personal baggage to sell or distribute, the travelers would be subject to the prior notice requirements.

[3] While FDA includes whole eggs in its proposed definition of food that would be subject to the prior notice requirements, it exempts egg products in proposed 21 C.F.R. § 1.276(b)(4).

[4] FDA is proposing to require the submission of the complete FDA product code as an element of the identity of the product. The FDA product code is a unique code used for classification and analysis of merchandise. The FDA product code is currently available via the Internet at www.accessdata.fda.gov/scripts/ora/pcb/pcb.htm as a "buildable" code that is used to describe the food by industry, industry class, subclass, container/packaging, process, and specific product.

The filer currently submits the FDA product code to Custom's ACS when entry is made; it subsequently is transmitted to FDA's OASIS for each entry line. FDA proposes that if all of the information concerning the product identity exists by noon of the calendar day before the article will arrive at

the port of entry, it would have to be included in the prior notice and the prior notice could not be subsequently amended. If any of the product identity information does not exist by the deadline, the information that does exist would have to be provided to FDA, and the submitter would have to indicate that it will amend the prior notice.

FDA notes that, in determining whether the information exists, the standard set out in the Proposed Rule is not whether the submitter knows the information when filing the prior notice, but whether the information **could be known** by the submitter by the noon deadline. FDA solicits comment on this standard.

[5] FDA is proposing to require the submission of the quantity of food described from smallest package size to largest container as an element of the identity of the product. The number of container units and units of measure would be submitted in decreasing size of packing unit (starting with the largest). FDA requests comment on whether changes in quantity will occur after the deadline for prior notice and, if so, how commonly changes occur and how significant the changes usually are.

[6] In a proposal with serious implications for importers who use multiple growers for single shipments, the FDA Prior Notice System would accommodate submission of only up to **three different growers**.

[7] FDA would require identification of the importer, owner, or consignee to assure that food is refused admission for inadequate notice if not delivered to the importer, owner, or consignee illegally.