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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 02N–0278]

RIN 0910–AC41

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is issuing an interim final regulation that requires the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the United States. The interim final rule implements the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which requires prior notification of imported food to begin on December 12, 2003, even in the absence of a final regulation. The interim final rule requires that the prior notice be submitted to FDA electronically via either the Bureau of Customs and Border Protection (CBP) Automated Broker Interface (ABI) of the Automated Commercial System (ACS) or the FDA Prior Notice System Interface (FDA PN System Interface). The information must be submitted and confirmed electronically as facially complete by FDA for review no more than 5 days and no less than 8 hours (for food arriving by water), 4 hours (for food arriving by air or land/rail), and 2 hours (for food arriving by land/road) before the food arrives at the port of arrival. Food imported or offered for import without adequate prior notice is subject to refusal and, if refused, must be held.

DATES: This interim final rule is effective December 12, 2003. Submit written or electronic comments by December 24, 2003.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Deborah Ralston, Office of Regulatory Affairs, Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6230.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background

In the **Federal Register** of February 3, 2003 (68 FR 5428), the Department of Health and Human Services (FDA) and the Department of Treasury (U.S. Customs Service) issued a joint notice of proposed rulemaking requiring submission to FDA of prior notice of human and animal food that is imported or offered for import into the United States. The events of September 11, 2001, had highlighted the need to ensure that FDA had additional tools to help prevent a food-related bioterrorism event or other public health emergency. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107–188), which was signed into law on June 12, 2002. The Bioterrorism Act includes a provision in Title III (Protecting Safety and Security of Food and Drug Supply), Subtitle A'Protection of Food Supply, section 307, which changes when FDA will receive certain information about imported foods by requiring the Secretary of Health and Human Services (the Secretary), after consultation with the Secretary of the Treasury, to issue an implementing regulation by December 12, 2003, to require prior notification to FDA of food that is imported or offered for import into the United States. Under

the Homeland Security Act of 2002 (Pub. L. 107–296), the Secretary of the Treasury has delegated all relevant Customs revenue authorities to the Secretary of Homeland Security who has, in turn, delegated them to the Commissioner of the Bureau of Customs and Border Protection (CBP or Customs). Thus, we are issuing this interim final rule jointly with the Secretary of Homeland Security.

Section 307 of the Bioterrorism Act amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding section 801(m) (21 U.S.C. 381(m)) and amending section 301 (21 U.S.C. 331). (In the regulation itself, which is codified in Title 21 of the Code of Federal Regulations, the Federal Food, Drug, and Cosmetic Act is referred to as ''the act.'' Thus, when the regulation is quoted in this preamble the term ''the act'' will be used to refer to the Federal Food, Drug, and Cosmetic Act. However, in this preamble we refer to the Federal Food, Drug, and Cosmetic Act as ''the FD&C Act'' in the preamble to distinguish it from the Bioterrorism Act.)

The Bioterrorism Act also requires FDA to issue regulations requiring certain food establishments to register with FDA (section 305), directs FDA to issue regulations regarding maintenance of certain records (section 306), and grants FDA the authority to administratively detain food (section 303). FDA has published proposed rules implementing section 305 of the Bioterrorism Act (68 FR 5378, February 3, 2003), section 303 of the Bioterrorism Act (68 FR 25242, May 9, 2003), and section 306 of the Bioterrorism Act (68 FR 25188, May 9, 2003). The interim final rule implementing the food facility registration requirements is published elsewhere in this issue of the **Federal Register**.

A. Current Process—Admissibility Determinations Under Section 801(a) of the FD&C Act

Section 801(a) of the FD&C Act sets out current standards and procedures for FDA review of imports under its jurisdiction. Section 801(a) provides for examination of imports and also authorizes FDA to refuse admission of imports that appear, from examination or otherwise, to be, *inter alia*, adulterated or misbranded. When an FDA-regulated product is imported, generally customs brokers submit entry information to CBP on behalf of the importers of record. CBP then provides entry information to FDA to enable admissibility decisions to be made. Under CBP authorities, entry of the merchandise can be made up to 15 days after arrival.

CBP regulations provide for different kinds of entries. Commonly, merchandise is the subject of an entry for consumption or warehouse (*i.e.*, unrestricted, general use) under a basic importation and entry bond at the port of arrival. A warehouse entry is a CBP entry procedure as described in 19 CFR part 144. It allows imported product (with some restrictions) to be entered without payment of duty, provided it is kept in a bonded warehouse and not distributed. CBP authorities also allow for an Immediate Transportation or IT entry of merchandise for transportation under a custodial bond from the port of arrival to another port where the consumption or warehouse entry will be made or the product will be admitted into a foreign trade zone (FTZ) located outside of the port area. In addition, if the merchandise is going to an FTZ in the port area, FTZ admission documents are presented to CBP. Finally, a transportation and exportation (or T&E) entry may be filed if the merchandise is to be transshipped from the port of arrival through the United States to another port for export.

FDA currently receives electronic information about entries from CBP through CBP's ABI of the ACS. FDA receives this information through its Operational and Administrative System for Import Support (OASIS). The entry types currently transmitted through the ABI/ACS interface with OASIS include consumption entries and warehouse entries but not IT entries, T&E entries, or admissions into FTZs. The customs broker or self-filer electronically submits entry information to ABI/ACS, including: The identification of the product by the Harmonized Tariff Schedule (HTS) code; the entry type; the entry number (including both the ACS line number and the FDA line number); the arrival date; the port; the port of unlading; the carrier code; the vessel name and voyage, flight or trip number; importer and ultimate consignee; the quantity; value; country of origin; bill of lading or airway bill number; the manufacturer; the importer of record; and the ultimate consignee. The HTS codes are flagged to indicate which products will require FDA review; all FDA-regulated products are covered, not just foods. The additional information that is currently transmitted through the ABI/ACS interface to FDA includes: The FDA manufacturer; the FDA shipper, the FDA Country of Production (country of origin); the complete FDA product code; a description of the food in common business terms; the quantity for each FDA line, and, as ''Affirmations of Compliance,'' information specific to certain products, such as the Food Canning Establishment (FCE) Number.[1] CBP regulations do not mandate electronic transmission of entry information; therefore, some entries are filed in paper. If a ''paper'' entry is filed, it is customary for CBP to require that copies of entry documentation by submitted to FDA. The entry documents contain the same information as the electronic filing, typically the information required on CBP's Entry/Immediate Delivery (CF3461), and a copy of the foreign invoice. The paper entries may be presented at the time of arrival or after.

After information is transmitted from ABI/ACS, OASIS performs additional validations on the data. If no corrections from the customs broker or self-filer are needed, it screens the entry information against FDA admissibility criteria. If the FDA electronic review determines that further evaluation of the information or article of food is not necessary, the system transmits a message back through the FDA/CBP interface that the article of food ''may proceed without FDA examination.'' If further evaluation is necessary, FDA staff will review the entry information and may request additional information necessary to make an admissibility determination or may examine or sample the product. Section 801(b) of the FD&C Act provides for the release of FDA regulated products to the importer or owner, under bond, before the FDA admissibility decision is made. Accordingly, FDA examination may take place at a location to which the product has been moved. Because there are no restrictions on movement, the product may be at the border, within the confines of a port, at a public storage facility in the vicinity of the importer, or at the ultimate consignee's warehouse. Finally, if the FDA electronic review indicates that the product appears ''by examination or otherwise'' to be subject to refusal of admission under section 801(a) of the FD&C Act (*e.g.*, appears to be adulterated or misbranded), the FDA reviewer will evaluate the entry information based on FDA guidance, take appropriate action, and notify the importer as well as the customs broker.

Under current laws and regulations, FDA may receive the information about some food imports some days after the food has arrived in the United States,

[1] Affirmations of Compliance are data elements that a customs broker or self-filer currently uses when transmitting certain information to FDA through ABI/ACS to OASIS. Each provides a mechanism to indicate (or affirm) compliance with a specific FDA regulatory requirement.

has been moved from the port of arrival, and has been delivered to the ultimate consignee. While FDA may ultimately receive electronic entry notification of IT entries when the consumption entry is later filed, FDA does not receive electronic notification with information about food entered for transshipment for export or when the food is admitted to an FTZ.

The admissibility standard in section 801(a) of the FD&C Act largely focuses on whether the article of food appears to have been safely produced, contains no contaminants or illegal additives or residues, and is properly labeled. Section 801(a) provides that an article of food is subject to refusal of admission if it ''appears, from physical examination or otherwise': (1) To have been manufactured, processed, or packed under insanitary conditions; (2) to be forbidden or restricted in sale in the country in which it was produced or from which it was exported; or (3) to be adulterated or misbranded. The food adulteration and misbranding provisions (sections 402 and 403 of the FD&C Act) set out most of the FD&C Act's safety and labeling standards for foods.

B. Process After December 12, 2003—Prior Notice Determination Followed by Admissibility Determination

Section 801(m) provides that an article of food is subject to refusal of admission if adequate prior notice has not been provided to FDA. Thus, the refusal standard in section 801(m) focuses in the first instance on whether the requisite information has been provided in a timely fashion, while the refusal standard in section 801(a) focuses on whether the article was safely produced, contains no contaminants or illegal additives or residues, and is properly labeled.

By adding the prior notice requirement to the FD&C Act, Congress, in the Bioterrorism Act, changed when information about FDA-regulated food imports must be provided to FDA and what happens if the information is not provided. The prior notice provisions require that notice must be provided on imported food shipments to FDA before arrival. If adequate notice is not provided, section 801(m) of the FD&C Act provides that the food is subject to refusal, and that refused food must be held until adequate notice is given and may not be delivered to the importer, owner, or consignee. The stated purpose of requiring notice of imported food shipments before arrival in the United States is to enable FDA to conduct inspections of imported food at U.S. ports (see section 801(m)(1) of the FD&C Act). Thus, FDA intends to use prior notice information to make decisions about which inspections to conduct at the time of arrival. Currently, we intend to focus on conducting these inspections when our information suggests the potential for a significant risk to public health.

As explained in greater detail in the following paragraphs, FDA and CBP are coordinating FDA's new prior notice requirements with CBP's and FDA's existing entry requirements to the greatest extent possible. Thus, the interim final rule allows prior notice to be submitted electronically to FDA through either ABI/ACS or the FDA Prior Notice (PN) System Interface. The HTS codes will be flagged within ABI/ACS to indicate which HTS codes contain foods subject to prior notice requirements. In addition, the ABI/ACS interface will provide a new transaction for transmission of prior notice information on IT and T&E entries, and FTZ admissions, *e.g.*, the types of entries of which FDA was not aware or did not know about until many days after arrival in the United States. This will allow for FDA electronic screening and FDA staff evaluation of the information so that FDA can assess, before the food arrives, whether to inspect and to be prepared to conduct that inspection upon arrival.

FDA expects approximately 90 percent of prior notice submissions for all importations of foods to be transmitted by a customs broker or self-filer through the ABI/ACS interface to FDA. FDA estimates that only 10 percent (or less) of the total importations cannot be accommodated by the ABI/ACS interface and, therefore, will be submitted via the FDA PN System Interface.

In addition to requiring submission of the information currently sent to FDA for admissibility determinations, information identifying the grower (if known), the country from which the article is shipped, and anticipated arrival information is also required for prior notice. If all of the prior notice information is transmitted through the ABI/ACS interface, no additional transmission of information for admissibility determinations under section 801(a) of the FD&C Act will be necessary. If prior notice is submitted through the FDA PN System Interface, additional transmission through ABI/ACS may be necessary for CBP purposes and FDA's admissibility evaluation.

Regardless of the mode of transmission, the prior notice information will undergo both a validation process and screening in OASIS for food safety and security criteria. After the validation step is complete, the prior notice will be confirmed by FDA for review and a reply message sent to the transmitter indicating the prior notice has been received and confirmed for FDA review. The form of this reply messaging depends upon the mode of initial transmission: ABI/ACS or FDA PN System Interface. The clock starts for determining if prior notice was timely when this prior notice confirmation message is sent by FDA.

If the FDA system does not indicate that further evaluation of or action on the notice or article of food is necessary for prior notice purposes, the system will transmit a message back through the OASIS to ABI/ACS interface for CBP that the article of food ''may be conditionally released under section 801(b) of the act.'' However, if additional evaluation of the prior notice information is necessary, FDA headquarters staff, operating 24 hours a day, 7 days a week, will review and assess the information and may initiate an examination or other action by FDA or CBP of the article of food at the port of arrival or elsewhere, or in the case of rail shipments, within the confines of the closest appropriate examination site.

In addition, the OASIS system review will determine if further staff evaluation of the article of food is necessary for admissibility determinations under section 801(a) of the FD&C Act (*e.g.*, subject to the guidance in an import alert). If so, FDA staff in the appropriate district office will take action, which, in addition to the review and evaluation of the submitted information or other documentation, could include an examination of the article of food for admissibility purposes. This admissibility examination may take place at the border but may also take place at an examination site, a public warehouse, or other appropriate locations. If FDA determines that refusal under section 801(a) of the FD&C Act is appropriate, it will follow appropriate procedures.

II. Overview of the Interim Final Rule and Significant Changes Made to the Proposed Rule

The highlights of this interim final rule are described briefly in the following paragraphs and are discussed in more detail later in the preamble.

A. ''What Definitions Apply to This Subpart?'' (Section 1.276 Proposed as § 1.277)

- The term ''the act'' was not changed.
- The term ''calendar day'' was not changed.

• The term ''country from which the article originates'' was added and defined as ''FDA Country of Production.''

• The term ''country from which the article of food was shipped'' was revised to ''country from which the article is shipped.''

• The term ''FDA Country of Production'' replaces the term ''originating country.'' For an article of food that is in its natural state, the FDA Country of Production is the country where the article of food was grown, including harvested or collected and readied for shipment to the United States. If an article of food is wild fish that was caught or harvested outside the waters of the United States by a vessel that is not registered in the United States, the FDA Country of Production is the country in which the vessel is registered. If an article of food that is in its natural state was grown, including harvested or collected and readied for shipment, in a Territory, the FDA Country of Production is the United States. For an article of food that is no longer in its natural state, the FDA Country of Production is the country where the article was made; except that, if an article of food is made from wild fish aboard a vessel, the FDA Country of Production is the country in which the vessel is registered. If an article of food that is no longer in its natural state was made in a Territory, the FDA Country of Production is the United States.

• The term ''food'' has been redefined. The new definition excludes ''food contact substances'' as defined in section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)) and ''pesticides'' as defined in 7 U.S.C. 136(u).

• The term ''grower'' has been added to the interim final rule. It means a person who engages in growing and harvesting or collecting crops (including botanicals), raising animals (including fish, which includes seafood), or both.

• The term ''international mail'' has been added to the interim final rule. The term ''international mail'' means foreign national mail services, but not express carriers, express consignment operators, or other private delivery services.

• The term ''no longer in its natural state'' has been added to the interim final rule. The term means that an article of food has been made from one or more ingredients or synthesized, prepared, treated, modified, or manipulated. Examples of activities that render food no longer in its natural state are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. However, crops that have been cleaned (*e.g.*, dusted, washed), trimmed, or cooled attendant to harvest or collection or treated against pests, waxed, or polished are still in their natural state for purposes of the prior notice interim final rule. Likewise, whole fish headed, eviscerated, or frozen attendant to harvest are still in their natural state for purposes of the prior notice interim final rule.

• The term ''port of entry'' has been defined, as having the meaning given in 19 CFR 101.1.

• The term ''port of arrival'' has been added to the interim final rule. The interim final rule defines ''port of arrival'' to mean ''the water, air, or land port at which the article of food is imported or offered for import into the United States, *i.e.*, the port where the article of food first arrives in the United States.''

• The term ''registration number'' has been added to the interim final rule. Registration number refers to the registration number assigned by FDA under section 415 of the FD&C Act, 21 U.S.C. 350d, and 21 CFR part 1, subpart H.

• The term ''shipper'' has been added to the interim final rule. The interim final rule defines ''shipper'' as ''the owner or exporter of the article of food who consigns and ships the article from a foreign country or the person who sends an article of food by international mail to the United States.''

• The term ''United States'' has been added to the interim final rule. It defines ''United States'' as the Customs territory of the United States, *i.e.*, ''the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico.''

• The term ''you'' has been revised to reflect the removal of limitations on who is authorized to submit prior notice.

B. ''What is the Scope of This Subpart?'' (Section 1.277 Proposed as § 1.276)

This provision has been revised. Section 1.277(a) clarifies that the interim final rule applies to all food for humans and other animals that is imported or offered for import into the United States. This covers food for use, storage, or distribution in the United States, and includes food for gifts, 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. FTZ. Section 1.277(b) sets out the exclusions from prior notice. It excludes food for an individual's personal use when it is carried by or otherwise accompanies the individual when arriving in the United States (*i.e.*, for consumption by themselves, family and friends, not for sale or other distribution); food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (*i.e.*, for nonbusiness reasons) to an individual in the United States; food that is imported then exported without leaving the port of arrival until export; and meat food products, poultry products, and egg products that, at the time of importation, are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (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.*).

C. ''Who Is Authorized to Submit Prior Notice?'' (Section 1.278 Proposed as § 1.285)

This provision has been revised. The interim final rule has been revised to remove the restriction that the submitter be the U.S. importer or purchaser. The interim final rule provides that any person with knowledge of the required information may submit prior notice or have it transmitted on their behalf.

D. ''When Must Prior Notice Be Submitted to FDA?'' (Section 1.279 Proposed as § 1.286)

This provision has been revised. FDA had proposed that all information required in the prior notice be submitted to FDA no later than 12 noon of the calendar day before the day the article of food arrived at the border crossing in the port of entry. Under the interim final rule, prior notice must be submitted to FDA and confirmed for FDA review no less than 2 hours before arrival by land via road, no less than 4 hours before arrival by air and land via rail, and no less than 8 hours before arrival by water. If the article of food is arriving by international mail, the prior notice must be submitted before the food has been sent to the United States and the parcel must be accompanied by confirmation of FDA receipt of prior notice. With the exception of prior notice for international mail, prior notice may not be submitted more than 5 calendar days before the anticipated date of arrival at the anticipated port of entry. When an article of food that is carried by or otherwise accompanies an individual is subject to prior notice, the prior notice must be submitted within the timeframe established for the mode of transportation, and the food must be accompanied by a copy of the FDA confirmation including the PN Confirmation Number. Because we

reduced the timeframes for submitting prior notice in the interim final rule to the minimum amount of time that we need to meet our statutory responsibility to receive, review, and respond to prior notice submissions, the interim final rule does not provide for amendments or updates to the prior notice. However, as discussed in more detail in section D, FDA and CBP will be actively exploring ways to reduce prior notice timeframes, while fulfilling the Bioterrorism Act mandates.

E. How Must You Submit Prior Notice? (Section 1.280 Proposed as § 1.287)

FDA proposed that prior notice, amendments, and updates be submitted electronically to FDA through the FDA PN System. The interim final rule provides that prior notice must be submitted electronically, in English (except an individual's name, the name of a company, or the name of a street), through either CBP's ABI/ACS or the FDA PN System Interface. All information must be submitted using the Latin (Roman) alphabet. The interim final rule eliminates submission of duplicative information to FDA by those who can file import entry information through ABI/ACS. FDA and CBP are upgrading and interfacing their respective electronic systems so that information required for prior notice can be submitted through ABI/ACS. Information required by the interim final rule also can be submitted through the FDA PN System Interface. The interim final rule also provides that if a customs broker's of self-filer's system is not working or if ABI/ACS is not working, prior notice must be submitted through the FDA PN System Interface. If the FDA PN System Interface or OASIS is not operating, prior notice information must be submitted by e-mail, or by fax to the FDA, but not in person.

F. What Information Must Be in a Prior Notice? (Section 1.281 Proposed as § 1.288)

The interim final rule requires the following information to be submitted in the prior notice:

- Submitter (name of individual, individual's telephone, fax, e-mail, name/address of submitting firm);
- Transmitter, if different than submitter (name of individual, individual's telephone, fax, e-mail, name/address of transmitting firm);
- Entry type;
- CBP entry identifier, such as the CBP entry number or in-bond number;
- The identity of the article of food as follows: The complete FDA product code; the common or usual name or market name; the estimated quantity described from largest container to the smallest package size; and the lot or code numbers or other identifier of the food if required by the FD&C Act or FDA regulations;
- Manufacturer, for food no longer in its natural state (name, address, registration number, except that the requirement to provide registration number does not apply to an article of food that is imported for transshipment or other export;
- Grower, if known, for an article of food that is in its natural state (name and growing location);
- Consolidator may voluntarily be provided by the submitter, at the submitter's option, if the grower is not known (name and address);
- FDA Country of Production;
- Shipper (name, address, registration number; except that the requirement to provide registration number does not apply to an article of food that is imported for transshipment or other export;
- The country from which the article is shipped;
- Anticipated arrival information (port of arrival and crossing location within that port, date, and time) or, if the food is imported by international mail, the anticipated date of mailing;
- The name and address of the importer, owner, and ultimate consignee, unless the shipment is imported or offered for import for transshipment through the United States under a T&E entry, or, if the food is imported by international mail, the U.S. recipient (name and address);
- Mode of transportation;
- Carrier (SCAC/Standard Carrier Abbreviated Code or IATA/International Air Transportation Association code or, if codes are not applicable, the name and country of the carrier) (except for food imported by international mail);
- Planned shipment information as applicable (except for food imported by international mail), including 6-digit HTS code; and
- If the article of food is under hold for failure to submit prior notice or submit an adequate prior notice, the location where it is being held, the date the article has arrived or will arrive at the location, and the name of a contact individual at the location.

FDA eliminated from the interim final rule telephone and fax numbers and e-mail addresses for most firms, entry line numbers, trade or brand name, and consumption entry information (port of entry/anticipated date of entry for Customs purposes). FDA revised information requirements regarding the quantity, lot/code identifier, manufacturer, grower, and carrier in the interim final rule. FDA added mode of transportation and planned shipment information to the interim final rule. In the interim final rule, registration numbers are required only for manufacturer and shipper, if the shipper is a facility that is required to be registered under section 415 of the FD&C Act (21 U.S.C. 350d) and 21 CFR part 1, subpart H, for that article of food. For clarity, the interim final rule segregates the information required for food arriving by international mail (§ 1.281(b)) and also segregates the information required for food refused under section 801(m) of the FD&C Act (§ 1.281(c)).

Table 1A, which appears later in this preamble, describes the information required in prior notice.

G. ''What Must You Do If Information Changes After You Have Received Confirmation of a Prior Notice From FDA?'' (Section 1.282 Proposed as §§ 1.289 to 1.294)

This provision has been revised in the interim final rule. The proposed rule allowed one product identity amendment for certain product identity information that was not known at the time of submission and for arrival updates. Product identity amendments could be submitted up to 2 hours before arrival at the border. Arrival updates were required if the port of entry changed or if the time of arrival was expected to be more than 3 hours later or 1 hour earlier than the anticipated time of arrival.

The interim final rule does not provide for product identity amendments or arrival updates. Because we reduced the timeframes for submitting prior notice in the interim final rule to the least amount of time that we need to meet our statutory responsibility to receive, review, and respond to prior notice submissions, the interim final rule does not provide for amendments or updates. The interim final rule requires that if required information (except estimated quantity, anticipated arrival information including the anticipated date of mailing, and planned shipment information) changes after FDA has confirmed prior notice for review, the prior notice should be cancelled and a prior notice with the correct information must be submitted.

H. ''What Happens to Food That Is Imported or Offered for Import Without Adequate Prior Notice?'' (Section 1.283 Proposed as § 1.278)

FDA revised the proposed rule to provide for more specificity, to clarify

the status of refused food, and to provide a mechanism for FDA review after refusal. In the interim final rule, FDA identifies the consequences and procedures for the following situations:

1. Inadequate Prior Notice (No, Inaccurate, or Untimely Prior Notice)

Unless immediately exported with CBP concurrence, an article of food that is refused for inadequate prior notice shall be held in accordance with § 1.283.

2. Status and Movement of Refused Food

- A refused food is considered general order merchandise under section 490(a) of the Tariff Act of 1930, as amended (19 U.S.C. 1490(a)).
- The refused food must be moved under an appropriate custodial bond. FDA must be notified of the location where the food has been or will be moved within 24 hours of refusal. If the food is held, it must be taken directly to the designated location within 48 hours, shall not be entered, and shall not be delivered to any importer, owner, or ultimate consignee.

3. Segregation of Refused Foods

If a refused food is part of a shipment that contains other articles, the refused food may be segregated from the rest of the shipment within the port of arrival or at the hold location if different.

4. Costs

Neither FDA nor CBP are liable for transportation, storage, or other expenses resulting from refusal.

5. Export After Refusal

A refused food may be exported with CBP concurrence and supervision (unless CBP or FDA has administratively detained or seized the article under other authority).

6. No Post-Refusal Submission or Request for Review

If no prior notice submission or request for FDA review is submitted in a timely fashion after a food is refused, the food will be dealt with as set forth in CBP regulations relating to general order merchandise. It may only be sold for export or destroyed as agreed to by CBP and FDA.

7. Food Carried by or Otherwise Accompanying an Individual

For food that is not for personal use, if the article of food is refused because prior notice is inadequate or the individual cannot provide FDA or CBP with a copy of the PN confirmation, the article may be held at the port or exported. If the individual cannot make arrangements for holding or export, the food may be destroyed.

8. Post-Refusal Prior Notice Submissions

If an article of food is refused for no or inaccurate prior notice, the prior notice must be submitted or corrected and resubmitted to FDA and confirmed by FDA for review.

9. FDA Review After Refusal

After refusal, only the submitter, importer, owner, or ultimate consignee may submit a written request asking FDA to review whether the article is subject to the requirements of this subpart under § 1.276(b)(5) and § 1.277, or whether the prior notice submission is accurate. The interim final rule also sets out procedures and timeframes for the review process.

10. International Mail

In the case of food arriving by international mail, if prior notice is inadequate or if the PN Confirmation Number is not affixed, the article will be held by CBP for 72 hours 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.

11. Prohibitions on Delivery and Transfer

A refused article of food may not be delivered outside of the port where the article is held and may not be delivered to the importer, owner, or ultimate consignee or transferred by any person from the port or secure facility until FDA has examined the prior notice, determined the adequacy of the prior notice, and notified CBP and the transmitter that the article is no longer refused. After this notification by FDA to CBP and transmitter, entry may be made in accordance with law and regulation.

12. Relationship to Other Admissibility Provisions

A determination that an article of food is no longer subject to refusal under section 801(m)(1) of the FD&C Act is different than, and may come before, determinations of admissibility under other provisions of the FD&C Act or other U.S. laws. A determination that an article of food is no longer subject to refusal under section 801(m)(1) of the FD&C Act does not mean that it will be granted admission under other provisions of the FD&C Act or other U.S. laws.

I. What Are the Other Consequences of Failing to Submit Adequate Prior Notice or Otherwise Failing to Comply With This Subpart? (Section 1.284 Proposed as § 1.278)

The interim final rule provides that failure of a person who imports or offers to import an article of food to submit prior notice is a prohibited act under section 301(ee) of the FD&C Act (21 U.S.C. 331(ee)) and sets out the civil, criminal, and debarment actions that the United States may bring against persons who are responsible for the commission of a prohibited act.

J. What Happens to Food That Is Imported or Offered for Import From Unregistered Facilities That Are Required to Register Under 21 CFR Part 1, Subpart H? (Section 1.285)

The interim final rule also sets out the consequences concerning what happens at the border to food from facilities that are not registered as required under section 415 of the FD&C Act and 21 CFR part 1, subpart H. These are similar to provisions in the interim final rule for dealing with food that is refused for inadequate prior notice.

Table 1A of this document shows the information required by sections 1.281(a), (b), and (c). For clarity, the table also identifies under what circumstances certain information is not required, *e.g.*, registration numbers when the article of food is imported or offered for import for transshipment, storage and export, or further manipulation and export.

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Table 1A.--Prior Notice Information Required by Category

Information	Transshipment, Storage and Export, Manipulation and Export	Carried by or Accompanies an Individual	Food Not in Natural State	Food in Natural State	Mail	After Section 801(m) Refusal
§1.281 paragraph(s)	(a) and (c)	(a) and (c)	(a), (b), and (c)	(a), (b), and (c)	(b)	(c)
Submitter	Y	Y	Y	Y	Y	Y
Transmitter	Y	Y	Y	Y	Y	Y
Entry Type	Y	Y	Y	Y	Y	Y
Entry Identifier	Y	Y	Y	Y	Y	Y
FDA Product Code	Y	Y	Y	Y	Y	Y
Common, usual, or market name	Y	Y	Y	Y	Y	Y
Estimated Quantity	Y	Y	Y	Y	Y	Y[2]
Lot/Code #	Y	Y	Y	N	Y	Y
Manufacturer	Y	Y	Y	N	Y/N	Y
Manufacturer Registration #[1]	N	Y	Y/N	N	Y/N	Y
Grower, if known	Y	Y	N	Y	Y	Y
Cty of Production	Y	Y	Y	Y	Y	Y
Shipper	Y	Y	Y	Y	Y	Y
Shipper Registration #[1]	N	Y	Y	Y	Y	Y
Country Shipped	Y	Y	Y	Y	Y	Y
Port of Arrival	Y	Y	Y	Y	N	Y[2]
Date of Arrival	Y	Y	Y	Y	N	N
Time of Arrival	Y	Y	Y	Y	N	N
Date of Shipment	N	N	N	N	Y	N
Importer	N	Y	Y	Y	N	Y
Owner	N	Y	Y	Y	N	Y
Ultimate Consignee	N	Y	Y	Y	N	Y
U.S. Recipient	N	N	N	N	Y	Y
Mode of Transport	Y	N	Y	Y	N	Y
Carrier	Y	Y	Y	Y	N	Y
Airbill or Bill(s) of Lading	Y	N	Y	Y	N	Y[2]
Vessel/Voyage	Y	Y	Y	Y	N	Y[2]
Flight #	Y	Y	Y	Y	N	Y[2]
Trip #	Y	Y	Y	Y	N	Y[2]
Container #	Y	N	Y	Y	N	Y[2]
Car #	Y	N	Y	Y	N	Y[2]
License Plate #	Y	Y	Y	Y	N	Y[2]
HTS code	Y	Y	Y	Y	N	Y
Hold Location	N	N	N	N	N	Y

[1] Registration numbers are required only if the firm is required to register for a facility associated with the article of food under section 415 of the FD&C Act, 21 U.S.C. 350d and 21 CFR part 1, subpart H; if registration number is provided, city and country can be provided instead of the full address.

[2] After arrival, therefore, no longer anticipated or planned.

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III. Comments on the Proposed Rule

FDA received approximately 470 timely responses containing one or more comments in response to the proposed rule. To make it easier to identify comments and responses to the comments, the word ''Comments'' will appear before the description of the comment, and the word ''Response'' will appear before our response. A summary follows which includes a description of the appropriate section in the interim final rule.

A. General Comments and Outreach

(Comments) Some comments suggest revision of section 307 of the Bioterrorism Act. Other comments recommend that FDA repropose the rule or not implement the rule.

(Response) Changes to the statute are beyond the scope of this rulemaking. Postponing implementation of or not implementing the rule is not viable under section 307(c) of the Bioterrorism Act, which not only directs the FDA to ''promulgate proposed and final regulations for the requirement of

providing notice in accordance with section 801(m)'' by December 12, 2003, but also provides that an 8 hour prior notice requirement takes effect on this date even if FDA has not promulgated regulations that are in effect by this deadline. However, we are publishing this rule as an interim final rule and are, accordingly, soliciting comment on its provisions.

(Comments) Most comments generally support the protections of the food supply provided under the Bioterrorism Act. Although comments recommend that the final rule be amended to reflect more accurately industry practices, other comments suggest the regulation should be strengthened to ensure that FDA has all of the information required to identify foods that may pose a health or security threat. Some comments argue that FDA already has access to information currently submitted to CBP to allow for identification and quick interdiction of foods that may pose a health or security threat. Other comments question how the final rule would enhance FDA's ability to improve food safety and whether the benefits outweigh the costs.

(Response) Through section 307 of the Bioterrorism Act, Congress amended the FD&C Act to require the submission to FDA of a notice providing information regarding food before its importation into the United States. Congress also required FDA to issue implementing regulations to be effective not later than December 12, 2003. Thus, a postponement of the rule is not an option. Although FDA is aware that the prior notice regulation will affect industry, Congress determined the need for prior notice by passing the Bioterrorism Act. Prior notice of imported food will give FDA better information about the food earlier, enabling FDA to review and respond to the information before the arrival of the food at the border. Prior notice also will give FDA information with which it will be able to better focus its inspection resources. Section V of this preamble, Analysis of Economic Impacts, discusses the benefits of this interim final rule in detail. To address many of the concerns raised by the comments, FDA has made significant modifications in the interim final rule. However, we are publishing this rule as an interim final rule and are, accordingly, soliciting comment on its provisions.

(Comments) Some comments ask that FDA provide clear guidance and training to industry and agency field personnel about the procedures for implementing the regulation.

(Response) FDA conducted extensive outreach on the proposed prior notice rule, including having relevant FDA staff attend 6 international meetings and over 100 domestic meetings to ensure that affected parties were aware of the Bioterrorism Act prior notice requirements. On January 29, 2003, FDA held a public meeting (via satellite downlink) to discuss both the registration and prior notice proposed rules (*see* 68 FR 1568, January 13, 2003) or *http://www.accessdata.fda.gov/scripts/oc/ohrms/advdisplay.cfm.* Nearly 1,000 participants in North and South America and the Caribbean viewed that live broadcast. The meeting was later re-broadcast to Europe, Asia, Africa, and the Pacific. FDA has also posted transcripts of the broadcast in English, French, and Spanish on the agency's Web site.

FDA plans similar outreach efforts directed to both domestic and international stakeholders after publication of the interim final rule implementing the registration and prior notice provisions of the Bioterrorism Act. Outreach will include many methods of communication:

- Dissemination of materials to guide affected domestic and international food facilities through the new processes established to implement the registration and prior notice requirements;
- Domestic outreach meetings to State regulators and industry;
- A satellite downlink video broadcast and a series of videoconferences to various regions of the world;
- Materials and events for the media;
- International outreach to food trading partners;
- Presentations by FDA officials and exhibits at professional and trade conferences and meetings to inform industry and state and local government representatives of the new requirements; and
- Cooperative arrangements with CBP and other Federal agencies to ensure that information on the interim final regulations and their requirements is disseminated to affected companies and individuals.

More specifics regarding each of these will be included in FDA's Web site at *http://www.fda.gov.* In addition, FDA also plans training in new or revised procedures for its field personnel, as well as CBP field personnel. FDA will also provide guidance on enforcement to its staff containing the agency's policies on injunctions, prosecution, and debarment related to failure to provide timely and accurate prior notice, as well as the agency's policies regarding refusals under section 801(m)(1) of the FD&C Act and holds under section 801(l). As described in greater detail later, FDA intends to include a transition period in this guidance, during which it will emphasize education to achieve compliance. Guidance documents are available to the public, and FDA will shortly publish a notice of availability in the **Federal Register**.

FDA will notify the World Trade Organization (WTO) of this interim final rule. Shortly after publication of this interim final rule, FDA will begin disseminating at U.S. ports flyers and posters summarizing the new requirements and informing representatives of affected entities how to provide prior notice to FDA. Online assistance and a help desk will be available when the interim final rule becomes effective.

B. Foreign Trade Issues

(Comments) Some comments questioned the consistency of the proposed regulation with U.S. obligations under various WTO agreements, NAFTA, and other international agreements.

(Response) FDA is aware of the international trade obligations of the United States and has considered these obligations throughout the rulemaking process for this regulation and the interim final regulation is consistent with these international obligations.

(Comments) Some comments asserted that the proposed regulation is burdensome, confusing, costly, disproportionate, discriminatory, and will have a negative impact on foreign trade.

(Response) In drafting the proposed rule, FDA considered how best to structure the proposed rule consistent with the statutory mandates of the Bioterrorism Act and, at the same time, to reduce the costs associated with compliance. As discussed in more detail in the following paragraphs, FDA has carefully considered comments received regarding the burden imposed by the proposed rule, including its effects on international trade. Furthermore, based on the comments received on the proposed requirements, FDA has made a number of significant changes that minimize the impact of prior notice requirements on the food industry. These changes include removing restrictions on who can submit prior notice; allowing submission to be made either through ABI/ACS (the existing mechanism for filing entry information with CBP) or the FDA PN System Interface (the FDA PN Web system described in the proposed rule); reducing the timeframes for submission of prior notice and tying them to mode

of transport; and streamlining the information requirements.

C. ''What Definitions Apply to This Subpart?'' (Section 1.276 Proposed as § 1.277)

1. The Act (§ 1.276(a))

The proposed rule defined ''the act'' as the Federal Food, Drug, and Cosmetic Act. The proposed rule also applies the definitions of terms in section 201 of the act (21 U.S.C. 321) to such terms as used in the proposed rule.

(Comments) FDA did not receive comments on the definition of ''the act.''

(Response) We did not change the definition in the interim final rule. We have clarified that the definitions in the FD&C Act do not apply if a term is defined differently in the interim final rule.

(Interim final rule) Section 1.276(a) of the interim final rule defines ''the act'' as the Federal Food, Drug, and Cosmetic Act. Section 1.276(b) provides the definitions in the FD&C Act apply unless a term is defined differently in the interim final rule.

2. Calendar Day (§ 1.276(b)(1))

The proposed rule defined ''calendar day'' as ''every day shown on the calendar.''

(Comments) FDA did not receive comments on the definition of ''calendar day.''

(Response) We did not change the definition in the interim final rule.

(Interim final rule) ''Calendar day'' is defined in § 1.276(b)(1) of the interim final rule as ''every day shown on the calendar.''

3. Country From Which the Article Originates (§ 1.276(b)(2))

Section 801(m)(1) of the FD&C Act requires that ''the country from which the article originates'' be identified in a prior notice. The proposed rule used the term ''originating country'' and defined it as ''the country from which the article of food originates.''

(Comments) Comments were received on the proposed definition of ''originating country.'' These comments are addressed under ''FDA Country of Production,'' which is the term that FDA has chosen in the interim final rule to replace ''originating country.''

(Response) The term ''the country from which the article originates'' has been added to the interim final rule to refer back to the statutory language.

(Interim final rule) ''Country from which the article originates'' is defined as ''FDA Country of Production.''

4. Country From Which the Article Is Shipped (§ 1.276(b)(3))

The proposed rule defined ''country from which the article of food was shipped'' as ''the country in which the article of food was loaded onto the conveyance that brings it to the United States.'' A conveyance is the means of transportation, *e.g.*, ship, truck, car, van, plane, railcar, *etc.,* not the shipping container that can be moved from a ship to a truck to a train. FDA requested comment on whether the phrase ''country from which the article of food was shipped'' should include the countries of intermediate destination.

(Comments) Several comments support identifying countries of intermediate destination, noting that it would be desirable to have this information to support product tracing. One states that even if a food product were merely shipped through another country without further manufacturing/processing, the potential for tampering would still exist. This comment is concerned that, without information on every intermediate country, FDA would lack the ability to trace food for potential contamination back through the distribution chain. Another comment supports providing the countries of intermediate destination. It states that, except in the case of sealed containers, the manufacturer cannot control manipulation that occurs in countries of intermediate destination.

Several comments state that the information required in a prior notice should not include countries of intermediate destination. Other comments note that: An imported article may pass through a number of ports or stops in a variety of countries and never be unloaded; a U.S. importer in most cases has no control of which ports or stops a carrier may make; and exporters cannot guarantee which ports the ship will enter or pass through on its way to a U.S. port. Another comment states the information would not be necessary for sealed containers because alteration or absence of a seal alerts the owner to tampering, but it may be necessary for bulk or unpackaged products. Most of the comments that object conclude that submission of additional countries of intermediate destination would be unreasonable and burdensome and would not improve the safety and security of the food supply.

(Response) Section 801(m)(l) of the FD&C Act uses the singular ''country'' when it directs submission of the identity of the country from which the article is shipped, not the plural ''countries.'' Thus, FDA has concluded that the text of the statute dictates that the definition be singular. The interim final rule thus retains the proposed definition of the term ''country from which the article was shipped.''

(Comments) One comment states that the proposed definition of ''country from which the article of food was shipped'' is clear and suggests that it be maintained. Several commenters suggest that ''country from which the article of food was shipped'' should be defined as the country from which the goods were ''exported'' to the United States as that phrase is used in the CBP regulations defining ''country of export.''

Other comments suggest that FDA's definition failed to take into account the following considerations: That ocean and air carriers routinely use ''feeder'' vessels/aircraft to move cargo from the country of origin to a ''gateway'' for transfer to a larger vessel or aircraft that will transport the cargo to its final destination; and that ocean vessels frequently discharge containers destined for the United States in Canada where they are transferred to a motor carrier for transport to the United States. The comments conclude that the proposal, if implemented, would confuse importers and require them to attempt to obtain the cargo routing from master carriers. They suggest that FDA require instead the reporting of the last country in which a product was stored if that is different from the country in which it was produced (the country of production).

(Response) Section 801(m)(1) of the FD&C Act requires that prior notice submissions identify ''the country from which the article is shipped.'' ''Country of export'' is not a term formally defined in CBP's regulations.

We acknowledge that food may pass through more than one country before it reaches the United States. However, we do not believe that this practice changes the definition dictated by the statutory language. Several examples may be helpful. In one scenario, a shipper in country A arranges for a food manufactured in country B to be transported to the United States via country C. The food arrives in country C on an ocean vessel and is transferred to a truck that brings it to the U.S. port of arrival. In this first scenario, the country from which the article is shipped is country C.

In a second scenario, a shipper in country A arranges for a food manufactured in country B to be transported to the United States by a ship that is loaded in country B but stops in country C and then continues to the United States where the food is discharged. In this second scenario, the country from which the article is

shipped is country B. In a third scenario, if the food was transferred to a different vessel in country C, the country from which the article is shipped is country C.

(Interim final rule) Section 1.276(b)(3) of the interim final rule defines ''country from which the article is shipped'' as ''the country in which the article of food is loaded onto the conveyance that brings it to the United States.'' We changed the term from ''country from which the article was shipped'' to ''country from which the article is shipped'' to accurately reflect the language of the statute.

5. FDA Country of Production and Originating Country (§ 1.276(b)(4))

The proposed rule defined ''originating country'' as ''the country from which the article of food originates,'' which means the country where the article of food was grown and harvested, or if processed, where the article of food was produced.

(Comments) Many comments regarding the definition of ''originating country'' suggest that FDA use the ''country of origin'' definition used by CBP, or the standard rules of origin used by CBP, USDA, and associations such as the WTO.

(Response) Section 801(m)(1) of the FD&C Act requires prior notice submissions to FDA identify ''the country from which the article originates.''

We have not changed the definition of ''originating country'' to align it with ''country of origin'' as that term is defined by CBP. CBP defines ''country of origin'' at 19 CFR 134.1(b) as follows:

> the country of manufacture, production, or growth of any article of foreign origin entering the United States. Further work or material added to an article in another country must effect a substantial transformation in order to render such other country the ''country of origin'' within the meaning of this part; however, for a good of a NAFTA country, the NAFTA Marking Rules will determine country of origin.

In rulings, CBP has further defined ''country of origin'' and substantial transformation to identify the country of growth of the main ingredient in a processed food rather than the country of production of ''the *article [of food]''* (emphasis added) in the form it is being imported into the United States. For example, a CBP ruling identified the country of origin as the United States where beans were rehydrated and canned in the Dominican Republic, but grown and dried in the United States (Ref. 1). 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. We believe that it best serves the language and the purposes of section 801(m)(l) of the FD&C Act to define the term to focus on the country of production of the specific article of food that is being shipped to the United States. 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.

(Comments) One comment suggests that ''EU'' (European Union) be acceptable for use as an originating country.

(Response) FDA disagrees. Section 801(m) of the FD&C Act requires identification of ''the *country* from which the article originates'' (emphasis added). Accordingly, for purposes of this provision, each sovereign country must be identified when declared as part of the prior notice submission.

(Comments) Several comments suggest that the definition of ''country of origin'' for fish be the country in which the vessel is flagged or in which the fish was last processed. Another comment asks FDA to use the definition of ''country of origin'' being used by USDA's Agricultural Marketing Service for fish and seafood.

(Response) We generally agree. The proposed rule relied in part on USDA's proposed definition as set out in USDA guidance published in the **Federal Register** on October 11, 2002, and is based on the Farm Security and Rural Investment Act of 2002 (commonly known as the 2002 Farm Bill), as amended. As set out in § 1.276(b)(4) of the interim final rule, if an article of food is wild fish that is still in its natural state and was caught or harvested outside the waters of the United States by a vessel that is not registered in the United States, the FDA Country of Production is the country in which the vessel is registered. If the article of food is made from wild fish aboard a vessel, the FDA Country of Production is the country in which the vessel is registered.

(Comments) Several comments express concern that the proposed definition, ''[o]riginating country means the country from which the article of food originates,'' does not take into consideration the producer, processor, vessel or common carrier feeder and consolidation practices in which components of the shipment may be composites or commingled from more than one country. One comment asks that FDA describe when the country of canning would be the originating country, and when it would not. One comment suggests that decaffeinating or blending coffee be considered processing and that decaffeinated or blended coffee be considered as processed food for the purposes of prior notice.

(Response) Some of these comments appeared to confuse the proposed definition of ''country from which the article of food was shipped'' with the proposed definition of ''originating country,'' another reason why we decided to use the term ''FDA Country of Production.'' As explained above in the discussion of ''the country from which the article is shipped,'' the two countries will sometimes be different. When determining which country is the FDA Country of Production, the focus should be on the production of the specific article of food. For example, if the article of food is raw, whole, unpeeled carrots, the FDA Country of Production is the country where the carrots were grown and harvested. If the article of food is raw peeled and chopped carrots or canned carrots, the FDA Country of Production is the country where the carrots were peeled and chopped or canned. As a general matter, for canned foods, the FDA Country of Production should be the country where food was canned. Similarly, we consider decaffeinated coffee to be no longer in its natural state and the FDA Country of Production would be the country in which the coffee was decaffeinated.

(Interim final rule) Section 1.276(b)(4) of the interim final rule defines the ''FDA Country of Production'' for an article of food that is in its natural state, as country where the article of food was grown, including harvested or collected and readied for shipment to the United States. If an article of food is wild fish, including seafood, that was caught or harvested outside the waters of the United States by a vessel that is not registered in the United States, the FDA Country of Production is the country in which the vessel is registered. For an article of food that is no longer in its natural state, the FDA country of production is defined as the country where the article was made; except that, if an article of food is made from wild fish, including seafood, aboard a vessel, the FDA Country of Production is the country in which the vessel is registered. If an article of food that is no longer in its natural state was made in

a Territory, the FDA Country of Production is the United States.

6. Food (§ 1.276(b)(5))

The proposed rule defined ''food'' as having the meaning given in section 201(f) of the FD&C Act. The proposed rule provided examples of food including:

> fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food, dietary supplements and dietary ingredients; infant formula, beverages, including alcoholic beverages and bottled water, live food animals (such as hogs and elk), bakery goods, snack foods, candy, and canned foods.

a. *Food packaging and other food contact substances.*

(Comments) We received several comments on the subject of food contact substances, including packaging. The comments ask that FDA clarify the definition of ''food'' because the proposed rule included as examples of food not only those items traditionally understood as food, but also items that come into contact with and may migrate into food during processing or packaging. In particular, the comments ask that food packaging and components of food packaging, other food contact articles (such as food processing equipment and components of such equipment, glassware, dishware, cutlery, kitchen appliances), and so-called indirect additives (including those applied to food contact surfaces) be excluded from the final rule's definition of ''food.''

In support, the comments contend the legislative history of the prior notice provisions establish that Congress did not intend to apply prior notice requirements to these substances even though they can be food within the meaning of section 201(f) of the FD&C Act. In addition, some point to language in section 415 of the FD&C Act (21 U.S.C. 350d) relating to registration and language in section 414(b) of the FD&C Act relating to recordkeeping (21 U.S.C. 350c). Finally, some comments argued that an overly broad definition of ''food'' would dilute the government's resources, thereby hampering the government's opportunity to achieve the protective goals of the Bioterrorism Act.

(Response) We expressly included food packaging and other food contact materials in the proposed definition, with the result that prior notice would have been required for food packaging and other food contact materials and their components (see 68 FR 5428 at 5430). The breadth of the proposed definition of ''food'' was based on both the statutory definition in section 201(f)(3) of the FD&C Act, which defines articles used as components of food as ''food,'' as well as the case law interpreting the definition, including *Natick Paperboard* v. *Weinberger,* 525 F.2d 1103 (1st Cir. 1975) (paperboard containing PCBs intended for food use is adulterated food; *U.S.* v. *Articles of food * * * 688 Cases * * * of Pottery (Cathy Rose),* 370 F. Supp. 371 (E.D. Mi. 1974) (ceramic pottery that leaches lead is adulterated food).

The comments on food contact substances raise the question of what Congress intended ''food'' to mean for purposes of prior notice. In construing the prior notice provision of the Bioterrorism Act, FDA is confronted with two questions. First, has Congress directly spoken to the precise question presented? (''*Chevron* step one'') *Chevron, U.S.A., Inc.* v. *NRDC, Inc.,* 467 U.S. 837, 842 (1984). To find no ambiguity, Congress must have clearly manifested its intention with respect to the particular issue (*Young* v. *Community Nutrition Institute,* 476 U.S. 974, 980 (1986)). If Congress has spoken directly and plainly, the agency must implement Congress's unambiguously expressed intent (*Chevron,* 467 U.S. at 842–843). If, however, the Bioterrorism Act is silent or ambiguous as to the meaning of ''food,'' FDA may define ''food'' in a reasonable fashion (''*Chevron* step two''); *Chevron,* 467 U.S. at 842–843; *FDA* v. *Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 132 (2000)).

The agency has determined that, in enacting section 801(m) of the FD&C Act, Congress did not speak directly and precisely to the meaning of ''food.'' As noted, the FD&C Act has a definition of ''food'' at section 201(f). It may be a reasonable assumption that, when the term ''food'' is used in the FD&C Act, section 201(f) applies. However, although there may be ''a natural presumption that identical words used in different parts of the same act are intended to have the same meaning [citation omitted], * * * the presumption is not rigid * * *.'' (*Atlantic Cleaners & Dyers, Inc.* v. *U.S.,* 286 U.S. 427, 433 (1932); (*accord: U.S.* v. *Cleveland Indians Baseball Co.,* 532 U.S. 200, 213 (2000)). Thus, the same word may be given different meanings, even in the same statute, if Congress intended different interpretations or if such different interpretations are reasonable (at step 2) (*Atlantic Cleaners & Dryers, Inc., supra*).

Even before the Bioterrorism Act amendments, the term ''food'' was not defined identically throughout the FD&C Act. For example, in construing the parenthetical ''(other than food)'' in section 201(g)(1)(C) of the FD&C Act, the Seventh Circuit Court noted that Congress meant to exclude only ''articles used by people in the ordinary way that most people use food—primarily for taste, aroma, or nutritive value'' and not all substances defined as food by section 201(f) (*Nutrilab, Inc.* v. *Schweiker,* 713 F.2d 335, 338 (7th Cir. 1983)). Similarly, section 409(h)(6) of the FD&C Act defines a ''food contact substance'' as ''any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding *food* if such use is not intended to have any technical effect in *such food*'' (emphasis added). This definition makes sense only if ''food'' in this context excludes materials that contact food because components of food contact materials are plainly intended to have a technical effect in such materials.[2]

Thus, in this larger statutory context, FDA has evaluated section 801(m) of the FD&C Act to determine whether the meaning of the word ''food'' is ambiguous. In conducting this *Chevron* step one analysis, all of the traditional tools of statutory interpretation are available to determine whether the language Congress used is ambiguous (*Pharmaceutical Research & Manufacturers of America* v. *Thompson,* 251 F. 3d 219, 224 (D.C. Cir. 2001)). Beginning with the language of the statute, in section 801(m) of the FD&C Act, ''food'' is used to describe which subset of FDA-regulated articles are subject to prior notice:

> In the case of an article of *food* that is being imported or offered for import into the United States, the Secretary, after consultation with the Secretary of the Treasury, shall by regulation require, for the purpose of enabling such article to be inspected at ports of entry into the United States, the submission to the Secretary of a notice * * * (emphasis added).

The Bioterrorism Act is silent as to the meaning of ''food.'' Congress did not specify whether it intended the definition in section 201(f) of the FD&C Act to apply, one of the other

[2] FDA's long-standing interpretation of the FD&C Act's definition of color additive, section 201(t), is an additional example of where ''food'' is used more narrowly than as defined in section 201(f). A color additive is defined in section 201(t) of the FD&C Act as a substance that ''when applied to a food * * * is capable * * * of imparting color thereto * * *.'' The agency's food additive regulations distinguish between color additives and ''colorants,'' the latter being used to impart color to a food-contact material (21 CFR 178.3297(a); see also 21 CFR 70.3(f)). Thus, ''food'' as it appears in the statutory definition of color additive, necessarily excludes food contact materials.

possibilities noted above, or another meaning. Where, as here, the statutory language on its face does not clearly establish Congress's intent, it is appropriate to consider not only the particular statutory language at issue, but also the language and design of the statute as a whole (*Martini* v. *Federal Nat'l Mortgage Association,* 178 F. 3d 1336, 1345 (D.C. Cir. 1999), *citing K Mart Corp.* v. *Cartier, Inc.,* 486 U.S. 281 (1988)). Indeed, the analysis should not be confined to the specific provision in isolation, because the meaning or ambiguity of a term may be evident only when considered in a larger context (*FDA* v. *Brown & Williamson Tobacco Corp., supra* at 132 (2000)).

Consistent with this instruction, FDA has considered other parts of the Bioterrorism Act in assessing whether the meaning of ''food'' in section 801(m) of the FD&C Act ambiguous. In particular, FDA has considered the language of section 415 of the FD&C Act. The Bioterrorism Act's registration provision is one piece of several enacted by Congress to enhance the safety of the U.S. food supply. Registration is designed to work in concert with prior notice. This is reflected in the Bioterrorism Act's amendment of section 801 of the FD&C Act to provide that food from an unregistered foreign facility be held at the port when imported or offered for import (section 801(l) of the FD&C Act). The information provided by registration will allow FDA to cross-check prior notice submissions against registration data to confirm the identity of manufacturers and others who are required to register. Furthermore, the information provided by prior notice submissions can serve as a cross-check as to whether firms are registered as required and have been providing the necessary updates.

As explained in the preamble to the interim final registration rule published elsewhere in this issue of the **Federal Register**, FDA has concluded that the meaning of the term ''food'' in section 415 of the FD&C Act is ambiguous. First, the use, in section 415(a)(1) of the FD&C Act, of the phrase ''for consumption'' after the word ''food'' creates an ambiguity because it could be read to suggest that ''food'' within the context of the section 415 registration requirement only refers to food that is ordinarily thought of as ''consumed.'' By modifying the term ''food,'' Congress apparently intended to limit the term ''food'' to something less than the broad definition in section 201(f) of the FD&C Act. In addition, in section 415(b)(1) of the FD&C Act, when defining ''facility'' for purposes of section 415, Congress expressly exempted ''farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer * * *.'' These exemptions do not make clear whether Congress intended them to cover only food that is ordinarily eaten at some point by consumers primarily for taste, aroma, or nutritive value or whether, for example, a retail food establishment could include retailers of food contact materials, such as retail cookware stores.

The legislative history of section 415 of the FD&C Act also supports the conclusion that Congress did not speak directly to the meaning of ''food'' in that Bioterrorism Act provision. Such history is appropriately consulted at *Chevron* step one (*Atherton* v. *FDIC,* 519 U.S. 213, 228–29 (1997)). In particular, the Conf. Rept. to H.R. 3448, which became the Bioterrorism Act, explains what Congress intended by ''retail food establishments,'' which is used to create an exemption from registration.

> The Managers intend that, for the purposes of this section, the term 'retail food establishments' includes establishments that store, prepare, package, serve, or otherwise provide articles of food directly to the retail consumer for human consumption, such as grocery stores, convenience stores, cafeterias, lunch rooms, food stands, saloons, taverns, bars, lounges, catering or vending facilities, or other similar establishments that provide food directly to a retail consumer.

(H. Conf. Rept. No. 481, 107th Cong., 2d Sess., 133 (2002)). Similarly, the Conf. Rept. notes that the term ''non-profit food establishments'' includes not-for-profit establishments in which food is prepared for, or served directly to the consumer, such as food banks, soup kitchens, homebound food delivery services, or other similar charitable organizations that provide food or meals for human consumption'' (*Id.* at 133–34). Notably, the examples provided by Congress for both types of exempt food establishments are not those that generally sell or distribute food contact materials. Accordingly, the legislative history of section 415 of the FD&C Act creates additional ambiguity as to the meaning of ''food.''

This ambiguity in the word ''food'' is further underscored by the legislative history of section 801(m) of the FD&C Act. For example, the Conf. Rept. states that the prior notice provision is to be construed not to apply to ''packaging materials if, at the time of importation, such materials will not be used for or in contact with food * * *'' (see H. Conf. Rept. No. 481, 107th Cong., 2d Sess., 136 (2002)). This statement implies that Congress was not relying on the definition of food in section 201(f) of the FD&C Act. For example, the statement could be read to mean that the term ''food'' does not include packaging or other materials that contact food.

Having concluded that the meaning of ''food'' in section 801(m) of the FD&C Act is ambiguous, FDA has considered how to define the term to achieve a ''permissible construction'' of the prior notice provision (*Chevron, USA, Inc.* v. *NRDC, Inc., supra* at 843). In conducting this *Chevron* step two analysis, the agency has considered the same information evaluated at step one of the analysis (*Bell Atlantic Telephone Co.* v. *FCC*, 131 F. 3d 1044, 1049 (D.C. Cir. 1997); *Chevron U.S.A., Inc.* v. *FERC*, 193 F. Supp. 2d 54, 68 (D.D.C. 2002)). FDA has determined that it is permissible, for purposes of the prior notice provision, to exclude food contact materials from the definition of ''food.''

Restricting ''food'' to substances other than food contact materials is consistent with the legislative history of the prior notice provision relating to food packaging and other food contact substances. In addition, it is consistent with the ''food for consumption'' language in section 415(a)(1) (FD&C Act) of the registration provision. That is, foods that are ''consumed'' are generally those eaten for their taste, aroma, or nutritive value. In addition, excluding food contact materials from ''food'' in this regulation is consistent with the exemptions in section 415(b)(1) of the FD&C Act, as well as the legislative history of section 415.

As discussed in the following paragraphs in responses to other comments, FDA has also interpreted ''food'' for purposes of section 801(m) of the FD&C Act to exclude pesticides as that term is defined under 7 U.S.C. 136(u). Accordingly, FDA has determined that a reasonable interpretation of ''food'' for purposes of section 801(m) of the FD&C Act is as follows and has revised § 1.276(b)(5) of this interim final rule to provide:

> Food has the meaning given in section 201(f) of the act, except for purposes of this subpart, it does not include food contact substances as defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)); or pesticides as defined in 7 U.S.C. 136(u). Examples of food 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.

Importantly, FDA still considers food packaging and other food contact substances to be ''food'' within the meaning of section 201(f) of the FD&C Act when they, or their components, migrate into other food. Therefore, these items are still ''food'' for purposes of the other provisions of section 801 of the FD&C Act (with the exception of section 801(l), which shares the same definition of food as section 801(m)). Accordingly, although not subject to the section 801(m) of the FD&C Act requirement of prior notice, food packaging materials and other food contact substances will remain, as they have been, subject to determinations of admissibility under section 801(a) of the FD&C Act.

b. *Food processing aids.* (Comments) One comment argues that food processing aids and ''indirect food additives'' should not be considered food for purposes of section 801(m) of the FD&C Act. According to the commenter, these substances resemble food contact substances, which Congress, as evidenced by the prior notice legislative history of food contact substances, did not expect FDA to subject to prior notice.

(Response) Whether a food processing aid or ''indirect additive'' is subject to prior notice depends upon whether such a substance is ''food'' under this rule. As noted, for purposes of the interim final rule, ''food'' excludes ''food contact substances'' as defined at section 409(h)(6) of the FD&C Act. Among other things, unlike food processing aids and ''indirect additives,'' ''food contact substances'' are not ''intended to have any technical effect in food,'' section 4091(h)(6) of the FD&C Act. In addition, ''food'' excludes pesticides as defined at 7 U.S.C. 136(u). Thus, if the substance is not a pesticide and is intended to have a technical effect in the food being processed, the substance is not exempt from the definition of ''food'' under § 1.276(b)(5) in the interim final rule. This is a reasonable result in that such processing aids are intentionally and directly added to ''traditional'' foods.

c. *Antimicrobial pesticides.* (Comments) One comment expresses concern about including antimicrobial pesticides within the scope of this regulation. The comment states that pesticides are imported pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), not the FD&C Act, and are subject to Environmental Protection Agency (EPA) approval before they are admitted to the United States. The comment asks that FDA clarify that this regulation is not applicable to antimicrobial pesticides with FDA and/or EPA approved food contact uses. The comment states that including antimicrobial pesticides within the scope of this regulation would impose unnecessary burdens on antimicrobial pesticide registrants, without enhancing the protection of the food supply.

(Response) As discussed previously, the meaning of ''food'' in section 801(m) of the FD&C Act is ambiguous. Therefore, FDA may define ''food'' in a reasonable manner. FDA believes that excluding pesticides from the definition of food is reasonable. Pesticides, including those used in or on food for human or animal use, are comprehensively regulated by the Federal Government. Under FIFRA, 7 U.S.C. 136 *et seq.*, all pesticides (both food and nonfood use) are registered with EPA. As part of the registration process, establishments in which pesticides are produced must register with EPA (40 CFR 167.3 and 167.20). As part of the importation process, prior notice of pesticide shipments must be provided to EPA (19 CFR 12.112).

Importantly, the Federal regulatory scheme for pesticides was substantially revised in 1996 by the Food Quality Protection Act (FQPA) (Pub. L. 104–170), and EPA's authority over pesticides was consolidated and expanded. As a result of FQPA, pesticides and their residues are subject to substantial and comprehensive regulation by EPA. Where another Federal agency has the types of specific and comprehensive authority described previously to regulate the safety of a substance, FDA believes that it is appropriate to interpret ''food'' in section 801(m) of the FD&C Act as not including that substance. Accordingly, FDA has revised the definition of ''food'' in § 1.276(b)(5) to exclude pesticides as defined by FIFRA.

d. *Chemicals* (Comments) One comment seeks clarification as to whether chemicals are considered ''food.'' The comment expects that chemicals intended for human consumption will likely be included in the requirements for prior notice.

(Response) We are not sure exactly what substances or products the comment refers to; ''chemicals'' is a very broad term. Unless excluded because they are food contact substances or pesticides, chemicals that are ''used for food or drink'' or are ''used for components of any such articles'' are ''food'' under section 201(f) of the FD&C Act and the definition in the interim final rule (§ 1.276(b)(5)). If the substance is used in some applications that make the substance ''food'' and some that do not, the principles applicable to further processing and multi-use substances, set out in the following paragraphs, apply.

e. *Live animals.* (Comments) Two comments address inclusion of live animals. One comment urges FDA to exempt live food animals from this regulation, as it will have far-reaching impacts on all Canadian farmers who export live food animals to the United States. The other comment asks for clarification as to how prior notice applies to live food animals imported for further processing, such as finishing.

(Response) As discussed previously, the meaning of ''food'' in section 801(m) of the FD&C Act is ambiguous. Therefore, FDA may define ''food'' in a reasonable manner. FDA believes that it is reasonable to interpret ''food'' in section 801(m) of the FD&C Act to include live animals. Such inclusion is consistent with the explicit reference to animals in the statutory standard, ''serious adverse health consequences or death to humans or animals'' in section 801(m)(2)(B)(ii) of the FD&C Act—the provision that relates to FDA review of prior notices submitted for food refused for lack of adequate prior notice. In addition, it is consistent with the legislative history of section 801(m) of the FD&C Act that refers only to the exclusion of food contact substances. Moreover, the products of live food animals are an integral part of the food consumed in the United States, and thus, it is logical to protect the raw materials (*i.e.*, the live animals) by including them under the Bioterrorism Act's safeguards. Finally, the inclusion of live animals in the definition of ''food'' is consistent with the reasonable interpretation of the registration provision, section 415 of the FD&C Act. Accordingly, the interim final rule's definition of ''food'' includes live food animals. Defining ''food'' to include live animals is also consistent with the case law interpreting the term ''food'' in the broader context of the FD&C Act. See *United States* v. *Tuente Livestock*, 888 F. Supp. 1416 (S.D. Ohio, 1995).

f. *Articles for further processing or capable of multiple uses.* (Comments) Some comments ask that FDA clarify that the definition of ''food'' does not include substances that are not edible, but may be further processed to be rendered edible, for example, crude vegetable oils, crude petroleum, and minerals such as phosphates which may be refined and processed into food ingredients such as glycerin and phosphoric acid. The comments state that where bulk commodities have potential food and nonfood uses, there should be an exemption from import notification where these commodities have not been sufficiently refined to be

directly used as food ingredients without further processing or refining.

Another comment notes that gelatin is used for food, pharmaceutical, and technical applications and seeks assistance with establishing a labeling protocol to distinguish between edible gelatin, pharmaceutical gelatin, and technical gelatin. Some comments state FDA should require prior notice only for food intended for consumption and ask FDA to specify the articles that would be considered ''food.'' The comments also state that some imports have both food and nonfood uses and that prior notice should only be required for imports that will be used as a food. In addition, one comment strongly urges FDA to remove indirect food contact colors (*i.e.*, material used to color food contact material) from the requirements of prior notice. The comment indicates that food contact colors are often prepared in bulk and then shipped to companies that can use these pigments in both food and nonfood applications. The process of manufacturing color pigments could be many steps removed from the process of actually using these products in food packaging. Therefore, the decision to use the product in food may not be made until after the pigment has entered commerce.

(Response) For purposes of the interim final rule, ''food'' has the definition in section 201(f) of the FD&C Act except that ''food contact substances'' as defined at section 409(h)(6) of the FD&C Act and ''pesticides'' as defined at 7 U.S.C. 136(u) are excluded from ''food.'' Under section 201(f) of the FD&C Act, ''food'' means ''articles used for food or drink'' (section 201(f)(1)) and articles ''used for components of any such article'' (section 201(f)(3)). The determination of whether a substance is ''food'' is not a question of intended use (*Nutrilab* v. *Schweiker*, 713 F.2d. 335, 337 (7th Cir. 1983); *U.S.* v. *52 Drums Maple Syrup*, 110 F.2d 914, 915 (2d Cir. 1940); *U.S.* v. *Technical Egg Products*, 171 F.Supp. 326, 328 (N.D. Ga. 1959)). Courts interpreting the ''food'' definition in the FD&C Act have held that articles at both ends of the food continuum are ''food'' for purposes of the FD&C Act (*U.S.* v. *O.F. Bayer & Co.*, 188 F.2d 555 (2d. Cir. 1951); *U.S.* v. *Tuente Livestock*, 888 F. Supp. 1416 (S.D. Ohio, 1995) (live animals for food use are ''food'' under the FD&C Act); *U.S.* v. *Technical Egg Products, supra*, 171 F.Supp. at 328 (rotten eggs are ''food'')). Thus, FDA believes that an item may be food even if the food is not yet in the form in which it will be used for food. FDA will consider a product 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.

If the substance can be used in some applications that make the substance ''food'' and some that do not, the same principles apply. With respect to gelatin and other substances that may exist in multiple grades, including food grade, FDA will consider an article 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.

Finally, as set forth previously, the interim final rule excludes food contact substances from the definition of ''food.'' Thus, when substances to color food contact substances or their components are imported, they are not subject to prior notice. However, colors used in such substances are still subject to regulation as food under section 201(f) of the FD&C Act for purposes of other provisions of the FD&C Act.

(Interim final rule) In the interim final rule (§ 1.276(b)(5)), ''food'' has the meaning given in section 201(f) of the FD&C Act, except for purposes of this rule, it does not include ''food contact substances'' as defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)) or ''pesticides'' as defined in 7 U.S.C. 136(u). Examples of food 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.

7. Grower (§ 1.276(b)(6))

Although the statute and proposed rule used the term grower, the proposed rule did not define the term. However, FDA solicited comments on whether the term ''grower'' includes a harvester or collector of wild products, *e.g.*, some fish and botanicals.

(Comments) A comment states that although harvesters or collectors of wild botanicals do not grow botanicals and should be differentiated from growers for certain purposes, these can be included in the term ''grower'' consistent with the congressional intent in § 307 of the Bioterrorism Act to identify the direct source of the agricultural raw commodity.

(Response and interim final rule) FDA agrees. Accordingly, we have defined ''grower'' to mean a person who engages in growing and harvesting or collecting crops (including botanicals), raising animals (including fish, which includes seafood), or both.

8. International Mail (§ 1.276(b)(6))

Although the proposed rule applied to food imported or offered for import by mail, see, *e.g.*, 68 FR 5436, the proposed rule did not define ''international mail.''

(Comments) There were no comments received concerning any definition of ''international mail.''

(Response and interim final rule) The interim final rule imposes slightly different requirements relating to prior notice for food arriving by international mail. Thus, FDA determined that a definition of ''international mail'' would be helpful. The interim final rule defines ''international mail'' to mean ''foreign national mail services.'' It also expressly excludes express carriers, express consignment operators, or other private delivery services from this definition.

9. No Longer In Its Natural State (§ 1.276(b)(8))

Section 801(m)(1) of the FD&C Act requires that the identity of the manufacturer be submitted as part of a prior notice. However, the proposed rule did not define ''manufacturer'' or address what constituted the product of a manufacturer versus the product of a grower.

(Comments) Comments raised questions concerning when a manufacturer must be identified for an article of food.

(Response) These comments are discussed under the heading ''What Information Must be in a Prior Notice.'' However, as a result of the comments, we determined that a definition of when food would be ''no longer in its natural state'' would be helpful to clarify when the identity of a manufacturer versus the identity of a grower must be provided in a prior notice.

(Interim final rule) The interim final rule (§ 1.276(b)(8)), defines the term ''no longer in its natural state'' to mean that an article of food has been made from one or more ingredients or synthesized, prepared, treated, modified, or manipulated. Examples of activities that render food no longer in its natural state are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling,

pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. However, crops that have been cleaned (*e.g.*, dusted, washed), trimmed, or cooled attendant to harvest or collection or treated against pests, waxed, or polished are still in their natural state for purposes of the prior notice interim final rule. Likewise, whole fish headed, eviscerated, or frozen attendant to harvest are still in their natural state for purposes of the prior notice interim final rule.

10. Port of Arrival (§ 1.276(b)(9)) and Port of Entry (§ 1.276(b)(10))

The proposed rule defined ''port of entry'' as ''the water, air, or land port at which the article of food is imported or offered for import into the United States, *i.e.*, the port where food first arrives in the United States.''

(Comments) Many comments suggest harmonizing with, or adopting, the CBP definition for ''port of entry.'' In the opinion of two comments, the CBP definition is consistent with congressional intent and the FDA departure from the CBP definition is unsupported. Many of these comments state the two definitions would cause confusion in the import community and could delay proper prior notice. Other comments suggest changing the FDA definition of ''port of entry'' to the ''port of arrival.'' Another comment suggests defining ''port of entry'' as the entering point of a country where the merchandise is checked by official authorities. Two comments state that defining ''port of entry'' as the port of arrival would change business practices by essentially stopping the use of CBP ''in-transit'' (*i.e.*, IT) entries under bond to inland ports.

(Response) Section 801(m)(2)(A) of the FD&C Act states that FDA's implementing regulations must require that the notice ''be provided by a specified period of time in advance of importation of the article involved * * *.'' The stated purpose of section 801(m)(1) is ''enabling [articles of food] to be inspected at ports of entry into the United States * * *.'' Moreover, the overall purpose of the Bioterrorism Act is ''[t]o improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies.'' (Pub. L. 107–188.) The ability to examine or, if necessary, hold a suspect article of food when it first arrives at a port of entry in the United States, rather than later at the port where CBP will process the entry, will most effectively serve this overall purpose. Thus, to ensure that there is clarity that prior notice must be provided in advance of arrival, we are defining the term ''port of arrival'' as the water, air, or land port at which the article of food is imported or offered for import into the United States, *i.e.*, the port where the article of food first arrives in the United States.

In addition, we are adopting the CBP definition of ''port of entry'' to allow flexibility when designating where refused merchandise will be held. The CBP ''Port of entry'' definition states:

The terms ''port'' and ''port of entry'' refer to any place designated by Executive order of the President, 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 to enforce the various provisions of the Customs and navigation laws. The terms ''port'' and ''port of entry'' incorporate the geographical area under the jurisdiction of a port director. (The Customs ports in the Virgin Islands, although under the jurisdiction of the Secretary of the Treasury, have their own Customs laws (48 U.S.C. 1406(i)). These ports, therefore, are outside the Customs territory of the United States and the ports thereof are not ''port of entry'' within the meaning of these regulations) (19 CFR 101.1).

This flexibility will ensure that food that has been refused may move to the port of destination where, for example the consumption or warehouse entry will be filed, unless directed by CBP or FDA. Generally, we do not intend to hold shipments at the border unless our assessment of the situation leads us to believe it is warranted, *e.g.*, the food may present a serious risk to public health or that the prior notice violation is egregious. We intend to implement prior notice, both in terms of determining what warrants a refusal in the first place, and in terms of determining which shipments may move to the port of destination, in a risk-based way.

(Comments) Other comments state rail transportation would be especially affected because inbound trains often are not required to stop at the U.S. border but proceed to inland terminals.

(Response) As explained later, rail shipments that have been refused admission per section 801(m)(1) of the FD&C Act are considered to have the status of general order merchandise. In many cases, it will be operationally difficult to stop an entire train because an article of food on it has been refused admission because of inadequate prior notice. Under CBP regulation, general order merchandise may be stored by the carrier or as the CBP port director may direct (see 19 CFR 123.10(f)). Moreover, in situations involving shipments by rail, FDA and CBP have the discretion to allow the movement of the cargo from the border crossing to the nearest point where it can be safely and securely held. We intend, whenever possible, to examine articles of food arriving by rail at the appropriate examination site closest to the border. However, if the shipment might pose an immediate danger to public health and safety, an article of food arriving by train may be held at the border pending resolution of the situation.

(Interim final rule) The interim final rule, § 1.276(b)(9) defines ''port of arrival'' as ''the water, air, or land port at which the article of food is imported or offered for import into the United States, *i.e.*, the port where the article of food first arrives in the United States,'' (§ 1.276(b)(9)). This port may be different from the port where consumption or warehouse entry or FTZ admission documentation is presented to CBP. The interim final rule (§ 1.285(b)(10)) also defines port of entry as follows:

11. Registration Number (§ 1.276(b)(11))

Although the term appears in several places in the proposed rule, the term ''registration number'' was not defined.

(Comments) No comments addressed the definition or meaning of ''registration number.''

(Response) To clarify that the term refers to registration of food facilities, the interim final rule defines ''registration number'' as the registration number assigned by FDA under section 415 of the FD&C Act and 21 CFR part 1, subpart H, § 1.276(b)(11). Specific comments addressing when a registration number is required and other aspects of providing registration numbers as information submitted in prior notice are addressed later in this preamble—see ''What Information Must be in a Prior Notice?'.

12. Shipper (§ 1.276(b)(12))

Section 801(m)(1) of the FD&C Act requires that the ''shipper of the article'' be provided in a prior notice submission. The proposed rule included the shipper as required information in a prior notice, but did not define the term ''shipper.''

(Comments) FDA received no comments concerning the meaning of this term.

(Response) In the proposed rule, we described the ''shipper'' as ''the person who arranges for a shipment to get to its first destination in the United States * * *. The shipper is usually a foreign firm that is located or maintains an address in the country from which the

article was shipped.'' (68 FR 5437). However, in drafting the interim final rule, we have realized that this description was not written in a way that was useful in identifying the shipper in the case of food imported by international mail. Accordingly, we have revised the description of the ''shipper'' and included it in the definitions to make it easier to find.

The definition is based on the description of ''shipper'' used by CBP in their proposed rule, ''Required Advance Electronic Presentation of Cargo Information,'' published in the **Federal Register** on July 23, 2003 (68 FR 43574 at 43577), which is similar to, but clearer than, the description we used in the preamble to the proposed prior notice rule.

(Interim final rule) The interim final rule (§ 1.276(b)(12)), defines ''shipper'' as ''the owner or exporter of the article of food who consigns and ships the article from a foreign country or the person who sends an article of food by international mail to the United States.''

13. United States (§ 1.267(b)(13))

Although the term appears in several places in section 801(m) of the FD&C Act itself, the proposed rule did not contain a definition of ''United States.''

(Comments) A comment seeks clarification whether the prior notice regulation applies to food imported into Guam, the U.S. Virgin Islands, the Northern Mariana Islands, and other U.S. Territories.

(Response) This comment raises the question of what the term ''United States'' means for purposes of section 801(m) of the FD&C Act. In construing the prior notice provision of the Bioterrorism Act, FDA is confronted with two questions. First, has Congress directly spoken to the precise question presented? (''*Chevron* step one'') (*Chevron, U.S.A., Inc.* v. *NRDC, Inc.,* 467 U.S. 837, 842 (1984)). To find no ambiguity, Congress must have clearly manifested its intention with respect to the particular issue (*Young* v. *Community Nutrition Institute,* 476 U.S. 974, 980 (1986)). If Congress has spoken directly and plainly, the agency must implement Congress's unambiguously expressed intent (*Chevron*, 467 U.S. at 842–843). If, however, the Bioterrorism Act is silent or ambiguous as to the meaning of ''United States,'' FDA may define ''United States'' in a reasonable fashion (''*Chevron* step two''); (*Chevron*, 467 U.S. at 842–843; *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000)). The agency has determined that, in enacting section 801(m) of the FD&C Act, Congress did not speak directly and precisely to the meaning of ''United States.''

The FD&C Act does apply to Guam, the U.S. Virgin Islands, the Northern Mariana Islands, and other U.S. Territories. Section 201(a)(1) of the FD&C Act (21 U.S.C. 321 (a)(1)) defines the term ''State'' to mean any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico. The term ''Territory'' is defined to mean any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone, section 201(a)(2) of the FD&C Act (21 U.S.C. 321(a)(2)). However, the terms ''State'' and ''Territory'' are not used in section 801(m) of the FD&C Act.[3] Instead, section 801(m) of the FD&C Act deals with ''articles imported or offered for import into the United States,'' (section 801(m)(1)).

The term ''United States'' is not defined in the FD&C Act's general definitions in section 201. Nor is it defined in section 801(m) of the FD&C Act. It is defined for purposes of section 702(a) of the FD&C Act (21 U.S.C. 372(a)), which provides:

> In the case of a food packed in the Commonwealth of Puerto Rico or a Territory [FDA] shall attempt to make inspection of such food at the first point of entry within the United States * * *. For the purposes of this subsection, the term 'United States' means the States and the District of Columbia.

This definition in section 702(b) seems to imply that, in other places in the FD&C Act, the term ''United States'' would include all Territories. However, in section 801(m) of the FD&C Act, the term ''United States'' appears as part of the phrase ''for purposes of enabling inspection of such [food] articles at *the ports of entry* into the United States'' (emphasis added). As defined by CBP, ''port of entry'' means ports within the part of the United States that has been denominated as the ''Customs territory of the United States.'' (19 CFR 101.1 and 101.3). Notably, though, the Territories are not considered part of the Customs territory of the United States. CBP defines ''Customs territory of the United States'' to ''include[] only the States, the District of Columbia, and Puerto Rico.'' (19 CFR 101.1).

Because of this reference to ''the ports of entry into the United States,'' FDA has concluded that the term ''United States'' is best interpreted in section 801(m) of the FD&C Act to be the Customs territory of the United States and include only the 50 States, the District of Columbia, and Puerto Rico, but not the U.S. Territories and possessions. Defining the ''United States'' to be the Customs territory of the United States will maximize FDA's ability to coordinate prior notice with the CBP entry process, as CBP entry is made for articles from the Territories when they arrive in the Customs territory of the United States. Thus, section 801(m) of the FD&C Act does not apply to articles of food imported or offered for import into Guam, the U.S. Virgin Islands, the Northern Mariana Islands, and other U.S. Territories; section 801(m) does apply, however, when articles of food are imported or offered for import from the Territories into the United States as defined by § 1.276(b)(11) of the interim final rule.

(Interim final rule) The interim final rule (§ 1.276(b)(13)), defines ''United States'' to mean the Customs territory of the United States, *i.e.*, the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico, but not any other part of the United States.

14. You (§ 1.276(b)(14))

The proposed rule defined ''you,'' based on who was authorized to submit prior notice, as ''the purchaser or importer of an article of food who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or importer or the arriving carrier * * *'' or, if known, the in-bond carrier.

(Comments) No comments were received concerning the definition of ''you.'' However, comments were received about who may submit prior notice.

(Response) Discussion of those comments and our responses are found in the section ''Who is Authorized to Submit Prior Notice?'' FDA decided, based on revisions to who may submit prior notice, to revise the definition of ''you.'' The interim final rule clarifies that ''you'' means the persons (*i.e.*, individuals and firms) submitting or transmitting the prior notice. The submitter is responsible for the prior notice. The persons who send the prior notice are transmitters. If the submitter sends the prior notice, he or she is both

[3] The terms ''State'' and ''Territory'' are key to the FD&C Act's definition of ''interstate commerce,'' which is, in turn, key to many of the FD&C Act's general inspection and enforcement provisions, see, *e.g.*, sections 301, 304, and 704 (21 U.S.C. 331, 334, and 374). However, while articles that ''are imported or offered for import into the United States,'' section 801(m)(1) of the FD&C Act, are in ''interstate commerce,'' see, *e.g., U.S.* v. *2,998 Cases * * * First Phoenix Group, Ltd, 64 F.3d 984 (5th Cir. 1995), the term* ''interstate commerce'' does not appear in section 801(m).

the submitter and transmitter. FDA notes that all messages sent via the FDA PN System Interface will be sent to the transmitter. If prior notice is submitted via ABI/ACS, all messaging goes to the customs broker or self-filer via ABI/ACS.

(Interim final rule) The interim final rule (§ 1.276(b)(14)), defines ''you'' as the person submitting the prior notice (the ''submitter'') or the person transmitting prior notice information on behalf of the submitter (the ''transmitter'').

13. Summary of the Interim Final Rule

The interim final rule defines the following terms:

- The act;
- Calendar day;
- Country from which the article originates;
- Country from which the article is shipped;
- FDA Country of Production;
- Food;
- Grower;
- International mail;
- No Longer in Its Natural State;
- Port of arrival;
- Port of entry;
- Registration Number;
- Shipper;
- United States; and
- You.

D. ''What Is the Scope of This Subpart?'' (Section 1.277 Proposed as § 1.276)

FDA proposed that the prior notice requirements apply to food for humans and other animals that is imported or offered for import into the United States. The proposed rule specified that this included food that is imported or offered for import into U.S. FTZs, for consumption, storage, immediate export from the port of entry, transshipment through the United States to another country, or import for export. The proposed rule said that prior notice did not apply to food carried by an individual in that individual's personal baggage for that individual's personal use, meat food products, poultry products, and egg products that are subject to the exclusive jurisdiction of USDA.

(Comments) Some comments state that the prior notice requirements should not apply to food that is brought across the U.S. border but not for consumption in the United States. In particular, the comments focus on food exported from the port of arrival, food imported for transshipment and export from another port, and food imported for further processing and export. The comments argue that Congress did not envision that the prior notice requirements would cause importers to give notice of food not for consumption within the United States and that notice of such food would not give FDA any useful or actionable information. One comment states that the Bioterrorism Act repeatedly refers to ''offered for import into the United States'' and concludes, based on this phrase, that prior notice should apply only to food for consumption by the citizens of the United States. One comment points to statutory language that stipulates ''for human and animal consumption.'' Based on this language, the comment argues that FDA would exceed its statutory authority by requiring prior notice for shipments not intended for consumption within the United States. Another comment states that prior notice should not apply to food of U.S. origin, especially if it was simply transshipped through another country then ''re-imported'' into the United States.

(Response) These comments on scope raise the question of what Congress intended the phrase ''imported or offered for import into the United States'' to mean for purposes of section 801(m) of the FD&C Act. In construing the prior notice provision of the Bioterrorism Act, FDA is confronted with two questions. First, has Congress directly spoken to the precise question presented? (''*Chevron* step one''). (*Chevron, U.S.A., Inc.* v. *NRDC, Inc.,* 467 U.S. 837, 842 (1984)). To find no ambiguity, Congress must have clearly manifested its intention with respect to the particular issue (*Young* v. *Community Nutrition Institute*, 476 U.S. 974, 980 (1986)). If Congress has spoken directly and plainly, the agency must implement Congress's unambiguously expressed intent (*Chevron*, 467 U.S. at 842–843). If, however, the Bioterrorism Act is silent or ambiguous as to the meaning of ''imported or offered for import into the United States,'' FDA may interpret the phrase in a reasonable fashion (''*Chevron* step two''); (*Chevron*, 467 U.S. at 842–843; *FDA* v. *Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 132 (2000)).

The agency has determined that, in enacting section 801(m) of the FD&C Act, Congress did not speak directly and precisely to the meaning of ''imported or offered for import into the United States.'' For the reasons in the following paragraphs, FDA has determined that, for purposes of section 801(m) of the FD&C Act, the phrase ''imported or offered for import into the United States'' can reasonably be interpreted to apply to articles that are brought into the United States for consumption in the United States, for transshipment through the United States and export to another country, for further processing in the United States and export, and articles of U.S. origin that are ''re-imported'' back into the United States. We have also determined that the phrase ''imported or offered for import into the United States'' can reasonably be interpreted to exclude articles that are brought to the United States for the purpose of being exported without ever leaving the port of arrival until export.

Neither the Bioterrorism Act nor the FD&C Act defines this phrase. Moreover, courts that have considered the meaning of ''import'' or similar terms in other statutes have not always arrived at the same conclusions: Sometimes ''import'' means simply to bring in, but other times ''import'' means to bring in with the intent to unlade or enter (*Procter & Gamble Manufacturing Co.* v. *U.S.,* 19 C.C.P.A. 415, 422 (C.C.P.A. 1932) (to import ''may mean to bring goods within the jurisdictional limits of the country * * *; or it may mean the time when it is withdrawn from the warehouse and enters the commerce of the country''); *compare, e.g., Canton R. Co.* v. *Rogan,* 340 U.S. 511, 514–15 (1951) (''to import means to bring into the country''); *Brown* v. *Maryland,* 25 U.S. 419, 426, 437–38 (1827) (''What, then, are 'imports'? The lexicon informs us, they are 'things imported.' If we appeal to usage for the meaning of the word, we shall receive the same answer. They are the articles themselves which are brought into the country.'') *with United States* v. *Watches, Watch Parts, Calculators & Misc. Parts,* 692 F. Supp. 1317, 1321 (S.D. Fla. 1988); *United States* v. *Commodities Export Co.,* 14 C.I.T. 166, 169–70 (Ct. Int'l Trade 1990) (''once goods are within the jurisdictional limits of the United States with the intent to discharge, they are imports under this definition''); *United States* v. *Boshell,* 14 U.S. Cust. App. 273, 275–77 (Ct. Cust. App. 1922) (''The common ordinary meaning of the word 'import' is to bring in. Imported merchandise is merchandise that has been brought within the limits of a port of entry from a foreign country with intention to unlade, and the word 'importation' as used in tariff statutes, unless otherwise limited, means merchandise to which that condition or status has attached'')).

In considering what is a reasonable interpretation, we considered the language and purpose of section 801(m) of the FD&C Act, as well as the other provisions of the Bioterrorism Act and section 801 of the FD&C Act. Section 801(m)(1) of the FD&C Act states, ''In the case of an article of food that is

being imported or offered for import into the United States, the Secretary * * * shall by regulation require * * * the submission to the Secretary of a notice * * *.'' FDA notes that Congress did not explicitly limit this provision to articles of food that are intended for consumption in the United States. However, such limiting language does appear in section 415 of the FD&C Act, which requires certain food facilities to register with the agency. This shows that when Congress crafted the Bioterrorism Act, it knew how to impose the limitation sought by the comments. But neither section 801(m) of the FD&C Act nor its legislative history contains language suggesting this limitation.

The purpose of the Bioterrorism Act is ''to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies.'' The prior notice provision furthers this goal by enhancing the agency's ability to inspect imported food upon arrival in the United States. Excluding from prior notice food that is brought into the United States for transshipment or further processing, rather than consumption, would run counter to the purpose of the Bioterrorism Act. Articles entered at the port or arrival under T&E entries with the stated intent to transship and export may be diverted for consumption in the United States and thus remain here rather than leave from another port. Some of this diversion is legitimate; under CBP regulations, importers may change their minds and file a superseding consumption entry. In addition, unscrupulous importers may file a T&E entry instead of a consumption entry to avoid paying duties on foods for consumption in the United States. Unscrupulous importers may also file a T&E entry instead of a consumption entry to try to avoid FDA review of their merchandise: generally, FDA does not receive any notice of these kinds of entries from CBP because these entries are not filed through ABI/ACS.

If we were to interpret ''imported or offered for import'' to exclude those entries, we could be creating a significant potential gap in section 801(m) of the FD&C Act's coverage. An importer could simply bring in an article of food under a T&E entry without giving prior notice and then, as allowed by CBP regulations, file a consumption or other entry. Thus, this exclusion would create a loophole that could be exploited by those who want to avoid giving prior notice, even for articles of food that are for consumption in the United States. Given the stated purposes of the Bioterrorism Act and of section 801(m) of the FD&C Act, FDA has concluded that it is reasonable to interpret ''imported or offered for import into the United States'' to include articles of food entered for transshipment and exportation.

Section 801(a) of the FD&C Act sets out the basic admissibility procedure and standards for foods, drugs, devices, and cosmetics, ''which are being imported or offered for import into the United States.'' As with section 801(m) of the FD&C Act, nothing in section 801(a) limits its requirements just to articles that are intended for consumption in the United States. Indeed, section 801(d)(3) of the FD&C Act exempts from section 801(a)'s admissibility standards certain drugs, devices, food additives, color additives, and dietary supplements if these items are intended at the time of ''importation'' for further processing or incorporation into a product that will be exported. This exemption is only necessary if the phrase ''imported or offered for import'' in section 801(a) includes the bringing into the country of some types of goods that are for processing but not consumption in the United States. Thus, in the context of section 801(a) of the FD&C Act, ''imported or offered for import into the United States'' applies to more than food intended for consumption in the United States. Finally, section 801(d)(1) of the FD&C Act, which limits the circumstances under which U.S.-made drugs can be imported back into the United States, makes it clear that the phrase ''imported or offered for import'' in section 801(a) applies to items made in the United States, exported, and then ''re-imported.''

In light of the text of section 801(m) of the FD&C Act, its purpose, and these other provisions in section 801, we believe it is reasonable that this interim final rule applies to food that is brought into the United States for ''consumption'' (immediate or otherwise) in the United States, for transshipment through the United States and export, or for further processing in the United States and export (often referred to as ''import for export''), and to food that is ''re-imported.'' In addition, FDA has concluded in this interim final rule that there are compelling policy reasons for adopting this reasonable definition of ''imported,'' ''offered for import,'' and ''importation.''

However, when it comes to articles that are imported then exported directly from their port of arrival, we have concluded that it is reasonable to interpret the term ''imported or offered for import'' to exclude them from the prior notice requirements.

Food that is brought to a U.S. port but is then directly exported from that port of arrival is entered under a CBP IE entry and subject to the limitations of an IE bond. In essence, this food may not leave the port of arrival until export. These imports are thus subject to almost identical restrictions as food that is refused under section 801(m)(1) of the FD&C Act—foods that are imported under an IE entry may not leave the port of arrival unless exported. Given that controls already exist to ensure that these articles are not released from the port of arrival, FDA believes that it is reasonable to interpret 801(m) as excluding these imports from section 801(m) of the FD&C Act's prior notice requirements.

(Comments) One comment asks that other products covered by USDA programs (such as products included in ''CFR(Q37)'') be exempt from prior notice in the same manner as foods under the exclusive jurisdiction of USDA.

(Response) The comment did not provide more detail concerning what program is referred to by ''CFR(Q37).'' As set out in section 801(m)(b)(3)(B) of the FD&C Act, the interim final rule provides that meat food products, poultry products, and egg products that are subject to the exclusive jurisdiction of the USDA under the 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.*) are not subject to FDA's prior notice requirements. With regard to other USDA programs, section 315 of the Bioterrorism Act states that no part of Title III should be construed to alter the jurisdiction between USDA and FDA. Notably, under current practice, FDA may have jurisdiction over an imported food under the FD&C Act and USDA may have jurisdiction over an imported food under one or more statutes that it administers, or the two agencies may have joint jurisdiction over an imported food. Under its section 315, the Bioterrorism Act does not change this structure. Accordingly, only imported food that is regulated exclusively by USDA is exempt from prior notice.

In addition, we believe that the statute requires prior notice to be submitted to FDA. As described elsewhere in greater detail, we are working with CBP to modify our existing ABI/ACS and OASIS systems to permit additional data sharing to satisfy prior notice. Although it is theoretically possible for FDA to obtain information from agencies other than CBP, the stringent

timeframes for issuing this interim final rule do not provide FDA adequate time to reconcile the different information required or to work with the other agencies to have them amend their existing requirements to capture all the information FDA needs. Merely obtaining existing information about the food from other agencies would not guarantee that FDA has the information required by section 801(m) of the FD&C Act's prior notice requirements because there is wide variation in the purposes and information required by other government programs. We would also need to work with other agencies to ensure the confidentiality of nonpublic prior notice information under relevant information disclosure laws, *e.g.*, 21 CFR 20.85 (Federal), 20.88 (State), and 20.89 (foreign). Because a purpose of providing prior notice to FDA is to assist FDA in responding to bioterrorism incidents or other food-related emergencies, FDA must have the required information readily accessible. If FDA has to coordinate with other agencies or governments to obtain from them the information necessary to respond to such an emergency, FDA may be prevented from responding to the emergency in a timely manner.

FDA notes that it is dedicated to increasing information-sharing capabilities with other agencies even after this interim rule is in effect, and we will continue to work with other government agencies to further streamline the prior notice process, consistent with our statutory obligations.

(Comments) Several comments suggest that exclusion for baggage in the proposed rule should be broadened in the final rule to include all food in baggage, even food that is not for the traveler's personal use. For example, one comment reasons that samples carried in the baggage of company representatives (or sent unaccompanied) generally do not enter commercial trade.

(Response) FDA disagrees. Except as already provided for, section 801(m) of the FD&C Act does not authorize an exclusion from prior notice for all food imported or offered for import into the United States in baggage. In the preamble to the proposed rule, we explained that the information that section 801(m)(1) of the FD&C Act requires in a prior notice, in conjunction with the purpose of the provision, demonstrates that Congress did not intend prior notice to apply to food that travelers bring into the United States in their personal baggage for personal use (*i.e.*, consumption by themselves, family or friends, not for sale or other distribution). We reasoned that when travelers bring food back from their travels in their personal baggage for their own use, we do not believe that Congress intended for us to characterize such travelers as ''shippers'' for purposes of section 801(m) of the FD&C Act.

When food is not being carried by or otherwise accompanying an individual for his or her personal use, there is a ''shipper''—the person or entity on whose behalf the traveler is bringing in the food. Thus, by its terms, section 801(m) of the FD&C Act requires that food carried by or otherwise accompanying an individual arriving in the United States that is not for personal use be subject to prior notice. In addition, were we to adopt such an exemption, it would create a potentially significant loophole, which could defeat the purpose of prior notice. For example, travelers coming from Latin America sometimes carry local soft cheeses for sale in the United States (Ref. 16). In fact, these travelers often are not staying in the United States for any period of time, but are merely transporting cheese to sell in the United States in their luggage or baggage. These cheeses have been tested by FDA and found positive for listeria, salmonella, and other pathogens associated with raw milk and insanitary conditions. Consumption of such contaminated cheese has been associated with illnesses and deaths. Another example is travelers arriving by automobile who carry cases of shellfish from unapproved foreign growing locations. These shellfish may be contaminated with a variety of illness-causing pathogens including vibrio cholerae or Norwalk virus. These shellfish are often not destined for personal consumption but for sale directly to the public or for consumption by the public at restaurants. Finally, trade samples are imported or offered for import to generate sales, which is a commercial, not personal, use. Thus, there is a ''shipper'' when these samples are brought to the United States.

FDA notes that it is changing the proposed rule by removing the term ''baggage'' and referring instead to food carried by or otherwise accompanying an individual. This change clarifies that the exclusion applies to food that might not be regarded as ''baggage'' but, nonetheless, accompanies the traveler. For example, food in the trunk of a car is not in baggage, but it accompanies the driver and any passengers.

(Comments) Comments ask that any food imported for personal use which arrives in the country by common carrier (*e.g.*, express carrier, truck, plane) should be treated the same as food imported for personal use and carried with a traveler.

(Response) FDA disagrees. Section 801(m) of the FD&C Act does not authorize a broad exclusion from prior notice for all food imported or offered for import for personal use. In the preamble to the proposed rule, we explained that the information that section 801(m)(1) of the FD&C Act requires in a prior notice, in conjunction with the purpose of the provision, demonstrates that Congress did not intend prior notice to apply to food that travelers bring into the United States in their personal baggage for personal use (*i.e.*, consumption by themselves, family or friends, not for sale or other distribution). We reasoned that when travelers bring food back from their travels in their personal baggage for their own use, we do not believe that Congress intended to characterize such travelers as ''shippers'' for purposes of section 801(m) of the FD&C Act. However, when food is shipped by an individual or business in another country to a consumer in the United States for his or her personal use (or otherwise), there is a ''shipper'' as that term is used in section 801(m)(1) of the FD&C Act and defined in § 1.276(b)(10). Accordingly, there is no basis in section 801(m) of the FD&C Act for concluding that Congress did not intend prior notice to apply to articles sent (as opposed to carried) to the United States for the recipients' personal use.

(Comments) One comment asked that FDA address the issue of noncommercial family food shipments and to add these to the list of exemptions from prior notice. Another comment stated that a food shipment consisting of one noncommercial shipper sending food to another noncommercial recipient (*e.g.*, a friend abroad shipping cookies to a friend in the United States) should be outside the scope of the prior notice requirement.

(Response) FDA agrees in part and we have added a provision that excludes personal gifts of homemade food from prior notice. Although we believe that this food is imported into the United States, the information that § 801(m)(1) of the FD&C Act requires in a prior notice, in conjunction with the purpose of the provision, demonstrates that Congress did not intend prior notice to apply to homemade food sent as a personal gift by the maker to a recipient in the United States. In particular, under § 801(m)(1) of the FD&C Act, a prior notice must contain the identity of the manufacturer of the food. When an individual makes a food in their home as a gift for a relative or friend, we do not believe that Congress intended for

us to characterize such cooks as ''manufacturers'' for purposes of § 801(m) of the FD&C Act.

(Comments) Several comments suggest that the final rule should not apply to foods that arrive by international mail or express carriers.

(Response) FDA disagrees. Except for the exclusions already described for food for personal use that is carried by or otherwise accompanying a traveler and homemade gifts, section 801(m) of the FD&C Act applies to food regardless of the method of importation. Thus, foods that arrive by international mail and by express carriers (*e.g.*, Federal Express, United Parcel Service, *etc.*) are subject to section 801(m)'s prior notice requirements. Indeed, FDA notes that foods, drugs, devices, and cosmetics that arrive by mail or express carriers are currently subject to admissibility determinations under section 801(a) of the FD&C Act, which also uses the phrase ''imported or offered for import.'' Finally, were we to adopt such an exemption, it would create a potentially significant loophole, which could defeat the purpose of prior notice. Those who did not want to or could not comply with prior notice requirements would be able to bring articles of food in by mail or express carrier. While this might not be practical for all kinds of foods, many foods are regularly imported by mail or express carrier, *e.g.*, dietary supplements and specialty foods ordered by U.S. consumers from foreign firms. For example, one commenter states its company provides, through Internet sales, special dietary foods and fresh baked foods that are shipped via express carriers directly to consumers at the rate of around 1,000 home deliveries per week.

(Comments) Several comments suggest that the final rule should not apply to various kinds of samples, including trade and market research samples (*i.e.*, samples sent or carried in for the purpose of selling products or conducting market research), trade show samples, samples for testing for nutritional, safety, quality control, or quality assurance reasons, and samples for basic research. These comments reason that samples used for marketing are not intended for retail consumption and generally do not enter commercial trade and, thus, are not intended for use as food. In the case of samples for testing, comments reason that these samples are for the individual's specific and limited personal use and not for further distribution to others and should be exempted as samples are under federal poultry and meat inspection regulations.

(Response) FDA agrees in part. If the samples are items that are in such early stages of research and development that they cannot yet be considered food under § 1.276(b)(5) of the interim final rule, 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. However, samples of food, including those for test marketing, are clearly subject to prior notice as they are ''articles of food imported or offered for import'' as stated in section 801(m) of the FD&C act. For example, in the summer of 2003, FDA received a report from a poison control center in country T concerning the acute poisoning of 9 men (one died) from ingestion of an herbal fermented wine. Symptoms occurred within minutes. Reports indicated that this product may have been exported to the United States in small quantities for test marketing in restaurants. This underscores the importance of FDA receiving prior notice of all food imported or offered for import.

(Comments) One comment suggests that food for research and development purposes sent directly to facilities that are registered under section 415 of the FD&C Act should be exempt.

(Response) If the item is indeed food under this subpart and it is not otherwise excluded under § 1.277(b), prior notice is required. There is no basis in the statute for an exemption based on the fact that an article of food is being sent to registered facilities.

(Comments) Comments ask that articles of food that are of *de minimis* value (*i.e.*, less than $200) be exempt from prior notice. The comments argue that such small shipments for personal use could hardly qualify as a risk to the domestic food supply. They also point out that enforcing prior notice on such articles would be difficult and burdensome to FDA. In addition, they state that prior notice for these items would be a burden on consumers as they usually do not have an agent in the United States to represent them.

(Response) FDA notes that it has removed the restrictions on who can submit prior notice. Thus, foreign sellers or shippers can file prior notices for these kinds of shipments under the interim final rule. Low-value food items are clearly subject to the terms of section 801(m) of the FD&C Act as they are ''articles of food imported or offered for import'' as stated in section 801(m). Moreover, we do not agree that low value shipments are always imported for personal use or would present only *de minimis* risks, such that an exemption can be justified under the *de minimis* doctrine. First, a low value is not necessarily a good indication that the article is for personal use. Many food items (*e.g.*, produce) can have a low invoice value at importation, especially if the shipment is not large. Moreover, in our experience, many specialty, gourmet, ethnic, and exotic foods are often imported for commercial purposes in very small amounts. Thus, a shipment of bottled cooking oil or a beverage contaminated with toxic chemicals may be represented as low-value or low-volume but could have a wide, and very negative, public health impact. In addition, we note that misdeclaration of value of articles of food at entry can be a problem. Finally, any burden such an exemption might relieve would likely be offset by the burden of administering it.

(Comments) Comments ask for an exemption for food imported into the United States for sale in duty free stores.

(Response) FDA disagrees. Unless the food is imported and exported without leaving the port of arrival until export, as set out in § 1.277(b)(2), there is no basis in section 801(m) of the FD&C Act for such an exemption.

(Comments) Some comments recommend that prior notice be waived for foods in situations that they characterize as ''low risk.'' These situations were identified in the comments as any one of the following:

- Exported from U.S.-owned foreign companies;
- Transferred between commonly owned facilities (intra-company transfers);
- Subject to high quality control standards and/or produced in highly-regulated businesses;
- Shipped under seal or in bond;
- Entered as high-volume, repetitive shipments;
- Processed through CBP's Border Release Advanced Selectivity Screening (BRASS); and
- Associated with a program of assessment of low risk, such as the Customs-Trade Partnership Against Terrorism (C–TPAT); Free and Secure Trade program (FAST); or food safety and security programs of foreign government regulatory authorities.

(Response) FDA disagrees. As explained previously, section 801(m) of the FD&C Act applies to all food imported or offered for import into the United States except as outlined in § 1.277(b). Nothing in section 801(m) of the FD&C Act authorizes an exemption for articles of food that are ''low risk'' or covered by programs of other agencies, such as CBP or foreign government regulatory authorities.

Summary of the Interim Final Rule

Section 1.277(a) provides that the interim final rule applies to food for humans and other animals that is imported or offered for import into the United States. This covers food for use, storage, or distribution in the United States, including food for gifts, 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. FTZ. Section 1.277(b) sets out the exclusions from prior notice. It excludes food carried by or otherwise accompanying an individual arriving in the United States for that individual's personal use (*i.e.*, consumption by the individual or his or her family or friends, not for sale or other distribution); food that was made by an individual in his or her personal residence and sent by that individual as a personal gift (*i.e.*, for nonbusiness reasons); food that is imported then exported without leaving the port of arrival until export; and meat food products, poultry products, and egg products subject to the exclusive jurisdiction of USDA under the 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.*).

E. ''Who Is Authorized To Submit Prior Notice?'' (Section 1.278 Proposed as § 1.285)

The proposed rule (§ 1.285) provided that a purchaser or importer of an article of food who resides or maintains a place of business in the United States or an agent thereof was authorized to submit prior notice. FDA noted that a broker/filer would be authorized to be a submitter if it was the U.S. agent of the U.S. importer or U.S. purchaser.

FDA further proposed that if the article of 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 carrier making the in-bond entry.

(Comments) Many comments object to the limitation that only a person who resides or maintains a place of business in the United States can submit the prior notice. Some comments state that foreign-based companies that sell food directly to U.S. individuals for their own use, including companies that sell via the Internet, cannot expect their individual customers to submit prior notice. In addition, comments point out that, under some circumstances, the U.S. importer or purchaser or carrier would not have all the information required by prior notice, but that other entities, *e.g.*, the foreign manufacturer/processor, shipper, or exporter, would have the required information. Many comments state that entities other than U.S. firms or carriers should be allowed to submit prior notice.

(Response) FDA agrees and has removed this restriction on who can submit prior notice. Accordingly, § 1.278 of the interim final rule provides that any person with knowledge of the required information may submit prior notice to FDA. Thus, any person may now take responsibility for submitting prior notice for a particular article of food, as long as that person can provide all the required information. This person is referred to as the submitter in the interim final rule. The interim final rule also states that the submitter may use another person to transmit the required information to FDA. For ease of reference, the person who transmits the prior notice is referred to as the transmitter in the interim final rule. If the submitter submits and transmits the prior notice, he or she is both the submitter and the transmitter. FDA notes that all reply messages sent by the FDA PN System Interface will be sent to the transmitter. If prior notice is submitted via ABI/ACS, all reply messaging goes to the customs broker or self-filer. FDA has also revised the definition of ''you'' accordingly.

(Comments) Comments from customs brokers noted that, although they are responsible for timely submission of all documentation required for import entry, they are not responsible for verifying the accuracy of information provided to them from their customer. Comments ask FDA to clarify in the final rule that the customs broker is merely an agent for the filing of information obtained from the importer and is not responsible for either the adequacy or accuracy of the data submitted. Comments assert that the responsibility of the customs broker is to accurately submit the information provided by his or her client in correct form and in a timely manner.

(Response) The submitter of prior notice information, regardless of the method of or person transmitting the information, is responsible for the accuracy of that information. If the transmitter is not the submitter, we expect the transmitter, whether he or she is a licensed customs broker or other kind of agent, to exercise diligence and care to transmit the information provided by the submitter accurately.

(Interim final rule) Proposed § 1.285 has been changed in the interim final rule to § 1.278, ''Who is authorized to submit prior notice?'' The interim final rule states that any person with knowledge of the required information may submit prior notice. 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 to FDA is the transmitter. The submitter and the transmitter may be the same person. The interim final rule also defines ''you'' to mean the submitter or transmitter (§ 1.276(b)(12)).

F. ''When Must Prior Notice Be Submitted to FDA?'' (Section 1.279 Proposed as § 1.286)

FDA proposed that the prior notice must be submitted to FDA no later than 12 noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry. As described in the proposal, this was based on FDA's assessment of what time was needed to meet its statutory mandate of receiving, reviewing, and responding to prior notice.

(Comments) Generally, the comments recommend that FDA adopt a shorter, rolling prior notice submission timeframe to reduce the burden of the prior notice requirement on the smooth flow of commerce. Many comments recommend a specific timeframe for submission of prior notice. These recommendations ranged from submission of an annual report for repetitive shipments, to submission of the notice at the time of distribution of the food after it arrives in the United States.

Many comments recommend that the prior notice submission timeframe be linked to a mode of transportation or type of port of entry, and others recommend that it be linked to the type of food. Many comments recommend a specific timeframe and associated that timeframe with either a mode of transportation/type of port or with a type of food or both. Comments recommend that prior notice be submitted 8 hours before arrival; some associate the 8 hours timeframe with a water mode of arrival only, while others associate the 8 hours timeframe with nonperishable foods. Many comments recommend that prior notice be submitted 4 hours before arrival; some associating the 4 hours timeframe with land and air modes of arrival only and some associating the 4 hours timeframe with perishable foods (produce and seafood) and live animals only.

(Response) FDA agrees that the time for submission of prior notice should be a rolling timeframe. FDA has determined that the time can be shortened to reduce the effect on the

smooth flow of trade while still providing FDA with sufficient time to receive, review, and respond to the information. FDA also agrees that timeframes should be different for different modes of transport. As such, FDA has revised the rule to require that the timing of submission will be no more than 5 days (except in the case of international mail) and that the prior notice submission be confirmed by FDA for review no less than 2 hours before arriving at the port of arrival by land via road, no less than 4 hours before arriving at the port of arrival by air and land via rail, and no less than 8 hours before arriving at the port of arrival by water.

When food carried by or otherwise accompanying an individual is subject to this rule, the timeframe associated with the manner of the individual's arrival applies. If the individual and article of food are arriving by land via road, the prior notice must be submitted and confirmed at least 2 hours before arrival. If the individual and article of food are arriving by air or by land via rail, the prior notice must be submitted and confirmed at least 4 hours before arrival. If the individual and article of food are arriving by water, the prior notice must be submitted and confirmed at least 8 hours before arrival.

Two major agreements between CBP and FDA allow FDA to reduce significantly the time necessary to receive, review, and respond to prior notice information. First, FDA and CBP have agreed to commission or use CBP staff to perform examinations for FDA when FDA is not present at the port of arrival. Since CBP staff generally will be available where FDA is not, this means that FDA no longer needs lead-time to travel significant distances to conduct inspections. In addition, CBP agreed to modify ABI/ACS to receive, transmit, and communicate prior notice information electronically between CBP and FDA for most entries of imported foods by the statutory deadline in the Bioterrorism Act of December 12, 2003. CBP's assistance with prior notice means that FDA needs far less time to respond to prior notices.

In considering how to modify the timeframes, FDA concluded that setting them by mode of transportation would be the best approach. Mode of transportation is clear and easy to apply and administer, so there is likely to be little confusion about what timeframes apply. If we were to set timeframes based on type of food, *e.g.*, perishable versus nonperishable, we would have to develop and implement a system for determining which articles of food were which. In addition, different articles of food in the same conveyance would be subject to different prior notice timeframes, which would subject all items in the conveyance to the longest timeframe and add an additional layer of complexity that could cause confusion and delays at the border. Moreover, many comments recommended mode of transportation, which suggests that many stakeholders, including industry, believe such a system is workable.

In determining the actual timeframes for submission of prior notice for each mode of transportation, FDA considered the need to provide sufficient time for the agency to review and respond to the information submitted, as well as the current ability of the food industry to provide the information required within the stated timeframe given the differences in lead time before arrival among different modes of transportation. We determined that information for shipments whose transport time is measured in days or weeks (*e.g.*, ocean shipments) is available further in advance of arrival than shipments whose transport time is measured in hours (*e.g.*, land and air shipments.) Staggered prior notice submission timeframes will allow FDA reviewers to direct additional resources to shipments with short transport times and to defer review of shipments with longer transport times. Based on these considerations, FDA established the prior notice timeframes in the interim final rule to associate with the mode of transportation.

FDA is committed to exploring ways to increase integration and reduce the prior notice timeframes further. Accordingly, FDA and CBP will continue working together to determine what is needed to achieve this goal. No later than March 12, 2004, the Commissioners of FDA and CBP will publish a plan, which will include an implementation schedule, to achieve the goal of a uniform, integrated system and to coordinate timeframes for import prior notice information while fulfilling the Bioterrorism Act mandates for air and truck modes of transportation with timeframes finalized by CBP when they finalize the rule entitled ''Required Advance Electronic Presentation of Cargo Information,'' published in the **Federal Register** on July 23, 2003 (68 FR 43574).

For imported food arriving via international mail, the interim final rule requires that prior notice be submitted before the food has been sent. This timeframe allows the FDA PN Confirmation Number to accompany the package, which is necessary to establish that prior notice has been submitted and to match the prior notice submission to the package upon arrival.

(Comments) Some comments recommend that the prior notice submission timeframe be waived for foods exported from U.S.-owned foreign companies. Other comments recommend that a different timeframe be established for foods associated with a program of assessment of low risk, such as the C–TPAT.

(Response) The interim final rule does not provide for a waiver of the timeframe for foods imported by U.S.-owned firms. Nor does the rule provide for a different timeframe for foods or firms covered by programs of other agencies, such as C–TPAT. The interim final rule provides for greatly reduced timeframes for foods based on mode of transportation. These timeframes are what FDA has determined are the minimum timeframes necessary to allow it to satisfy the statutory mandate that the timeframes give the agency the time it needs to ''receive, review, and respond'' to prior notices. However, FDA is also interested in exploring flexible alternatives for submission of prior notice for foods or firms covered by programs of other agencies, such as C–TPAT, or imported by other agencies.

(Interim final rule) Section 1.279(a) in the interim final rule has been revised to require submission of the prior notice to FDA and the submission must be confirmed by FDA for review no less than 2 hours before arriving at the port of arrival by land via road, no less than 4 hours before arriving at the port of arrival by air and land via rail, and no less than 8 hours before arriving at the port of arrival by water. Under § 1.279(b), prior notice may not be submitted more than 5 calendar days before arrival, except in the case of food imported or offered for import by international mail.

Under § 1.279(c), if the article of food is arriving by international mail, the prior notice must be submitted before the food is sent to the United States.

Section 1.279(d) provides that the time of submission is fixed and the prior notice time will start for purposes of determining if prior notice is timely when the prior notice submission is confirmed by FDA for review. FDA will confirm a prior notice once all required information has been submitted and confirmed as facially complete. For example, if the information submitted were to include a registration number, name, city, and country for the manufacture of an article of food, and the system review were to reveal that the registration number does not exist or does not match the name, city, and country of the facility, the FDA PN

System Interface will not provide a confirmation for that prior notice. The transmitter will have an opportunity to correct the rejected information. When the information is corrected, transmitted, and determined to be facially valid, the system will then notify the transmitter and provide the PN Confirmation Number. As set out in § 1.279(d), FDA will notify the transmitter that the prior notice has been confirmed for review with a confirmation that contains a PN Confirmation Number. The prior notice will be considered submitted and the prior notice time will start when FDA has confirmed the prior notice for review.

Under § 1.279(e), the PN Confirmation Number must accompany any article of food arriving by international mail. Under § 1.279(f), a copy of the confirmation (with the PN Confirmation Number) must accompany any article of food carried by or otherwise accompanying an individual (unless excluded under § 1.277(b)(1)), and be provided to CBP or FDA upon arrival.

Additionally, under § 1.279(g) the PN Confirmation Number must accompany any article of food for which the prior notice was submitted through the FDA PN System Interface when arriving in the United States and must be provided to CBP and FDA upon arrival.

G. ''How Must You Submit Prior Notice?'' (§ 1.280 Proposed as § 1.287)

FDA proposed that prior notice and any amendments and updates must be submitted electronically to FDA through a new Web interface. The proposed rule also required submission of hard-copy prior notice, in person or by e-mail or fax, if the FDA system was not operating. Before issuing the proposed rule, FDA consulted with CBP, which was then the U.S. Customs Service of the Department of the Treasury, about the proposed rule and the feasibility of modifying ABI/ACS to accommodate the new prior notice requirement. During these consultations, CBP advised that ABI/ACS could not be modified to accommodate the data requirements of the prior notice regulation by the December 12, 2003, statutory deadline.

(Comments) Many comments focus on the proposed method of submission of prior notice. These comments fall into four broad categories. The first category, which includes the largest number of comments, suggests that FDA work more closely with other agencies, and in some cases other countries, to eliminate redundancies or conflicts in the method of submission. The majority of these comments urge the FDA to work more closely with CBP. A second group of comments addresses the viability of the proposed Web-based system for submission of prior notice. The third category includes suggestions about the prior notice form that was included in the proposed rule. The final category of comments asserts that existing systems and procedures provide adequate defense against a bioterrorism threat and that the proposed regulation is unnecessary.

1a. Work With Other Agencies To Eliminate Redundancies

(Comments) Most comments recommend that FDA and CBP work together to reduce the adverse impact of submission of information in both prior notice and CBP entries. Most of these comments suggest that the existing ACS–OASIS interface between CBP and FDA be used to accept prior notice information. Other comments suggest that much of the information required for prior notice was available in CBP's Automated Manifest System (AMS). Although many comments suggest that the existing systems contained sufficient information to meet the statutory requirements, others recognize that modifications were needed to meet the Bioterrorism Act's requirements.

(Response) FDA and CBP agree with many of the comments made about inter-agency cooperation as well as with the recommendation that we provide a single point of data entry for CBP and FDA for as many kinds of entries as possible. FDA and CBP are committed to the joint implementation of an automated approach to prior notice that will meet the following objectives: (1) Reduce submission of redundant data to the extent possible; (2) build on current operational procedures; and (3) implement the law with minimal disruption to current entry practices.

The interim final rule requires prior notice to be submitted electronically to FDA through CBP's ABI/ACS or the FDA PN System Interface. Prior notice may be submitted through ABI/ACS for all food imports subject to this interim final rule except food imported by international mail or other transactions that cannot be submitted through ABI/ACS and food that has been refused under section 801(m) of the FD&C Act. The proposed rule was based on an initial review by both FDA and CBP of the feasibility of implementing new operational procedures and enhancing existing systems. After further review of the potential technical, legal, and operational impacts, FDA and CBP have determined that the prior notice information required for most types of CBP entries of foods can be submitted through the existing ABI/ACS and provided to FDA. The existing ABI/ACS–OASIS interface allows for communication both between FDA and the customs broker or self-filer (necessary for the submission of prior notice to FDA as required by section 801(m)(1) of the FD&C Act), and between FDA and CBP (necessary for followup at the border). However, although much of the information required for prior notice currently existed in some automated form in ABI/ACS, not all the necessary data were available in the right sequence or at the right time to meet prior notice requirements. Thus, FDA and CBP have been working closely together and enhancing, ABI, ACS, and OASIS to craft operational procedures and systems that meet the requirements of the Bioterrorism Act with minimal impact on existing processes.

Since prior notice is required for some of imported food for which electronic transmission of information to CBP is not available via ABI/ACS and since submission of information through ABI/ACS is not mandatory, an alternative means to submit prior notice will still be needed. Although a CBP entry is not normally submitted in ABI/ACS for T&E entries and IT entries and FTZ admissions, a new transaction format, similar to the existing ABI transactions, will be available for submitting prior notice for these imports through ABI/ACS. The FDA PN System Interface will also be available for international mail, food refused under section 801(m) of the FD&C Act, and those who choose not to submit prior notice through ABI/ACS.

1b. CBP AMS

(Comments) Several comments note that some of the information FDA required for prior notice was already being submitted to AMS and suggested that FDA could retrieve data from AMS rather than ask for a separate submission for prior notice.

(Response) AMS is a module of ACS through which carriers, port authorities, or service bureaus transmit electronically the cargo declaration portion of the inward foreign manifest to CBP. The information submitted to AMS is not sufficient to satisfy section 801(m)(1) of the FD&C Act's requirements. For example, the identities of the manufacturer, grower, FDA product code, and quantity of each article are not submitted to AMS. FDA and CBP have consulted about interfacing with AMS for manifest data and determined that the general cargo data in AMS were simply not suitable to accommodate the detailed information requirements of section 801(m) of the FD&C Act. In addition, no

interface currently exists between AMS and the existing interface with OASIS through the ABI/ACS entry processes, which means FDA does not have any access to AMS data. However, section 801(m) of the FD&C Act requires that prior notice be submitted to FDA. Given the implementation date of December 12, 2003, CBP and FDA concluded that it was not practical to attempt to modify AMS to accommodate the new prior notice requirements when we could enhance the existing ABI/ACS–OASIS interface.

2a. Viability of a Web-Based System

(Comments) A common concern expressed by commenters is the viability of the FDA PN System Interface for the volume of data traffic and the time-sensitive nature of prior notice information. Multiple comments address system availability, the time needed to enter and process the data, and the need for confirmation.

(Response) FDA agrees that implementation of a new FDA PN System Interface as the primary means of data submission for 25,000 plus transactions a day would be challenging, particularly considering the effect on the food industry if the system were not responsive. That concern has been substantially addressed as a result of the commitment by CBP and FDA to work together to enhance the existing ABI/ACS–OASIS interface to accommodate the prior notice requirements. The decision includes the development of a new ABI/ACS ''transaction type'' that will accommodate prior notices for IT entries, T&E entries, and food shipped directly to an FTZ. This new feature further reduces the number and type of transactions that must be submitted through the FDA PN System Interface.

FDA anticipates that less than 10 percent of the total submissions will be submitted through the FDA PN System Interface. The FDA PN System Interface will be available 24 hours a day, 7 days a week. FDA has taken steps to ensure that the FDA PN System Interface can provide adequate response times to support data entry and return of confirmation by reply messaging.

2b. Contingency System

(Comments) FDA received several comments on the need for a contingency plan or backup plan in case of FDA Web system failure. The severity of the consequences if FDA were to fail to receive a prior notice, and the common experience with Web system failures, was of great concern to many of the system's potential users. Many suggestions were made for contingency plans, *e.g.*, information on what FDA plans to do if the automated system is unavailable.

(Response) FDA agrees that plans for contingencies are needed, even with the reduced volume of traffic on the FDA PN System Interface and the existence of two modes of submission. FDA does not plan to exempt any specific categories of food articles from prior notice if systems are not performing; FDA and CBP are working together to develop contingency plans for when the system(s) are not working. The interim final rule, § 1.279(b) through (d), sets out how we will handle prior notice in four ''down-time'' situations: The customs broker's or self-filer's access to ABI/ACS is not working; the ABI/ACS interface is not working; the FDA PN System Interface is not working; and OASIS is not working. In all these situations, an alternative form of prior notice information is required. If access to ABI/ACS is not available, prior notice must be submitted via the FDA PN System Interface. If FDA determines that FDA PN System Interface is not working, prior notice must be submitted manually by those who do not use ABI/ACS. If FDA determines that OASIS is not working, all prior notices must be submitted manually. FDA will issue notification through notices on the FDA Web site at *http://www.fda.gov,* at *http://www.access.fda.gov,* and through messages in ABI/ACS. Once FDA issues this notification, prior notice information must be submitted to FDA by e-mail or by fax.

Manual submissions must be submitted by e-mail or fax. Because all review is being done in a centralized location, we will not accept manual submissions in person. The FDA Web site at *http://www.fda.gov* will have a list of the information required for prior notice submission and the fax number(s) and e-mail address(es) where prior notice can be sent. The list of the information required can be printed. It can also be downloaded to the submitter's or transmitter's word processing system and used as a basis for submitting prior notice information to FDA. Because the FDA PN System Interface at *http://www.access.fda.gov* and FDA's Web site at *http://www.fda.gov* are located on independent platforms, this information will be available even when the FDA PN System Interface is not working. This fax number and the e-mail address will not be activated to accept prior notice information unless FDA determines that the FDA PN System Interface or OASIS is not working. Additional information about the down-time, *i.e.*, confirmation that the FDA PN System Interface or OASIS is down and estimated down-time will be posted at *http://www.fda.gov*—see ''prior notice'' and will be available from the help desk.

2c. Alternate Methods

(Comments) Several comments suggest more than one path for submission of prior notice information. Some comments ask that FDA allow for manual submission, either as a backup, or as an alternate path. Others suggest that some types of ''safe'' products be allowed to bypass prior notice if the system were not performing. Still others suggest that the potential for catastrophic system failure requires FDA to implement 2 interfaces for prior notice data, often implying that ACS was an appropriate alternative system.

(Response) FDA does not agree that a process for manual transmission is needed, except on a contingency basis. FDA believes that, in 2003, persons engaged in international commerce have, or can get, access to the Internet. If the Internet is not accessible by the submitter, he or she can use a customs broker to submit prior notice through ABI/ACS or another person to transmit prior notice through the FDA PN System Interface. As the primary mode of submission, manual transmission would not give adequate time for FDA personnel to receive, review, and respond, unless the timeframes for prior notice in the interim final rule were greatly extended. Thus, manual transmission will be used only as a contingency alternative. FDA also notes that the data quality of manual systems is usually less than satisfactory, because no automated data validation takes place during data entry. The U.S. Government has a strong commitment to reducing paper-based processes and moving toward e-commerce for all business transactions. Accordingly, under the interim final rule, paper-based submissions will not be allowed, except as set forth in § 1.280(c) and (d), by e-mail and fax. However, FDA and CBP do not expect system failures to be a common occurrence.

2d. Security of System

(Comments) Several comments question the security of the system and suggested that the system must have extraordinarily stringent security protocols in place to protect sensitive commercial information and prevent potential terrorists from obtaining information capable of providing cover.

(Response) FDA agrees the information must be secure. Any fraudulent or inadvertent changes in data could affect FDA response and thus affect the health and welfare of

consumers in the United States. FDA has determined that the data security and data integrity requirements of the prior notice data are on par with entry data currently submitted through ABI/ACS to OASIS. Prior notice data submitted through ABI/ACS will have the same security and access controls as entry data currently received through ABI/ACS. Adequate and effective security controls will be placed on the FDA PN System Interface through user account management and authentication processes, and password controls, to ensure data security and integrity.

A number of statutes, regulations, and policies address protection of sensitive information from unauthorized disclosure. Some that are relevant to prior notice include the Clinger-Cohen Act of 1996, the Computer Security Act of 1987, the Trade Secrets Act, 21 CFR 20.61 (Trade Secrets and Commercial or Financial Information Which Is Privileged or Confidential), OMB Circular A–130 (Management of Federal Information Resources), and FDA Staff Manual Guide 3250.15 (Information Technology Security, Data Security—Data Confidentiality). For example, Appendix III to OMB Circular No. A–130 establishes a minimum set of controls to be included in an agency's information security program and requires security controls to be commensurate with the risk and magnitude of the harm resulting from the loss, misuse, or unauthorized access to or modification of information.

3a. Prior Notice Form

(Comments) Several comments suggest changes to the proposed form. Most of these recommend changes in the order of items in the form.

(Response) The draft form that was provided as an attachment to the proposed rule was intended only to provide a graphic summary of the information to be collected by the FDA PN System Interface (68 FR 5334). The form was an illustration, intended to help potential users to visualize the data requirements and to better analyze their relationship and impact. FDA did not intend the draft form to be a sample of the screens that will be available to the user on the proposed FDA PN System Interface. Nor was it intended to be a draft paper form, since paper-based submission will not be acceptable, except as a contingency if the system is not operating.

The actual screens of the FDA PN System Interface are based on standard Web design principles, with primary attention to support of anticipated data entry. The screens will incorporate extensive use of ''pull-down'' lists to assist users in entering their data. For example, transmitters will use a predefined pull-down list of International Standards Organization (ISO) codes for countries to enter the country from which the article is shipped. Screen design places critical data entry items at the beginning of the submission process and uses those items to drive later processes. Data entry processing will also include robust and user-friendly data validation to ensure that transmitters enter data correctly and do not fail prior notice because of inadvertent errors in their data entry screens. Additional description of the FDA PN System Interface is included in the discussion of the interim final rule at the end of this section.

3b. Form Processing

(Comments) Several comments make suggestions about the way the form should be processed, requesting self-populating fields, the ability to change information without redoing the whole form, confirmation after submission, and other features that would make submission easier.

(Response) As noted previously, FDA did not intend the draft form in the proposed regulation to suggest processing sequences. Submitters or transmitters using the ABI/ACS interface to submit prior notice data to the FDA will be able to make full use of the capabilities of their particular ABI software's automation features. The FDA PN System Interface will permit initial partial data entry and will allow the user to save the information entered until all data are available for submission. The FDA PN System Interface is designed to accept ''header'' information that will permit repeated information to be automatically entered. This ''header'' would contain information consistent across several articles of food within the same submission, *e.g.*, date and time of arrival for several articles of food in one shipment. This will reduce the amount of data entry and potentially reduce typing and transcription errors. FDA has developed the FDA PN System Interface to allow submitters to automatically repeat information already entered in the submission where appropriate (*e.g.*, all information is the same except for the identity of the article or the manufacturer).

The order of information required in prior notice is displayed to best support user input. For example, the first information required is the identification of the submitter and transmitter, if applicable. The next information is the common information that may apply to all articles of food for which prior notice is being submitted at the same time, such as the manufacturer, shipper, carrier, etc. For example, when a manufacturer is identified for the first article of food, the submitter will be able to indicate, using a check box, that the manufacturer is the same for all articles of food in the shipment.

3c. Clarification of Fields

(Comments) A few comments ask for clarification on the meaning of specific fields.

(Response) Elsewhere in this rule FDA sets out the information that must be submitted in a prior notice (see § 1.281). In addition, online help will be available, which will include descriptive information on data fields, and their relationship to other required information and references to the requirements. FDA will also provide a help desk with staff who will answer questions that are not specifically answered by the online help. Information on how to contact the help desk will be available on both the FDA PN System Interface at *http://www.access.fda.gov* and the FDA Web site at *http://www.fda.gov*—see ''prior notice.''

4. Existing System Adequate

(Comments) Several comments suggest that the regulations proposed were unnecessary and that FDA already had the data required, so prior notice would not provide any additional security. These comments conclude that the proposed regulation is therefore functionally redundant.

(Response) Congress mandated prior notice when it enacted the Bioterrorism Act. FDA disagrees with the assertion that prior notice will not provide any additional security because similar information about food is already available. Current systems do not provide all of the information required by the Bioterrorism Act. Nor do they ensure that FDA is provided with the required information before arrival, as required by Congress when it passed the Bioterrorism Act.

5–11. Description of the Prior Notice Submission Systems

Prior notice submission and electronic review will be accomplished through several new or enhanced components of FDA's and CBP's existing electronic systems.

a. *ABI/ACS interface.* The existing ABI/ACS interface, which sends data from customs brokers or self-filers through ACS to OASIS, will be enhanced to support the prior notice requirement. For customs brokers or

self-filers providing prior notice as part of their CBP entry through the ABI/ACS interface, the process for submission and response will be similar to the current process for submitting entry information about FDA-regulated products. A customs broker or self-filer will enter and transmit the information currently required in a CBP entry, along with any additional information required in prior notice, using the software that currently supports submission of data through the ABI interface. (Changes will be required to the existing software to support the additional information required in the prior notice.) As it does currently, ACS will validate the submission to ensure that data required by CBP and FDA is entered. The existing validation will be enhanced to include validation of some prior notice information. If errors or deficiencies are found, the transmission will be rejected and the customs broker or self-filer can resubmit after correcting the errors or deficiencies.

Once ACS determines a submission is valid, the prior notice information and other data will be transmitted to OASIS. OASIS will perform additional data checks and validations. Validation is the process by which the data are checked for completeness and self-consistency by the system. It is a rapid process that does not include screening the data for potential public health concerns. That screening occurs after data validation. If the submission is determined to be facially valid, FDA will transmit a message through ACS to the customs broker or self-filer. The message will provide the Prior Notice Confirmation Number (PN Confirmation Number), which verifies that the prior notice has been confirmed by FDA for review.

If errors are found, OASIS will reject the submission and generate a message(s) identifying where the error occurs. No PN confirmation number will be issued. After the customs broker or self-filer is notified of the errors, the customs broker or self-filer can correct the errors and resubmit the entire entry using the same entry number through the existing CP transaction process (which is the existing transaction for brokers or self-filers to resubmit FDA-specific data through ACS). This process only allows FDA-specific data to be corrected for resubmission, and not CBP-specific data.

A new ABI/ACS-OASIS interface, modeled after the existing process, will be available to submit prior notice for an article of food entering the United States as an IT or T&E entry, or an FTZ admission. This new transaction will not require all of the information currently submitted to CBP at the time a consumption entry is filed, but will require complete prior notice information. Processing of these prior notices will be similar to that described for consumption entries. However, prior notice will be submitted by a new transaction type that will require only the information needed for prior notice and to support messages to CBP regarding the adequacy of the prior notice.

If CBP entry is later filed, the PN Confirmation Number for the article must be entered as an affirmation of compliance for OASIS purposes as evidence that prior notice for the product was submitted and confirmed before arrival. Depending on the capabilities of a customs broker's or self-filer's software, a copy of the ABI Cargo Release Summary will also show that the prior notice has been received, though not necessarily confirmed, by FDA.

The following list identifies the types of entries, with accompanying CBP description, for which prior notice may be submitted through ABI/ACS at the submitter's option:

''Consumption entries''—products entered for use or consumption in the United States;

''Warehouse entries''—products subject to duty but for which payment of duties is deferred. Merchandise entered into a warehouse may be stored, repacked, cleaned, manufactured, smelted, refined, or sold for export. Food must remain in the warehouse until withdrawn for consumption in the United States (and any applicable duty paid);

''IT entries''—in-bond transportation entries for merchandise that arrives at a Customs port of entry but is transported without appraisement to another Customs port of entry where it may be entered for consumption or warehouse, admitted into a FTZ or may be the subject of another transportation entry;

''T&E'' entries''—in-bond transportation entries for merchandise which arrives at a Customs port of entry and is to be transported without appraisement through the Customs territory and then exported; and

''FTZ admissions''—are for merchandise to be used in manufacturing or exhibition or to be manipulated in a FTZ. Merchandise admitted into the zone is not subject to the payment of duties. Merchandise may be withdrawn from the zone for consumption, warehousing, or exportation. There are various categories of merchandise in a zone.

b. *FDA PN System Interface.* The new FDA PN System Interface will be available for international mail and other transactions that are not accepted by ABI/ACS, food refused under section 801(m) of the FD&C Act, and those who choose not to submit prior notice through ABI/ACS. The FDA PN System Interface is available at *http://www.access.fda.gov.* FDA expects that less than 10 percent of transactions will be routinely submitted through the FDA PN System Interface. We estimated the number of informal entries that are not currently captured by ABI/ACS and international mail submissions based on discussions with CBP.

The FDA PN System Interface will allow the user to view and print a prior notice confirmation, including a PN Confirmation Number, the time the prior notice was confirmed, and a record of the information received and validated by FDA.

To submit prior notice information electronically by the FDA PN System Interface, the transmitter must establish a prior notice account. FDA's Unified Registration and Listing System (FURLS) at *http://www.access.fda.gov* will manage the issuance of user accounts for both food facility registrations and prior notice submissions. FURLS will be available 24 hours a day, 7 days a week, and will provide end-users access to the systems. After successfully logging in using the account password, FURLS will pass the user account credentials to the FDA PN System Interface. If the transmitter has not established a prior notice account, the transmitter will be directed to establish a prior notice account the first time he or she accesses the FDA PN System Interface. Subaccounts can also be created, at the discretion of the primary account, to allow more than one person associated with a prior notice to access the prior notice information.

A submitter or transmitter who elects to use the FDA PN System Interface will enter information online, using a series of screens designed to lead the submitter through the prior notice submission process. Data will be subject to the same validation criteria used in the ABI/ACS–OASIS interface, but the validation will be performed on-line, in real time. When the prior notice submission has been validated, the transmitter will receive a message showing that the prior notice has been received by FDA for review and accepted as facially complete. This message will include a unique PN Confirmation Number as well as the date and time of the submission and confirmation. The message will confirm that the prior notice is facially complete and has been received by the FDA for review. Capability will also be provided

to get a hard copy printout of the prior notice submission and a confirmation for verification upon arrival of the article of food, if needed.

If the prior notice was submitted through the FDA PN System Interface, this confirmation number must accompany the article of food when it arrives at the port of arrival. For food arriving by international mail, the PN Confirmation Number received from the FDA PN System Interface must be entered on the ''Customs Declaration—CN22 and CN23'' supplied when the article is mailed. When food subject to this subpart is carried by or otherwise accompanies an individual, the individual must have the PN Confirmation Number, as well. The number will provide CBP and FDA personnel at the border with the means to connect to the results of the FDA review of the prior notice information.

Receipt of a PN Confirmation Number is evidence only that a prior notice has been received for FDA review. Should the FDA review process determine that an article of food should be inspected, personnel at the border will examine the food.

Prior Notice covering a refused food (no prior notice or inaccurate prior notice) must be submitted through the FDA PN System Interface. In addition to prior notice information, the FDA PN System Interface will be used to inform FDA of the port or secure storage location where refused food is or will be held.

12. FDA Review

The FDA prior notice review process will operate 7 days a week, 24 hours a day to review prior notice submissions transmitted through both ABI/ACS and the FDA PN System Interface. This process begins with an automated screening process. If additional evaluation of the prior notice information is necessary, FDA headquarters staff, operating 24 hours a day, 7 days a week, will review the information and may initiate an examination by FDA or CBP of the article of food at the port of arrival, or in the case of rail shipments, within the confines of the closest appropriate examination site. The review process is and manual review by FDA staff. It will be designed to identify food products that may pose serious risks to public health so that appropriate action can be taken upon arrival in the United States. The review process is not impacted by the method of electronic submission. The results of this process will be transmitted to CBP.

The existing OASIS screening and FDA staff review and examination processes will determine admissibility under section 801(a) of the FD&C Act. Thus, food that has not been refused after review and/or examination of the prior notice information may be subject to further inspection and sampling at an inland destination for determination of admissibility under section 801(a) of the FD&C Act.

13. Summary of the Interim Final Rule

The interim final rule requires that prior notice be submitted electronically to FDA. All prior notice information must be submitted in the English language except 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. The prior notice may be submitted through ABI/ACS or the FDA PN System Interface at *http://www.access.fda.gov.* Prior notice must be submitted via the FDA PN System Interface for articles of food imported or offered for import by international mail or other transaction types that cannot be made through ABI/ACS and articles food that have been refused under section 801(m)(1) of the FD&C Act.

The interim final rule, in § 1.279(b) through (d), also sets out how we will handle prior notice in four ''down-time'' situations: The customs broker's or self-filer's access to ABI/ACS is not working; the ABI/ACS interface is not working; the FDA PN System Interface is not working; and OASIS is not working. In all these situations, an alternative form of prior notice information is required. If access to ABI/ACS is not available or if the ABI/ACS interface is not working, prior notice must be submitted via the FDA PN System Interface. If FDA determines that FDA PN System Interface is not working, prior notice may be submitted manually by those who do not use ABI/ACS. If FDA determines that OASIS is not working, all prior notices must be submitted manually. FDA will issue notification through notices on the FDA Web site at *http://www.fda.gov,* at *http://www.access.fda.gov* and through messages in ABI/ACS. Once FDA issues this notification, prior notice information must be submitted to FDA by e-mail or by fax. Hand delivery of hard copy to FDA is not allowed. The location for receipt of submission by e-mail or fax is listed at *http://www.fda.gov—see* ''prior notice.''

H. ''What Information Must Be in a Prior Notice?'' (§ 1.281 Proposed as § 1.288)

Proposed § 1.288 listed the information that was to be included in each prior notice. Part of the information was taken directly from section 801(m)(1) of the FD&C Act. The remainder of the list consisted of information that FDA and CBP have determined is necessary to ensure that we can enforce section 801(m) of the FD&C Act's prior notice requirements as intended by Congress. This additional information is thus authorized under section 701(b) of the FD&C Act (21 U.S.C. 371(b)). In the proposed rule, we explained why each of these items was necessary for the efficient enforcement of section 801(m) of the FD&C Act.

(Comments) Generally, comments assert that the proposed rule required too many data elements. Some comments state that the required information is more than that necessary to facilitate inspection; is burdensome on industry; and is more information than that authorized by the Bioterrorism Act, particularly with regard to product identity, port of entry, and identification of parties involved in prior notice. One comment argues that the prior notice was intended by Congress only to aid FDA in its efforts to ensure the security of the food supply, not to enhance compliance of imported food with all applicable FD&C Act requirements.

(Response) FDA agrees with many of these comments. Accordingly, the interim final rule will not require submission of the following information:

- Telephone and fax numbers and e-mail addresses for most firms;
- Registration numbers, except for the manufacturer and shipper, if otherwise required by section 801(l) of the FD&C Act;
- Entry line numbers;
- Brand or trade name;
- CBP port of entry;
- Anticipated date of entry for CBP purposes; and
- The identities of multiple carriers.

FDA has also revised the following information requirements to make them less burdensome:

- Quantity;
- Lot/code identifier;
- Manufacturer; and
- Grower.

Finally, FDA has added the following information requirements due to the changes in timeframe, the need to coordinate with CBP, and in response to comments:

- The mode of transportation; and
- Planned shipping information, including the 6-digit HTS code.

FDA does not agree that section 801(m) of the FD&C Act is limited to ''food security.'' The purpose of the Bioterrorism Act is ''[t]o improve the ability of the United States to prevent,

prepare for, and respond to bioterrorism *and other public health emergencies*.'' (Pub. L. 107–188 (emphasis added)). Title III of the Bioterrorism Act is titled, ''Protecting the *Safety* and Security of the Food and Drug Supply.'' (Pub. L. 107–188 (emphasis added)). Indeed, when reviewing prior notices that have been submitted after a food has already been refused for lack of adequate prior notice, Congress explicitly directs FDA to determine if it has in its possession any ''credible evidence or information indicating that such article present a threat of serious adverse health consequences or death to humans or animal,'' (section 801(m)(2)(B)(ii) of the FD&C Act). This standard is a health-based standard and is not limited to intentional acts of contamination.

For clarity, the interim final rule also has segregated the information requirements for food imported or offered for import by international mail as new § 1.281(b) and the information requirements for food refused under section 801(m) of the FD&C Act as new § 1.281(c).

1. Registration Numbers

(Comments) Comments note that the submitter may not know the necessary registration numbers and recommend that FDA confirm the registration numbers within its system. A comment reasons that, because FDA will have access to the contact information in its facility registration database, FDA should only require the registration number rather than the name, address, telephone number, fax number, and e-mail address to reduce the burden on submitters. Another comment states that it would be impossible to provide the FDA registration numbers of all operators that have handled the imported food and questions FDA's need for the registration numbers because the ''one up, one down'' recordkeeping provision added to the FD&C Act by section 306 of the Bioterrorism Act is sufficient to help FDA take appropriate steps. Other comments express concern about the confidentiality of registration numbers, *i.e.,* they may be denied access to the registration number or be unable to verify it. Other comments state that an importer who imports returned U.S. goods has no direct relationship with the U.S. manufacturer and therefore assert that these importers cannot obtain the registration number.

(Response) Registration of facilities that manufacture/process, pack, or hold food for consumption in the United States is required by new section 415 of the FD&C Act, which was added by section 305 of the Bioterrorism Act. FDA does not believe that the statute gives FDA authority to waive the registration requirement for facilities that manufacture/process, pack or hold food for consumption in the United States. The one instance when not providing a registration number may be appropriate is when the manufacturer is out of business or registration no longer is appropriate because the manufacturer has ceased making food products under FDA's jurisdiction.

If such a food is refused because of inadequate prior notice for failure to provide a registration number, or if the food is held under § 1.285(b), you may request an FDA review under § 1.285(j). As part of your request, you should provide FDA information to show that the facility associated with the food is out of business or inactive.

Registration is designed to work in concert with prior notice at the border, as reflected in new section 801(l) of the FD&C Act, which provides that food from facilities that must register may not be admitted into distribution for consumption in the United States unless the relevant facilities have been registered. To enforce section 801(l) of the FD&C Act as intended by Congress, FDA has determined that it must review registration status of manufacturers and shippers as part of prior notice. The information provided by registration will allow FDA to check prior notice submissions against registration data to confirm the identity. Moreover, the information provided by prior notice submissions can serve as a crosscheck as to whether these firms are registered as required and have provided the necessary updates. FDA thus believes that prior notice and registration will work in tandem to provide FDA with information about the article of food and a facility involved in its production and distribution that will inform and improve our risk-based border inspection decisions, as well as our later admissibility determinations.

FDA does not agree that it should confirm registration without requiring that the number be submitted. Each registered facility will be assigned a unique registration number by FDA. Thus, the registration number will help identify the manufacturer. Without a registration number, it may be difficult to determine exactly which registered facility to associate with the article: Different firms may have the same or similar names and more than one firm may operate from a particular location. In addition, requiring the registration number as part of manufacturer identity makes it clear to foreign exporters and U.S. importers from the outset when registration is required for imported food.

FDA does not agree that the registration number, when one is required, is sufficient by itself to ''identify'' a person in a prior notice submission. The additional information is needed to verify that the registration number is accurate. For example, without additional information, there is a significant possibility of typographical errors, leading to misidentification of facilities, which could lead to foods being stopped at the border for inadequate prior notice and registration. FDA is requiring identifying information in addition to the registration number (if one is required) to reduce the number of clerical or typographical errors in registration information that could result in refusals. The FDA PN System Interface will require the firm name and at least the city and country as ''confirmatory information,'' in addition to the registration number to allow for validation. (If registration is not required for the facilities associated with a particular article of food, a registration number may still be provided, along with the name of the facility and the city and country. If a registration number is not required and the submitter chooses not to provide the number voluntarily, the name and full address of the facility must be provided to ensure that FDA can fully identify the correct party.)

Finally, the systems will not automatically fill in the registration number on any documents or electronic screens that are provided to, or appear, to the submitter or transmitter.

To minimize the burden, the interim final rule only requires registration numbers for shippers (if the shipper is a facility required to register for that article of food) and the manufacturer. The interim final rule also states when a registration number is not required in a prior notice for these persons. Under section 415 of the FD&C Act, registration is only required for food for consumption in the United States. Thus, the interim final rule does not require that a prior notice include registration numbers of facilities associated with articles of food that are imported or offered for import for transshipment, storage and export, or further manipulation and export. The interim final rule does not require a registration number for the manufacturer if the article of food is sent by an individual as a personal gift (*i.e.*, for non-business reasons) to an individual in the United States.

2. Fax & E-mail Addresses

(Comments) Some comments state that the fax number and e-mail address should be optional.

(Response) FDA agrees, in part, and has eliminated the requirement for telephone and fax numbers and e-mail addresses in many instances. In the interim final rule, the telephone and fax numbers and e-mail addresses (if they exist) are only required for submitters and transmitters so that FDA can communicate with them, if necessary. The prior notice submission must declare if these persons do not have a telephone number, fax number, or e-mail address.

3. Submitter and Transmitter (§ 1.281(a)(1) and (a)(2) Proposed as § 1.288(a))

The proposed rule required the identity of the submitter and the associated submitting firm.

(Comments) Comments addressing the submitter focused primarily on who is authorized to submit prior notice and on the need for registration numbers and fax and e-mail information.

(Response) Comments regarding who may submit, as well as comments regarding registration numbers and telephone, fax, and e-mail information already have been addressed.

As explained in the proposal, the identification of the submitter is needed so that FDA knows who is responsible for the information in the prior notice and can communicate with them when necessary. The information is also necessary to follow up when audits, inspections, or enforcement are necessary.

The FDA PN System Interface will allow the information transmitted for identification of the submitter to be automatically repeated in the same submission if the submitting firm is also any other firm identified in the prior notice, such as the transmitter, importer, owner, ultimate consignee, etc. This ability to automatically repeat information may also be available for transmitters submitting prior notice through ABI/ACS, depending on the features of the ABI software package used by the transmitter.

(Interim final rule) Section 1.281(a)(1) requires submission of the name of the individual submitting the prior notice, *i.e.,* the submitter, and his or her business address, and telephone number, fax number, and e-mail address (if they exist), as well as the name and address of the submitting firm associated with the submitting individual, if it exists.

4. Transmitter (§ 1.281(a)(2))

The proposed rule allowed an agent to provide prior notice.

(Comments) Comments on the use of agents to provide prior notice are discussed under § 1.278.

(Response) Responses to comments on the use of agents are discussed under § 1.278.

(Interim final rule) If the prior notice is transmitted by a person other than the submitter, § 1.281(a)(2) requires the name of the individual transmitting the prior notice, *i.e.,* the transmitter, on behalf of the submitter and his or her business address, telephone number, fax number, and e-mail address, if they exist. The submission must also include the name of the firm associated with the individual transmitting the prior notice information, if it exists. The identification of the transmitter is needed so that FDA may confirm the prior notice, communicate regarding the prior notice after FDA review, and followup when audits, inspections, or enforcement are necessary.

5. CBP Entry Type (§ 1.281(a)(3) Proposed as § 1.288(b))

The proposed rule required the submission of the Customs entry type associated with the article of food being imported or offered for import (proposed § 1.288(b)).

(Comments) Comments state that the CBP entry type is not always available by noon of the day before arrival. They also note that entry type may change depending on quota status, *e.g.,* where a consumption entry was planned but then was changed to a warehouse entry because an entry quota on the product was temporarily filled or closed.

(Response) FDA and CBP believe that the significant shortening of the prior notice timeframe resolves many of the concerns about the availability of the CBP entry type. As discussed in the proposed rule, FDA needs this information for screening to identify the appropriate articles for inspection. It is also needed for communication with FDA and CBP staff at the border. Also, entry type determines which entry identifiers should be used (entry number, in-bond number) to identify the shipment. In addition, the CBP entry type tells us if the article of food is for consumption in the United States or is for export or other uses that, in turn, allows FDA to determine that certain information is not required (*e.g.,* registration numbers).

(Interim final rule) Section 1.281(a)(3) of the interim final rule requires submission of the entry type. Some examples of entry types are listed as follows: Consumption entries, warehouse entries, and temporary importation bond entries. Each of these types has a designated CBP code. For prior notice submissions made through ABI/ACS, the entry type will consist of the CBP entry code specific for that type of entry, *e.g.,* ''01'' for a consumption entry, ''21'' for a warehouse entry, ''23'' for a temporary importation bond entry, *etc.* These codes are ones customs brokers and self-filers currently provide to CBP at entry. For prior notice submissions made through the FDA PN System Interface, applicable entry types or other admission categories will be provided for selection in a drop-down menu, *e.g.,* consumption, IT, T&E, mail, FTZ, *etc.* Explanations of the different entry types or other admission categories will be available to help the transmitter choose the right one.

6. ACS Entry Line Number or Other Customs Identification Number (§ 1.281(a)(4) Proposed as § 1.288(c))

The proposed rule required the identification of the CBP entry number, the CBP ACS line number and the FDA line number. FDA explained that this information is necessary for screening and identification of the appropriate articles for inspection, as well as for matching the prior notice to the corresponding CBP entry to assess the adequacy of the prior notice when shipments arrive and are presented for review.

(Comments) Comments state that the CBP entry number is available only from a customs broker or self-filer, but not every import has a broker. Other comments state that the entry number is not assigned until the customs broker or self-filer transmits entry information through the ABI to ACS. Thus, the entry number is not available by noon of the day before arrival. Other comments state that entry and line numbers are not available earlier than 4 hours before arrival at land ports. Some comments suggest that FDA make this information voluntary.

(Response) FDA agrees in part and has removed the requirement for submission of line numbers. The interim final rule only requires submission of a CBP entry identifier. FDA believes that the entry identifier is necessary for proper identification of the information in a prior notice with the appropriate articles for inspection. FDA also believes that submission of the entry identifier is critical for matching the prior notice to the corresponding CBP entry, which is necessary to assess the adequacy of the prior notice when shipments arrive and are presented for review. For in-bond entries and FTZ

admissions, and for prior notices submitted through the FDA PN System Interface, an entry identifier is critical for matching the prior notice to the corresponding CBP entry if a consumption entry is submitted so FDA and CBP can ensure that prior notice requirements were satisfied. For transmitters submitting prior notice with CBP entry information through the ABI/ACS interface, the CBP entry number assigned by CBP is also the entry identifier. For customs brokers or self-filers submitting prior notice for a food entering the United States as an IT entry, a T&E entry, or FTZ admission, the CPB in-bond number or FTZ admission number assigned by CBP is also the entry identifier.

If prior notice is being submitted through the FDA PN System Interface, the entry identifier will depend on the entry type and the reason for Web submission. If available to the transmitter (*e.g.,* the prior notice is for a CBP entry but the ABI/ACS interface is not available), the CBP entry number must be used. Where appropriate, the in-bond number must be used as the entry identifier. If one of the entry identifiers described above does not exist, the transmitter can request a system-generated entry identifier. The FDA PN System Interface will provide online help to assist the user in determining what information to use as the entry identifier for a specific transaction.

This requirement to provide an entry identifier does not apply to articles of food imported or offered for import by international mail, nor those carried by or accompanying an individual, unless entry is otherwise required by CBP and an associated CBP entry identifier has thus been assigned. In these cases, the FDA PN System Interface will apply a system-generated entry identifier.

FDA agrees with the comments that line numbers are not necessary. Thus, the interim final rule does not require submission of a line number. For transmitters using the FDA PN System Interface, the system will assign each article of food a unique number for processing and, after validation, a PN Confirmation Number will be returned for each article of food. For ABI/ACS submissions, when they are confirmed, the CBP and FDA line numbers will be assigned as they are under current procedures, and the customs broker or self-filer will receive a confirmation number for each line through the OASIS/ACS messaging process.

7. Product Identity (§ 1.281(a)(5) Proposed as § 1.288(e)(1))

Section 801(m)(1) of the Bioterrorism Act states that a prior notice must contain the identity of the article of food being imported or offered for import. To ensure that each prior notice adequately and completely identifies the food being imported or offered for import, § 1.288(e)(1) of the proposed rule required the submission of the following information: FDA product code; common, usual, or market name; brand name; quantity; and lot, code, or other identifying number.

a. *General comments on product identity.* (Comments) Some comments ask that FDA obtain product identity information from existing Customs information. Other comments believe that the information on product identity should be limited to a general description of the product.

(Response) Under section 801(m) of the FD&C Act, FDA must have the information before arrival. Thus, although product identity is provided to CBP when entry is filed, currently that does not generally occur sufficiently before arrival for FDA to review and respond as envisioned by the Bioterrorism Act. Under the interim final rule, with the modifications to ABI/ACS, required product identity information can be provided through ABI/ACS. The transmission to CBP will be enhanced to include the additional product identity information required by prior notice, and will be used satisfy both FDA's prior notice requirements as well as current entry requirements.

FDA does not agree that product identity should be limited to a general description. For prior notice to accomplish its intended purpose and help FDA protect American consumers, a precise description of the product is necessary. For example, FDA needs to know that there are 100 cartons containing 24/12 ounce (oz) bottles of apple juice and 200 cartons containing 48/8 oz bottles of apple juice to make its decision whether to inspect, sample, or hold a shipment. Information about potential contamination may apply only to 8 oz bottles of apple juice. Therefore, it would be a drain on FDA resources, as well as cause delays at the border, to examine and sample all juice or all apple juice imports when only one kind of juice in one kind and size of packaging is affected. Currently, this information is provided to FDA when entry information is submitted via the ABI/ACS interface by a customs broker or self-filer. For those entries submitted via a paper mode, the invoice is included in the submission, as it was before OASIS and ABI/ACS. The precise description of a food product is commonly included on a commercial invoice, *e.g.* 200 cartons of 24/6 oz cans of albacore tuna.

(Comments) One comment asks for clarification as to how an ''article'' of food is defined.

(Response) The description of an ''article'' of food is not the same as the definition of ''food'' in § 1.276(b)(5). An ''article'' refers to a single food that is associated with the same complete FDA Product Code, the same package size, and the same manufacturer or grower. These requirements are found in the information required in the interim final rule in § 1.281(a)(5), (a)(6), or (a)(7) and again in § 1.281(b) and (c).

(Comments) Some comments assert that the proposed rule increases the paperwork burden by requiring separate notices for every article from a different manufacturer or grower. Comments recommend that one way to reduce this burden would be to allow a single prior notice to cover a shipment of multiple articles of food or allow one notice per shipment.

(Response) FDA disagrees. An article of food is a unique item related to a specific manufacturer or grower and a specific process or size. All of these pieces of information are critical for a risk-based assessment of the food. FDA currently receives most of this information from customs brokers or self-filers via ABI/ACS. The ABI/ACS system also provides the capability to submit information for multiple food items as lines in a single entry, when entry level information is consistent for a number of articles in a shipment. For example, shipment level information, such as estimated time of arrival, can be captured once for all articles within a shipment. The ability to minimize data entry by copying specific information from one article, or line, to another depends upon the sophistication of the software being used to create the submission to CBP. The FDA PN System Interface is designed to allow for simplified submission of similar articles of food by allowing the submitter to easily repeat common information (*e.g.*, FDA product code, manufacturer, etc.) while entering different quantities (*e.g.*, amount and package size). Both systems will thus significantly reduce the amount of repetitive entry of information while preserving the identity of each article of food.

b. *Complete FDA product code (§ 1.281(a)(5)(i) Proposed as § 1.288(e)(1)(i)).* FDA proposed to require the submission of the complete FDA product code as an element of the identity of the product (§ 1.288(e)(1)(i)).

The FDA product code is a unique numeric code currently used by FDA and customs brokers and self-filers to describe food products, as well as other products regulated by FDA.

(Comments) The majority of comments emphasize the need to use the existing and familiar HTS coding structure for product reporting instead of the FDA product code. Some comments ask FDA to update product codes with current food items, such as botanicals, additives, food contact substances, etc. Some comments state that the importer might not know the exact product they will be receiving until the product is shipped and, therefore, may not know the FDA product code by noon of the day before arrival. One comment recommends clarification of what the FDA product codes are and where they can be found. In addition, another comment was not able to access the FDA product database and urges FDA to correct this situation. Finally, one comment suggests that FDA eliminate this data element.

(Response) The FDA product code is an existing 7-character code that describes a product for FDA purposes by industry type and class, packaging, process, and specific distinctive character. For example, canned tuna is covered by FDA Product Code, 16AEE45. ''16A'' describes the product as vertebrate fish, the first ''E'' describes the metal package, the second ''E'' describes a commercially sterile process, and ''45'' describes the fish as tuna.

Although the HTS codes are currently utilized by CBP and FDA to identify generally which imports are subject to an FDA admissibility review, these codes are often not sufficient to specifically identify a product for FDA decisionmaking. For example, in many cases, the tariff code does not describe how the product was processed (*e.g.*, commercially sterile or shelf-stable) or how the product is packaged. For example, milk and cream are included in the same codes. These codes differentiate milk and cream for fat content, but do not indicate the process (pasteurization and refrigerated or commercially sterile) or packaging (cardboard carton, plastic bottle, or shelf-stable package). Thus, several products that FDA considers different from each other (because these differences affect the potential safety of the food) may be combined under one tariff number HTS code.

Both the HTS code and the FDA product code are currently required on FDA-regulated products and are submitted through the ABI/ACS interface. Therefore, the FDA product code is familiar to most of those who will be transmitting prior notice. The FDA product code is currently available via the Internet at *http://www.accessdata.fda.gov/scripts/ora/pcb/pcb.htm* as a ''buildable'' code.

FDA is requiring submission of this data element for prior notice as an integral part of the identity of the article. Risk-based screening criteria can be very specific. Therefore, the specificity provided by the FDA product code is necessary. In addition, the timing requirements for submitting prior notice have been decreased significantly. Therefore, the issue of adequately identifying the product code at the time of submission has been reduced to the extent possible, given the mandate from Congress to require prior notice.

The FDA PN System Interface has a menu-driven FDA product code builder that enables the submitter to appropriately describe the product. The FDA PN System Interface is also designed to allow a submitter who already knows the product code to enter it directly.

FDA routinely and continually updates the FDA product codes and product code builder electronic files to include more specific food items, such as additives, exotic produce, and some botanicals. FDA intends to issue guidance before the effective date of this rule that will provide the flagged HTS codes and FDA product codes identifying foods for which prior notice is required. This guidance will be posted at *http://www.fda.gov*, see ''prior notice.''

(Interim final rule) Section 1.281(a)(5)(i) requires the complete FDA product identity code for the article of food covered by a prior notice. The interim final rule allows for submission of product identity information through ABI/ACS. Customs brokers or self-filers, using ABI/ACS, currently may use the FDA product code builder, which is available to the public on the FDA Web site, to identify the appropriate product code. Those submitting prior notice through the FDA PN System Interface will be able to access a FDA product code builder specific to those food covered by the prior notice requirement.

c. *Common, usual or market name (§ 1.281(a)(5)(ii) Proposed as § 1.288(e)(1)(ii)).* FDA proposed to require the submission of the common or usual or market name of the article of food as an element of the identity of the product (§ 1.288(e)(1)(ii)). The customs broker or self-filer currently submits the common or usual or market name to ABI/ACS when entry is made, and it subsequently is transmitted to OASIS for each entry line, *e.g.*, article of food.

(Comments) One comment is concerned that the appropriate name of fresh produce or fishery products may not be known at the time of shipment.

(Response) This information is necessary to confirm the accuracy of the product code and we have thus retained the requirement to submit it in the interim final rule. The timing requirements for submitting prior notice have been decreased significantly. Therefore, the issue of adequately identifying fresh produce and ''catch of the day'' at the time of submission has been reduced to the extent possible, given the mandate from Congress to require prior notice.

(Interim final rule) Section 1.281(a)(5)(ii) requires that the submitter supply the common or usual or market name in a prior notice. (See 21 CFR 102.5 for additional information about common or usual names.)

d. *Trade or brand name (Proposed § 1.288(e)(1)(iii)).* FDA proposed to require the submission of the trade or brand name of the article of food, if it is different than the common or usual or market name, as an element of the identity of the product (§ 1.288(e)(1)(iii)).

(Comments) Comments ask for clarification as to why this information is required when the statute does not require it and the information will likely be confusing if provided. Commenters also recommend eliminating this data element. Comments state that some imported products do not have a trade or brand name (*e.g.*, agricultural products, fish, and seafood). In addition, comments note that a single product could have multiple brand names. Several comments note that the importer usually does not know a product's brand or trade name. Comments also recommend that FDA clarify in the final rule that it will not reject an article of food for failure to include trade or brand name when such information does not exist.

(Response) FDA agrees with the comments. FDA has also determined that this information is not critical for risk-based screening, given the other information in a prior notice.

(Interim final rule) FDA has eliminated the requirement to identify the trade or brand name in the interim final rule.

e. *Quantity (§ 1.281(a)(5)(iii) Proposed as § 1.288(e)(1)(iv)).* FDA proposed 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 (§ 1.288(e)(1)(iv)). The number of

container units and units of measure are to be submitted in decreasing size of packing unit (starting with the largest). The customs broker or self-filer currently submits the quantity of each line entry to ABI/ACS when entry is made, and quantity subsequently is transmitted by CBP to OASIS. FDA requested comments 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.

(Comments) There were many comments pertaining to quantity. Some commenters object to the requirement, stating that it can be difficult to identify quantity. For example, comments suggest that it can be difficult to identify quantity for processed goods, as quantity may change. Also, the exact quantity is difficult to identify for fresh produce and fresh fishery products due to the fast-paced shipping of perishables and day-to-day harvesting differences. Comments state that it is also difficult to ascertain the exact unit (*e.g.*, weight, volume) for bulk items. Comments also state that quantity information such as package size is not relevant to identify the presence of intentional contamination or a food safety hazard. Some comments object to the level of specificity, stating that the required quantity data is unduly detailed for inspection purposes, seldom needed for risk assessments, and not necessary to meet the statutory requirements. Other comments recommend that FDA allow a 2-hour amendment/update for needed flexibility and accurate reporting or adopt a percentage over/under discrepancy tolerance or approximated total units (*e.g.*, weight, volume). Comments confirm that changes in quantity occur after the proposed deadline for prior notice and that these changes commonly represent significant variations in quantity.

(Response) FDA continues to believe that quantity is a necessary component of product identity. The significant decrease in the filing deadlines addresses concerns raised by many comments. In addition, in further response to the comments on changes in quantity, FDA has revised the requirement to ''estimated quantity.'' This means that the submitter must tell FDA, at the time of submission of Prior Notice, the estimated amount of the article of food that they anticipate will be shipped. This change provides importers with leeway to adjust shipments, while still ensuring FDA has useful information about overall quantity.

FDA believes that package size is necessary and part of product identity. The base unit of measure is a critical characteristic of product identity and is thus necessary for effective review of the prior notice information. Base unit is critical to processing safety requirements and is particularly important when evaluating the safety of low-acid canned foods. Both base unit and total quantity (which includes knowing the smallest ''package size'') are necessary for response (examination) and communication with FDA and CBP staff at the border. As noted in FDA's ''Food Security Preventive Measures Guidance for Importers'' (Ref. 17), they are also critical for food security examinations to determine if the amount ordered is the amount received. For example, if more was received than was ordered, the guidance recommends an investigation to determine the cause of the discrepancy as additional and unwanted articles may have been added to intentionally contaminate the shipment. If less product is received than ordered or than shipped, some of the product may have been intentionally diverted. Both base unit and total quantity are currently data elements that can be submitted via ABI/ACS to OASIS. The tutorial in the FDA product code builder will be revised to recommend the appropriate association of base unit with product code, *e.g.*, FDA Product Code 16AEE45, canned tuna would recommend the base unit as **oz cans.

(Interim final rule) Section 1.281(a)(5)(iii) requires that the prior notice state the estimated quantity of food that will be shipped from largest container to smallest package size. Some examples of quantity descriptions are: 100 cartons of 48/6 oz cans each of tuna; 100 pallets of 2/100 pound (lb) totes each of frozen tuna loins for a total of 20,000 lb; 100 pallets of 2/100 lb cartons each of dehydrated pig ears for a total of 20,000 lb; 100 cartons of 20 lb of fresh watermelons each carton for a total of 2,000 lb, and 2,000 lb of wheat in bulk. A prior notice will not be inadequate if the estimated quantity changes between the confirmation of prior notice and the time of arrival. The interim final rule does not require that a prior notice be cancelled and resubmitted if the estimated quantity changes after confirmation.

f. *Lot or code numbers or other identifier (Proposed § 1.288(e)(1)(v)).* FDA proposed to require the submission of the lot or code numbers or other identifiers that are specific to the article of food, if applicable, as an element of the identity of the product (proposed § 1.288(e)(1)(v)). Currently, when entry information is presented to FDA through ABI/ACS, lot or code numbers may be transmitted as ''affirmations of compliance'' and there may be more than one identifier represented in an entry line.

(Comments) Comments state that the addition of lot, code, or other identifier information is burdensome and not valuable for inspection purposes. In addition, often the lot numbers are simply unknown. Comments ask that FDA clarify, if this data element is retained, what ''lot or code number or other identifier'' means and how it should be entered, such as by bar code, letters, or random number. Comments also ask that FDA consider that there is no lot or code number for bulk or commingled products. Many comments suggest that FDA consider making this data element voluntary or removing it completely.

(Response) FDA agrees in part. The lot or code numbers are the identification numbers or code of a production lot, which can more specifically identify a product for screening and examination purposes and for communication within FDA and with CBP and the grower or manufacturer, etc. For example, recalls involving serious health risks are often associated with a specific production lot, such as counterfeit infant formula or underprocessed canned food. FDA screening targets examinations based on information of public health emergencies or recalls in foreign countries. FDA regulations already require lot/code identifiers for some foods. Currently, low acid canned foods, acidified foods, and infant formula are required to bear lot codes or other identifiers (see 21 CFR 113.60(c) (low-acid canned foods); 21 CFR 114.80(b) (acidified foods); and 21 CFR 106.90 (infant formula low-acid canned foods)). The interim final rule requires lot/code or other identifiers only for these kinds of articles of foods. Many other foods may have lot or code identifiers that are not required by FDA regulation; submission of these identifiers is optional under the interim final rule.

(Comments) Some comments object to the limitation in the proposed rule that each lot number of a food would need its own prior notice and asserted that FDA should permit multiple lot numbers to be identified in one prior notice.

(Response) FDA agrees. Multiple lot numbers may be identified for an article of food. The systems are set up to permit such submissions.

(Interim final rule) Section 1.281(a)(5)(iv) provides that lot or code numbers or other identifiers are required in a prior notice for articles of food that are required to bear such numbers by the FD&C Act or by FDA

regulations. Submission of the required lot/code identifier will be accommodated by ABI/ACS as an affirmation of compliance or through the FDA PN System Interface. ACS currently allows for submission of more than one affirmation of compliance per article of food. The FDA PN System Interface will accept more than one lot identifier per article of food.

8. Manufacturer (§ 1.281(a)(6) Proposed as § 1.288(f))

As provided for in section 801(m)(1) of the FD&C Act, FDA proposed to require the submission of the identity of the manufacturer of each article of food. The customs broker or self-filer currently submits the identity of the manufacturer to ABI/ACS when entry is made, and it subsequently is transmitted to OASIS.

(Comments) Some comments state that some foods are not processed or manufactured food, *e.g.*, certain wild-caught or agricultural products; therefore, a manufacturer cannot be identified.

(Response) FDA agrees. Identification of a manufacturer only is required for a food that is no longer in its natural state. The FDA PN System Interface will recognize (by FDA product code) these foods. The manufacturer field must be completed for these foods (identified by FDA product code); if it is not completed, the initial validation will reject the submission through ABI/ACS or the FDA PN System Interface. Guidance regarding FDA product codes that require prior notice, which FDA intends to issue before implementation of this rule, will identify which product codes should be associated with a manufacturer.

FDA also recognizes that if an article of food is sent by an individual as a personal gift (*i.e.*, for nonbusiness reasons) to an individual, what will be available to the sender will be the name and address of the firm that appears on the label. Thus, this information may be supplied and a registration number need not be provided.

(Interim final rule) Section 1.281(a)(6) of the interim final rule requires that the identity of the manufacturer of an article of food that is no longer in its natural state be submitted as part of prior notice. However, if the article of food is sent by an individual as a personal gift (*i.e.*, for non-business reasons) to an individual in the United States, the name and address of the firm that appears on the label under 21 CFR 101.5 may be submitted.

9. Grower, If Known (§ 1.281(a)(7) Proposed as § 1.288(g))

As required by section 307 of the Bioterrorism Act, FDA proposed to require the submission of the identity of all growers of each article, if known, and the growing location if different from the grower's business address (proposed § 1.288(g)). If the submission is amended, the proposed rule required that the identity of all growers must be provided if known at the time of the amendment (§ 1.290(d)).

FDA solicited comments on whether the FD&C Act gives FDA any flexibility to exempt or otherwise treat differently so-called processed foods produced with products from more than one grower. FDA also solicited comments on whether the term ''grower'' includes a harvester or collector of wild products, *e.g.*, some fish and botanicals.

(Comments) A comment states that the agency does not need to identify flexibility to exempt processed foods produced with products from one or more grower, but rather should recognize that there is not a grower of a processed food.

(Response) FDA agrees. Once an article of food, for prior notice purposes, is no longer in its natural state, it has a manufacturer, but not a grower.

(Comments) A commenter states that it is an extremely rare occurrence for any single imported lot of a wild botanical raw material to have been collected by a single collector. Rather, the comment believes that the most common practice of consolidating a single lot of wild-harvested botanical raw material involve the product of many dozen or even hundreds of individual collectors.

(Response) FDA agrees and considers a harvester or collector to be the grower for the purposes of this provision as the definition of grower reflects § 1.276(b)(6)). The interim final rule also allows for the identification of a consolidator, when the submitter does not know the identities of all harvesters or collectors at the time of submission of the prior notice.

(Comments) Comments assert that if the grower is known, then workload for submission of prior notice will increase immensely. The comments recommend submitting a one-time listing of all growers that supply the importing firm with product and the responsible party could update the list as needed or keep a complete grower list with each firm and supply it to FDA when needed.

(Response) The proposed regulation restated the statutory requirement. FDA does not agree that a list would satisfy the statutory requirement, as it would not tell FDA which grower was associated with the particular article of food as envisioned by the statute.

(Comments) Comments state that it is very difficult to identify a grower for commingled products (fresh produce, fishery products, and grain) and such identification is not a typical industry practice. Comments also ask FDA to define ''bulk,'' and specifically how to address this issue with bulk grain.

(Response) There is only one grower per article of food that is not in its natural state. Thus, tomatoes from two different growers are different articles of food offered for purposes of prior notice. However, FDA has decided that if the identity of all growers is not known for an amount of raw agricultural product consolidated from more than one grower, including grain or aquacultured fishery products, the consolidator firm may be identified in the grower identity data field. 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 for consolidated foods, a separate prior notice must be submitted for each article of food represented by a known grower.

For example, if consolidator X commingles tomatoes from 5 growers into one lot of 90 cartons and the submitter does not know the identities of any of those 5 growers, then the submitter may opt to provide the identity of consolidator X. If consolidator X commingles tomatoes from 3 growers (growers A, B, and C) into one lot of 90 cartons and, although the submitter knows the identities of the growers, none of the tomatoes can be associated with the grower (no grower specific identifier accompanies each carton), then the submitter may opt to provide the identity of consolidator X.

If consolidator X commingles 30 cartons of tomatoes from grower A with 30 cartons of tomatoes from grower B and 30 cartons of tomatoes from grower C and the submitter knows the grower associated with each of those 30 carton lots, then each of those 30 carton lots represents an article of food and a separate prior notice must be submitted for each. However, if consolidator X commingles 30 cartons of tomatoes from grower A with 60 cartons of tomatoes commingled from other growers and the submitter knows the identity of grower A, then that 30 carton lot can be identified by grower and represents an article of food. Two prior notices are

required: The first prior notice would cover 30 cartons of tomatoes and must identify grower A; the second prior notice would cover the remaining 60 cartons, and the submitter may opt to identify consolidator X.

When bulk grains are commingled, they lose their association with each grower and the identity of grain would then be associated with the facility that commingled, *i.e.*, consolidated, the grain in a silo or truck or rail car before shipment. The submitter may opt to provide the identity of this consolidator in the prior notice.

(Comments) Comments suggest that FDA define ''if known'' and provide guidance as to the extent of effort that should be applied to find grower information and what will satisfy ''if known.''

(Response) Section 801(m)(1) of the FD&C Act requires that grower information be submitted (or provided to the transmitter for submission) if it is known. Thus, this information is not optional: If it is known by the submitter, it must be submitted. For purposes of this rule, FDA considers the information to be known if the submitter is aware of or learns the grower name and growing location due to business relationships. FDA is not requiring the submitter to seek out information of which the submitter is not aware. However, if the identity of the grower is in the possession of the submitter (*e.g.*, on documents), we believe the submitter is aware of the identity of the grower.

(Comments) Comments state that if knowing the grower is such crucial information, then it should be made mandatory.

(Response) Because the statute provides the identification of the grower ''if known,'' FDA does not have the authority under section 801(m) of the FD&C Act to require the identification of the grower in cases where that identity is not known to the submitter.

(Interim final rule) Section 1.281(a)(7) requires that a prior notice identify the grower, if known to the submitter for an article of food that is in its natural state. If a food comes from more than one grower, a prior notice must provide for an article of food associated with each grower, if their identity of that grower is known. As stated previously under discussion of product identity, an ''article'' refers to a single food that is associated with the same complete FDA Product Code, the same package size, and the same manufacturer or grower. FDA has determined that identification of the grower and the growing location address is a more appropriate identifier than the address of the grower. Therefore, FDA has revised the interim final rule to require the grower name and growing location. We have eliminated the grower's address. The interim final rule also allows that if the submitter does not know the identity of the grower or, if the article of food has been consolidated, the identity of any of the growers, the submitter may provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations.

As stated previously under discussion of ''manufacturer,'' the FDA system will recognize (by FDA product code) which products should be associated with a grower and will recognize (by FDA product code) which products should be associated with a manufacturer. Thus, if the manufacturer field is completed for a food that is in its natural state (as identified by FDA product code), the system will not accept the transmission. Guidance, which FDA intends to issue before implementation of this rule, regarding FDA product codes that require prior notice will identify which product codes should be associated with a grower. Submission of prior notice via the FDA PN System Interface will allow for association of ''header information'' with an article of food so that the transmitter would only have to identify list each grower and growing location. Each would be identified with a separate PN Confirmation Number associated with an entry identified. (See description under discussion of lot/code identifier in the previous paragraph in section III.H.7.f of this document.) A similar capability may be possible for submission through the ABI/ACS interface, but that is dependent upon the ABI software used by the broker or self-filer.

10. FDA Country of Production (§ 1.281(a)(8) Proposed as § 1.288(h)—Originating Country)

As provided for in section 801(m)(1) of the FD&C Act, FDA proposed to require the submission of the identity of the originating country of the article of food (proposed § 1.288(h)). This term was defined in proposed § 1.277(c)(2) as the country where the article of food was grown and harvested or if manufactured/processed, where the article of food was produced. It is proposed, that if the article of food is wild fish or seafood and it is harvested in the waters of the United States or by a U.S. flagged vessel or processed aboard a U.S. flagged vessel, the FDA Country of Production is the United States.

(Comments) Comments ask that FDA clarify which country should be identified when the major component of the final processed food may have come from a number of countries. Comments point to blended or decaffeinated coffee or apple juice produced from fresh apples and apple concentrates from more than one country as examples of such foods. Comments also ask that FDA clarify the definition of ''originating country'' to mean the country in which the product was last processed.

(Response) For a food that is no longer in its natural state, the FDA Country of Production is the country where the article of food was made. Therefore, for a food such as decaffeinated coffee or apple juice, the FDA Country of Production is the country in which the facility that made the food is located. For example, if the decaffeinated coffee is produced in Country C by decaffeinating a blend of coffees from Country A and Country B, the FDA Country of Production is Country C.

(Interim final rule) The interim final rule in § 1.281(a)(8), requires that a prior notice contain the FDA Country of Production of the article of food being imported or offered for import into the United States. As set out in its definition at § 1.276(b)(4), the FDA Country of Production is, for an article of food is in its natural state, the country where the article of food was grown, including harvested or collected and readied for shipment to the United States. If, however, an article of food is wild fish, including seafood, that was caught or harvested outside the waters of the United States or by a that is not registered in the United States, the FDA Country of Production is the country in which the vessel is registered. For a food that is no longer in its natural state, the FDA Country of Production is the country where the article of food was made. However, if an article of food is wild fish including seafood, that was made aboard a vessel, the FDA Country of Production is the country in which the vessel is registered. The interim final rule also provides that the FDA Country of Production of food grown and harvested or collected or made in a U.S. Territory is the United States.

11. Shipper (§ 1.281(a)(9) Proposed as § 1.288(i))

As provided for in section 801(m)(1) of the FD&C Act, FDA proposed to require the submission of the identity of the shipper of the article of food (proposed § 1.288(i)). The shipper is typically not the carrier.

(Comments) A comment states that this information could be obtained from Customs' AMS.

(Response) Although CBP's AMS contains information concerning the

shipper, that information is located in the AMS module of ACS and is not currently available to FDA, as required under section 801(m) of the FD&C Act, which provides that the information must be submitted to FDA. CBP and FDA have concluded that it is not practical, at this time, to attempt to modify AMS and the ACS–OASIS interface to provide this information to FDA.

(Interim final rule) § 1.281(a)(9) requires that the shipper be included in a prior notice. The interim final rule defines shipper (§ 1.277(b)(12)) as the owner or exporter who consigns and ships the article of food from a foreign country or the person who sends an article of food in international mail to the United States.

12. Country From Which the Article Is Shipped (§ 1.281(a)(10) Proposed as § 1.288(j))

As provided in section 801(m)(1) of the FD&C Act, FDA proposed to require the submission of the identity of the country from which the article of food was shipped (proposed § 1.288(j)). This term is defined in proposed § 1.277(c)(3) as the country in which the article of food was loaded onto the conveyance that brings it to the United States.

(Comments) Several comments state that this provision would require submission of information that FDA could obtain from Customs' AMS.

(Response) Although AMS contains information concerning the country from which the article of food is shipped, that information is located in the AMS module of ACS and is not currently available to FDA, as required under section 801(m) of the FD&C Act which provides that the information must be submitted to FDA. CBP and FDA have concluded that it is not practical, at this time, to attempt to modify AMS and the ACS/OASIS interface to provide this information to FDA.

(Interim final rule) Section 1.281(a)(10) requires that the country from which the article is shipped be included a prior notice. The interim final rule defines the country from which the article is shipped (§ 1.277(b)(3)) as the country in which the article of food is loaded onto the conveyance that brings it to the United States.

13. Anticipated Arrival Information (§ 1.281(a)(11) Proposed as § 1.288(k))—Anticipated Port of Entry, Anticipated Date of Arrival, Anticipated Time of Arrival)

FDA proposed to require the submission of the anticipated port of entry (defined as port of arrival), the anticipated date and anticipated time when the article of food will arrive at the port of entry in the United States (proposed § 1.288(k)) to coordinate resources for inspections, examinations, or sampling. FDA also proposed to require the prior notice to be updated if any of the anticipated arrival information changes after the submission of the prior notice (proposed § 1.288(k)(2)). Updates were deemed necessary so FDA could change its plan for coordinating resources when anticipated arrival information changes.

a. *General comments.* (Comments) Comments state that the proposed rule is more restrictive than the Bioterrorism Act. Others suggest that importers would have to work 24 hours a day, 7 days a week and that the proposed rule would eliminate their current methods of doing business. Several commenters ask FDA to recognize commercial realities of weather and traffic problems that result in port and arrival time changes and to provide more flexibility on the information requirements or elimination of the requirements altogether. Comments state that a lack of flexibility would amount to a limitation of the port that is prohibited by the Bioterrorism Act and could impede trade. Other comments state flexible arrival requirements are what Congress envisioned and ask that FDA not refuse food at the border based on inadequacy of anticipated arrival information, changes in border crossing, and other problems beyond the control of the importer.

(Response) The interim final rule requires that the prior notice identify the anticipated port of arrival. This information is necessary to ensure FDA can plan for inspections and communicate with CBP. FDA believes that the reduction of the timeframe for providing prior notice will reduce the number of changes that occur to the arrival information after submission. However, FDA also recognizes the realities of weather and traffic changes and has written the interim final rule to accommodate these variances.

As section 801(m)(1) of the FD&C Act prohibits any limitation on ports, a prior notice will not be inadequate if the anticipated port of arrival, the anticipated date of arrival, or the anticipated time of arrival changes between the time of confirmation of prior notice and the time of arrival. This is reflected in § 1.282(a) of the interim final rule that specifies what changes in information require resubmission of a prior notice. However, if FDA has determined that the article of food must be examined upon arrival and the anticipated arrival information has changed since timely submission of the prior notice, the article may be held by CBP at the port of arrival until the examination can be performed.

b. *Anticipated port of arrival.* (Comments) Comments state it was unclear whether the prior notice was to specify a particular bridge crossing or the port itself.

(Response) The anticipated arrival information must specify the anticipated port of arrival and, if there is more than one crossing location within that port, the anticipated crossing. For the most part, this applies to ports along the northern and southern borders of the United States where there are several crossings over many miles, but all are included in the same port. For example, a food arriving at the port of Buffalo-Niagara Falls may cross at the Peace Bridge or the Lewiston Bridge. For the purpose of this rule, to facilitate inspection, the identification of the bridge is required. However, the prior notice will not be inadequate if the anticipated crossing changes between the time of confirmation of prior notice and the time of arrival.

(Comments) Several comments ask that FDA allow importers to choose alternate border crossings or ports because of possible traffic delays and adverse weather conditions for air and land modes of arrival, or changing flight destinations for air modes of arrival. Comments state importers and even shippers and carriers do not know which border crossing will be used until the food arrives. Some comments note that portions of food may be discharged at different ports of arrival at the discretion of the carrier due to cargo space and weight limitations.

(Response) As noted previously, FDA agrees that arrival locations and times may change due to business practices, inclement weather, and traffic conditions. The interim final rule requires the submission of anticipated arrival information. This means that what must be submitted are the port, crossing location, date, and time that are known to the submitter at the time that prior notice is submitted to FDA. The interim final rule does not require that prior notice be cancelled and resubmitted if this information changes after FDA has confirmed the prior notice for review. A prior notice will not be inadequate if the anticipated port of arrival (including crossing location), the anticipated date of arrival, or the anticipated time of arrival changes between the confirmation of prior notice and the time of arrival.

c. *Anticipated date/time of arrival.* (Comments) Several comments ask for

clarification on the definition of time of arrival. For arrival by water, comments suggest defining arrival as the time the vessel reaches the entrance to the seaport where the importer will be taking delivery, the time the vessel reaches the port, or the time the vessel is unloaded. For arrival by land and air, comments suggest defining arrival as the time the vehicle reaches the border crossing, the time the vehicle reaches traffic backed up at the border crossing, or the time CBP begins processing the vehicle.

(Response) The interim final rule requires submission of anticipated time and date of arrival to provide FDA with information needed for planning resources for examinations of food at the border. From FDA's standpoint, ''time of arrival'' relates to when the food will first become available for examination at the border. For vessels, this would be when the vessel docks in the port. For planes, this would be when the plane lands. For land vehicles, such as trucks, buses, and trains, this would be when they cross at the border.

(Comments) Some comments ask for clarification regarding which time zone to use. Comments are concerned that, due to time zones, food may appear to arrive in the United States before it leaves the country from which it is shipped. Some comments suggest FDA use the time zone of the port of arrival.

(Response) The anticipated time and date of arrival relates to the time zone of the anticipated port of arrival. The time of prior notice submission, anticipated arrival, and actual arrival are all based on local time at the port of actual arrival.

(Comments) Several comments state that it was impossible for importers to know the exact time of arrival until the food arrives because of possible traffic delays and adverse weather conditions for air and land modes of arrival, or changing flight destinations for air modes of arrival. Other comments state that shippers and even carriers do not know when the truck will arrive. However, some comments note that exporters would be likely to know what flight the shipment was on.

(Response) The interim final rule requires the anticipated time and date of arrival. This is the time and date the submitter anticipates that the food will arrive at the port of arrival at the time the prior notice is submitted and confirmed for FDA review.

(Comments) Comments also suggest that FDA obtain the arrival information from AMS.

(Response) Although AMS contains some of this information, the information is located in the AMS module of ACS and is not available to FDA, as required under section 801(m) of the FD&C Act, which provides that the information must be submitted to FDA. CBP and FDA have concluded that it is not practical, at this time, to attempt to modify AMS and the ACS-OASIS interface to provide this information to FDA.

(Comments) Several comments state that the 4-hour window for updates of arrival time is too small and would cause delay in the arrival of food and create extra work in the form of amendments. Thus, the comments conclude the 4-hour window is unreasonable and should be removed. Comments note that even the best-intentioned carrier could fail to make the appointment because of waits of at least 5 hours at the borders. Others state additional delays occur on the Mexican border because the loads must change carriers. Some comments state that it was nearly impossible to predict an arrival time for a vessel within a 4-hour window because ships may arrive in port several days ahead or behind schedule and may sit in a harbor for hours or days before being granted permission to dock. Thus, these comments conclude the window for updates is not realistic for sea transportation. Others state the window for updates is impractical for rail transportation. Importers of live animals comment that the window for updates would be impossible to meet. Several comments suggest that FDA seek alternatives. One comment suggests a 6-hour window for updates. Another suggests importers be permitted to provide prior notice to FDA 2 hours before the carrier reaches the border. One comment suggests that prior notices identifying certain FDA-selected border crossings not be held to the arrival time and not be required to update the prior notice at the time of arrival.

(Response) The interim final rule requires submission of anticipated arrival information to provide FDA with information necessary for planning examinations and communicating with CBP for enforcement and examination purposes. FDA believes that the requirement for submitting anticipated arrival information serves these purposes. FDA has decided to delete the requirements for updating anticipated arrival information because of the reduction of the time requirements for submission. FDA recognizes that some of the anticipated information may change after submission due to unforeseen circumstances, such as business practices of carriers, weather conditions, and traffic conditions.

(Interim final rule) The interim final rule (§ 1.281(a)(11)) requires the submission of the anticipated port of arrival, including crossing location, if applicable, and the anticipated date and anticipated time when the article of food will arrive at that port. The interim final rule does not require that this information be updated if it changes after prior notice had been confirmed by FDA for review. The interim final rule does not require that a prior notice be cancelled and resubmitted if any of the anticipated arrival information changes after confirmation.

14. Port Where Entry Will Be Made for Customs Purposes (Proposed § 1.288(l))

FDA proposed to require the submission of the identification of the port where entry will be made for Customs purposes (§ 1.288(l)). Often, this port is different from the port where the article of food arrived in the United States. FDA proposed that this information is necessary to facilitate communication with CBP and FDA field offices concerning the adequacy of the prior notice and to enable FDA to coordinate resources for inspections, examinations, or sampling.

(Comments) A comment questions the usefulness of the information and asks that FDA delete the requirement because the Customs and FDA ports of entry can be different ports. Another comment states that providing the information would cost additional resources and time for investigation.

(Response) FDA agrees. Due to interfacing with ABI/ACS and development of various means of communication with CBP, this information is no longer necessary in the prior notice submission. Accordingly, FDA has eliminated this information requirement in the interim final rule.

(Interim final rule) The interim final rule does not require submission of the port where entry will be made for Customs purposes.

15. Anticipated Date of Customs Entry (Proposed § 1.288(m))

FDA proposed to require the submission of the anticipated date of entry for U.S. Customs purposes (proposed § 1.288(m)). FDA proposed that this information is critical to enable it to allocate resources for inspecting imported food shipments and efficient communication with and between CBP and FDA field offices.

(Comments) Several comments ask that FDA eliminate this requirement. Comments note that the Customs date of entry is not required by the Bioterrorism Act. Comments state that since the

Customs entry might be a considerable distance from the actual port of arrival, the date of Customs entry is difficult to predict. Another comment questions the usefulness of the Customs date of entry in determining whether to inspect the products at the port of arrival. A few comments ask for clarification of the Customs entry process.

(Response) FDA agrees. FDA has eliminated the Customs date of entry in the interim final rule. Due to interfacing with ABI/ACS and development of various means of communication with CBP, this information is no longer necessary in the prior notice submission.

(Interim final rule) The interim final rule does not require submission of the anticipated date of Customs entry.

16. Importer, Owner, Ultimate Consignee (§ 1.281(a)(12), (a)(13), and (a)(14) Proposed as § 1.288(n), (o), and (p))

Under section 801(m)(2)(B)(i) of the FD&C Act, an article of food that is imported or offered for import with inadequate notice may not be delivered to the importer, owner, or consignee. Thus, FDA proposed to require their identities so that FDA can take steps to ensure that food refused admission under section 801(m) of the FD&C Act is not delivered to them illegally. FDA proposed that only one importer, owner, and consignee could be identified for each prior notice.

(Comments) Some comments argue that section 307 of the Bioterrorism Act does not require the prior notice to identify the importer, owner, or consignee of the article of food that is the subject of the notice. They recommend that this requirement in the proposed rule be eliminated as beyond the scope of the statute and unnecessary for the purposes of section 307 of the Bioterrorism Act. One comment argues that FDA should not require submission of information about the consignee. However, another comment states that the level of detail required is generally consistent with the information submitted by customs brokers acting as agents for importers of record.

(Response) As requested by some of the comments, FDA considered deleting this information or making identity of importer, owner, and ultimate consignee optional. However, section 801(m) of the FD&C Act explicitly prohibits delivery of an article refused under section 801(m) to the importer, owner, or consignee. Section 801(l) of the FD&C Act likewise prohibits delivery of an article of food that has been imported from an unregistered foreign facility that is required to be registered under section 415 of the FD&C Act and 21 CFR part 1, subpart H. If we do not know the identity of these persons, we cannot determine if an article of food that has been refused or placed under hold has been illegally diverted and delivered. Accordingly, we have determined that this information is critical to ensure that we can efficiently enforce the prohibitions in section 801(m) and (l). In requiring this information, FDA is relying on both sections 801(m) and (l) and 701(b) of the FD&C Act.

Moreover, information identifying the importer of record and consignee is currently provided as part of the existing entry process (under OMB control number 0910–0046). Under the interim final rule, the CPB and FDA entry submission may be used to satisfy prior notice. We estimate that 80 percent of prior notices will be submitted through the CPB ABI/ACS entry process. We are concerned that deleting this information or making it optional for prior notice purposes could create considerable confusion about whether the information was still required for entry and admissibility purposes. For FDA, these pieces of information are necessary for administering section 801(a) of the FD&C Act and its implementing regulations, which require that FDA provide notice of sampling and notice of intent to refuse admission to the owner or consignee. Indeed, the identities of consignees and importers of record have long been provided to FDA. Prior to the availability of OASIS, FDA was provided with this information about imported foods on the FDA Form 701 (Ref. 18). In addition to the name and address of the importer of record and the consignee, FDA Form 701 included information such as: Entry number and date, bill of lading number, port of lading, country of origin, port of unloading, port of entry, value, container number, vessel name, arrival date, location of lot, date available, contact phone number, broker identification, manufacturer/shipper, quantity, packaging description, and a description of the food including the Food Canning Establishment number. Since the availability of OASIS, all information that has been submitted through the ABI/ACS interface has also included name and address of the importer of record and the ultimate consignee. Those who do not provide entry information electronically through ABI/ACS submit a ''paper'' entry to CBP and also provide FDA paper notification that includes information on importer and consignee. Some still use the FDA Form 701.

(Comments) One comment asserts that the identity of the consignee is proprietary, implying that it is protected from disclosure to FDA.

(Response) Where consignee information is proprietary, it is likely to be ''confidential commercial information'' and protected from public disclosure. However, the fact that it is considered ''proprietary'' is not a bar to requiring it in prior notice and entry submissions.

(Comments) Other comments ask that FDA decrease the burden of providing this information by using the registration number, which FDA could use to obtain the other identity information elements from its databases

(Response) FDA agrees in part. Although the interim final rule does not require the registration numbers of the importer, owner, or ultimate consignee, the FDA PN System Interface allows for submission of the name of the firm and limited address information (city and country) when a registration number is provided.

(Comments) Other comments seek to decrease the burden by asking FDA to require information regarding the entity submitting the prior notice, which could be the importer, owner, or consignee, but not regarding all three. Another comment concedes that FDA should require the identification of the owner, but that the owner is often the importer or the consignee.

(Response) FDA agrees. The FDA PN System Interface provides the transmitter with the ability to easily repeat information, *e.g.*, the submitter is the same as the importer or the owner is the same as the ultimate consignee. This feature may also be available for submission through ABI/ACS, depending on the specific ABI software used by the customs broker or self-filer. The identity of the owner is only needed if it is not the same as the importer or the ultimate consignee.

(Comments) Several comments state that FDA should be able to communicate its admissibility decisions and decisions about prior notice adequacy with the importer.

(Response) As set out in the interim final rule, in the first instance, the carrier will be notified regarding refusals under section 801(m) of the FD&C Act. Information identifying the importer will allow FDA to follow up with the importer and develop procedures for notifying them as well.

(Comments) A comment asks that FDA define ''importer'' consistently with CBP. Another comment expresses confusion as to the meaning of the term ''owner,'' asking whether the requirement for the owner's identity in

the prior notice refers to the owner of the article of food at the time it arrives at the port of arrival.

(Response) FDA believes that the persons affected by this interim final rule will know, in most situations, what entities are referred to by the terms ''importer'' and ''owner'' since these terms are commonly used in importation, including the CBP entry process. If experience with this interim final rule indicates confusion regarding these terms, then FDA will issue guidance on them.

Regarding the term, ''importer,'' FDA agrees with the comment. The agency believes this term should be interpreted the same as ''importer of record'' as that term is used by CBP in regard to the entry of merchandise.

Regarding the term, ''owner,'' FDA agrees that this is the owner of the article of food at the time of arrival. However, if a prior notice is given after the article is refused under section 801(m)(1) of the FD&C Act, then the owner is the owner or the article of food at the time the prior notice is submitted.

(Comments) Comments ask FDA to limit the information required to identify the importer, owner, and consignee to the registration number, which FDA could use to obtain the other identity information elements from its databases. In this way, comments seek to decrease the burden of prior notice submission by avoiding manual entry of addresses. Other comments seek to decrease the burden by asking FDA to require information regarding the entity submitting the prior notice, which could be the importer, owner, or consignee, but not regarding all three.

(Response) The interim final rule does not require the registration number of the importer, owner, or ultimate consignee. However, if a registration number is provided, city and country may be provided instead of the full address.

(Comments) A comment states that the identification of the importer, owner, and consignee could be obtained from AMS.

(Response) Although AMS may contain information concerning the consignee, that information is located in the AMS module of ACS and is not available to FDA, as required under section 801(m) of the FD&C Act, which provides that the information must be submitted to FDA. CBP and FDA have concluded that it is not practical, at this time, to attempt to modify AMS and the ACS/OASIS interface to provide this information to FDA.

(Interim final rule) Section 1.281(a)(12), (a)(13), and (a)(14) of the interim final rule require submission of information that identifies the importer, owner, and ultimate consignee. However, the identification of the importer, owner, and ultimate consignee are not required if the article of food is imported or offered for import for transshipment through the United States under a T&E bond.

17. Mode of Transportation (§ 1.281(a)(15))

In the proposed rule, the timeframe for prior notice was the same for all imports, regardless of mode of transportation. Thus, FDA did not propose submission of the identification of the mode of transportation.

(Comments) No comments were received on identification of the mode of transportation. However, as discussed earlier, many comments recommend that FDA should set the timeframes for prior notice by mode of transport. FDA agrees and has revised the timeframes accordingly.

(Response) In the interim final rule, the timeframes are tied to mode of transportation. Thus, mode of transportation is necessary to calculate when prior notice is timely. In addition, FDA has determined that, for submitting prior notice, identification of the mode of transportation is necessary for identification of the article of food at the time of arrival for the purposes of planning examinations and communicating with CBP for enforcement and examination. This information currently is provided to FDA by customs brokers or self-filers through ACS.

(Interim final rule) Section 1.281(a)(15) requires submission of information concerning the mode of transportation, except for those prior notice submissions covering articles of food arriving by international mail. For submissions through ABI/ACS, this information will take the form of the current ABI requirements for declaration of mode of transportation. For submissions through the FDA PN System Interface, selection of the mode of transportation will be accommodated by a drop-down menu.

18. Carrier (§ 1.281(a)(16) Proposed as § 1.288(q))

FDA proposed to require the identity of each carrier or transporter firm that transports the article of food from the country from which the article was shipped into the United States, including the submission of the SCAC. Identification of the carrier is necessary to enable FDA and U.S. Customs to identify the appropriate article of food for inspection or holding when the food arrives in the United States. FDA notes that a carrier typically is a different firm than the shipper. The broker or self-filer currently submits carrier information to ABI/ACS when entry is made, and it later is transmitted to OASIS.

(Comments) Comments agree that this information is helpful and necessary for locating cargo. Comments note that carrier information is currently submitted to CBP via ABI/ACS to OASIS. Other comments state that accurate carrier information cannot be provided by 12 noon the day before arrival.

(Response) FDA believes that identification of the carrier is necessary for the purpose of response to prior notice, both for examination purposes and communication with CBP. The shortened timeframes resolve the concern that the carrier may not be known by noon the day before arrival, to the extent possible, given the mandate from Congress to require prior notice.

(Comments) Comments ask that FDA eliminate the requirement to identify multiple carriers, suggesting that the only pertinent carrier is the one arriving at the U.S. port.

(Response) FDA agrees and has eliminated the requirement to identify each and every carrier that transported the article of food from the country of production to the United States, *i.e.*, multiple carriers. The interim final rule requires submission of the identity of the carrier that is or will be carrying the article of the food from the country from which the article is shipped to the United States.

(Interim final rule) Section 1.281(a)(16) requires submission of the carrier's SCAC or IATA code. If these codes are not applicable, the carrier's name and country must be submitted.

19. Planned Shipment Information (§ 1.281(a)(17))

The proposed rule did not require submission of planned shipment information beyond identification of the carrier.

(Comments) Some comments suggest that, in addition to carrier information, FDA should require vessel name, voyage/flight numbers, and bill of lading information.

(Response) FDA agrees. FDA has determined that additional planned shipment information is necessary for identification of the article of food for examination and communication with CPB. The requirement is to provide planned shipment information as it exists when the prior notice is submitted. FDA recognizes that some of this information may change after the

prior notice has been submitted and has addressed this in § 1.287(a), which specifies when changes require resubmission to FDA. Most of this information is currently submitted to FDA by customs brokers or self-filers through ABI/ACS. The planned shipment information is necessary to ensure the effective enforcement of section 801(m) of the FD&C Act. FDA and CBP have determined that the planned shipment information includes submission of HTS code information. The HTS code is particularly critical for communication between FDA and CBP for shipments that are entered for transportation in-bond without appraisement under 19 U.S.C. 1552 or 1553, and identification of the HTS will assist CBP in the efficient processing of prior notice through ACS. CBP uses the HTS number in ACS to ensure that the required FDA information accompanies the entry or entry summary transmitted through ABI/ACS to OASIS. For prior notices submitted through the FDA PN System Interface, the HTS numbers are needed to ensure that the data collected from the Customs entry when it is transmitted through ABI/ACS can be matched to prior notice.

(Interim final rule) Section 1.281(a)(17) requires submission of the following planned shipment information, as applicable, based on the mode of transportation:

- Airway bill number(s) or bill of lading number(s) (not applicable to food carried by or otherwise accompanying an individual);
- For food arriving by ocean vessel, vessel name and voyage number;
- For food arriving by air carrier, flight number;
- For food arriving by truck, bus, or rail, trip number;
- For food arriving as containerized cargo by water, air, or land, container number(s);
- For food arriving by rail, car number (not applicable to food carried by or otherwise accompanying an individual);
- For food arriving by privately owned vehicle, the license plate number and state or province; and
- The 6-digit HTS code that is applicable to the article of food.

The interim final rule does not require that prior notice be cancelled and resubmitted if this information changes after FDA has confirmed the prior notice for review. A prior notice will not be inadequate if any of the planned shipment information changes between the confirmation of prior notice and the time of arrival.

20. International Mail (§ 1.281(b))

FDA did not propose separate information requirements for prior notice for food imported or offered for import by international mail.

(Comments) No comments were received on information requirements for food imported or offered for import by international mail.

(Response) For clarity and ease of reference, the interim final rule segregates the information required in prior notice submissions for food arriving by international mail. In addition, FDA has clarified the information required in three instances. FDA has replaced anticipated arrival information with planned date of mailing. FDA has determined that identification of the recipient of an article of food arriving by mail is necessary instead of the importer, owner, or consignee. Thus, the interim final rule requires the identification of the recipient by name and address for food arriving by international mail. Finally, we also have not included information identifying the mode of transportation, carrier, planned shipment information, and hold information, as this information is not relevant to mail imports.

(Interim final rule) See table 1A in section II.J of this document for the information requirements for food imported or offered for import by international mail.

21. Refused Food (§ 1.281(c))

FDA did not propose separate information requirements for prior notice for food refused because of inadequate prior notice. However, proposed § 1.288(d) required identification of the location where the food is being held after the food had been refused for inadequate prior notice. This information is necessary to ensure FDA can locate the food for inspection and to ensure compliance with the hold requirement.

(Comments) No comments were received on separate information requirements for food refused because of inadequate prior notice. However, comments ask for clarification that the hold location information is only necessary if the prior notice was absent or inadequate, *e.g.*, the article of food has been refused under section 801(m) of the FD&C Act.

(Response) FDA agrees. For clarity and ease of reference, the interim final rule segregates the information required in prior notice submissions for food refused because of inadequate prior notice. Submission of the hold location information is not necessary for prior notice submissions covering an article of food arriving by international mail.

(Interim final rule) See table 1A in section II.J of this document for the information requirements for food refused under section 801(m) of the FD&C Act.

(Summary of the interim final rule) Table 1A in section II.J of this document shows a summary of all information required by § 1.281(a), (b), and (c). For clarity, the table also identifies under what circumstances certain information is not required, *e.g.*, registration numbers.

I. ''What Must You Do If Information Changes After You Have Received Confirmation of a Prior Notice From FDA?'' (Section 1.282 Proposed as §§ 1.289 through 1.294)

1. ''What Changes Are Allowed to a Prior Notice After It Has Been Submitted to FDA?'' (Proposed § 1.289)

FDA proposed to allow changes to certain information in the prior notice after a prior notice was submitted. FDA proposed to allow amendments to the product identity information when complete product identity did not exist by the deadline for the submission of a prior notice and updates to arrival information. The proposed rule also required that, if the identity of the grower was not known at the time of initial submission of the prior notice, but was known at the time of submission of amended or updated information, the identity of all known growers must be submitted. The proposed rule required that, in the event that other information in the prior notice changed, no amendment or update was permitted, and the prior notice must be cancelled and resubmitted.

(Comments) Comments ask FDA to be more flexible in allowing changes to prior notices. Some comments state that the time periods for prior notice and amendments and updates are not workable and should be made flexible. Comments note that requiring notice by noon of the day before the anticipated importation would cause an increased amount of amendments and updates.

Some comments note that the high degree of detail required in the prior notice will increase the need for amendments and that the likelihood of amendments will be more than FDA estimated. Some comments state that if the timeframe for submitting prior notice was changed, *i.e.*, shortened to 4 hours for land and air and 8 hours for water, then amendments and updates would not be necessary.

(Response) FDA agrees with the comments that state that if the deadline for submission of prior notice were reduced, amendments and updates would not be necessary. FDA has chosen timeframes that provide it with very little leeway in the time it has to ''receive, review and respond'' to the prior notice submissions. Thus, we concluded that we could no longer permit changes to prior notice without restarting the clock. In addition, the use of ABI/ACS precludes amendments and updates: changes to ABO/ACS submissions that have been electronically transmitted to FDA's OASIS and confirmed by FDA for review are not feasible because CBP also needs finality so it can complete its own screening of the entry. Therefore, the interim final rule does not allow for changes to a prior notice after the transmitter has been notified that FDA has confirmed the prior notice for review.

(Comments) One comment asks that FDA clearly define the circumstances under which updates and amendments to submissions of prior notice must be made. One comment asks FDA to clarify that a change in the anticipated arrival information is not the same as a product identity amendment and, therefore, is not subject to the same mandates as the procedure for changes in the product identity.

(Response) Because the interim final rule does not provide for amendments and updates, there is no need to address these comments asking for clarification.

(Comments) Some comments suggest that FDA allow amendments to all information in the prior notice. Some comments state that it is likely that companies filing numerous prior notices will inadvertently make clerical errors, such as telephone or fax numbers, Customs ACS entry line numbers, or Customs entry type. Others ask for clarification of any penalties associated with cancellation of a prior notice and resubmission of a correct notice.

(Response) FDA believes that the reduction of the deadline for submission of prior notice and the revisions to the information required have eliminated much of the need for amendments. FDA notes that transmitters should try to avoid clerical errors that could result in unnecessary rejections or refusals. To assist, FDA has designed the FDA PN System Interface to review presentation of some information before confirmation. The FDA PN System Interface will reject certain information if it is in the wrong format or does not match FDA's databases and the transmitter will be given an opportunity to make corrections during the submission process, before notice of confirmation from FDA that the prior notice has been submitted for review. The interim final rule provides for no penalty if a prior notice is cancelled. If prior notice has been submitted and confirmed and the food is no longer imported or offered for import, the prior notice should be cancelled. However, if the article of food is still imported or offered for import into the United States, submission of a corrected and timely prior notice is necessary.

(Interim final rule) Section 1.282 of the interim final rule requires that if the information except estimated quantity, anticipated arrival information, and planned shipment information changes after the transmitter receives notice that FDA has confirmed the prior notice for review, the prior notice should be canceled. If the article of food is still intended for import or will be offered for import, the prior notice must be resubmitted in accordance with this subpart. If you submitted the prior notice via the FDA PN System Interface, you should cancel the prior notice via the FDA PN System Interface. If you submitted the prior notice via ACS, you should cancel the prior notice by requesting that CBP delete the line or entry. The ''clock'' restarts after the confirmation of the submission containing the corrected information.

2. ''Under What Circumstances Must You Submit a Product Identity Amendment to Your Prior Notice After You Have Submitted It to FDA?'' (Proposed § 1.290)

FDA proposed that product identity information required by proposed § 1.288(e)(1) may be amended if all of the information about the identity of the food did not exist by 12 noon of the calendar day before the day of arrival. The proposed rule also provided that the common or usual or trade name, brand name, lot or code or identification numbers, and quantity may be amended. FDA also clarified that a prior notice may not be amended to change completely the identity of the article, *e.g.*, a prior notice identifying the food as lettuce may not be amended to identify the food as pears. The proposed rule provided that prior notice may be amended only once.

(Comments) Some comments suggest that FDA allow unlimited amendments to any information requirement at any time. Several comments express concern about the limitation of only one amendment. They explain if the process has to start over again because the information changes after submitting one amendment, there would be an additional 2-day delay before the product is allowed to cross the border. Some comments indicate that more than one amendment might be needed to provide accurate information. Some comments indicate specific additional information for which amendments should be allowed, such as the carrier and consignee.

(Response) FDA has chosen timeframes that provide it with very little leeway in the time it has to ''receive, review, and respond'' to prior notice submissions. Thus, we concluded that we could no longer permit changes to prior notice without restarting the clock. However, the significant shortening in timeframes should address many of the concerns. In addition, the submission systems will allow for correction of errors revealed by the systems' initial validation. The interim final rule has thus eliminated the requirement for amendments.

(Comments) One comment asks FDA to create an exemption from quantity amendments for bulk shipments for which the actual quantity is within 10 percent of the proposed actual quantity. (Response) The interim final rule requires submission of the estimated quantity. This revision nullifies the need for amendment to the quantity description by allowing the submitter to estimate the amount of food that is expected to arrive. The interim final rule provides for no penalty if the quantity of an article of food imported or offered for import differs from the quantity estimated in a prior notice.

a. *Intention to amend.* The proposed rule required that the submitter must indicate his or her intention to amend the product identity information at the time the prior notice is submitted.

(Comments) One comment contends that, if certain elements are amendable, FDA should not need additional advance notice of that fact. Other comments ask FDA to eliminate the requirement for the submitter to anticipate the need for an amendment. Other comments ask for clarification on whether the intent to amend or update must be evident on the initial prior notice or if a product identity amendment or arrival update can be made anytime within the minimum 2-hour requirement.

(Response) The interim final rule eliminates the requirement for amendments and updates. Thus, comments on the proposed limitation are moot.

b. *Topping off.* FDA recognized that the limitation on amendments might affect the practice of ''topping off a container'' by filling unused space in the shipping container or truck bed with last-minute shipments of other food

products not covered by prior notice. FDA solicited comments on how common ''topping off'' is and the quantities of food involved.

(Comments) Comments state that it is common practice to fill extra space in a shipment with additional product after an order has been filled. A comment suggests that there should be an allowance for last minute changes in a load. A comment suggests that more flexibility is needed to avoid the extraordinary cost of importing a partial shipment. A comment states that a prohibition on the practice of topping off would make some shipments, particularly of smaller items, less cost competitive and may reduce the overall availability of some products. Another states that late offers to add additional quantities or even additional products to a shipment at a discount make for more efficient commerce for importers and can provide economy and value to American consumers. Another comment suggests that FDA reconsider and adopt in the final rule circumstances under which shippers could amend notices to include foods from the same manufacturer or grower. The comment further states that this would allow the full utilization of transport space even when that space is filled with additional items not explicitly declared in the original prior notice.

(Response) The requirements of the statute are to provide FDA with notification of each article of food in advance of importation, not advance notice of some of the articles of food and post-arrival notification of others. The complete identity of each article of food is necessary for FDA to receive, review, and respond to the notice. FDA has significantly reduced the time required for submission of the prior notice before arrival. FDA has also revised the way information on quantity may be presented. The interim final rule requires the estimated quantity of the article of food. FDA believes that both of these revisions will allow for timely submission of accurate information and should limit, as much as is permissible under the statute, the effect of prior notice on the practice of ''topping-off.''

3. ''What Is the Deadline for Product Identity Amendments Under Proposed § 1.290?'' (Proposed as § 1.291)

FDA proposed a 2-hour minimum deadline for product identity amendments submitted under proposed § 1.291. FDA noted that product identity amendments are most likely to be needed for articles imported by land or air rather than water arrivals.

(Comments) Some comments are supportive of a deadline for amendments of up to two hours before arrival, but only if that gave FDA sufficient time to receive, review, and respond to the information. Some comments state that allowing amendments to be submitted up to 2 hours before arrival would not be problematic, while others contend that limiting amendments to two hours before arrival was too restrictive and would result in higher costs and compromised product integrity. Comments suggest changing the deadline to allow amendments up to 1 hour before arrival; until just before or at the time of arrival; after arrival (with a 3 hour limit, 24 hour limit, or no limit at all); or at any time before or after arrival. Several comments note that some information, such as the Customs entry number or quantity, cannot be verified by the proposed submitter until the shipment arrives. Several comments state that the carriers should be permitted to amend product identity information. A few commenters point out that the proposed 2-hour period for amendments before arrival is particularly problematic for multiple commodity exports. Comments indicate that the need for amendments might be identified at the time of loading, which may be less that one-half hour before arrival at the border.

(Response) FDA has chosen timeframes that provide it with very little leeway in the time it has to ''receive, review and respond'' to the prior notice submissions. Thus, we concluded that we could no longer permit changes to prior notice without restarting the clock. In addition, as noted earlier, ACS cannot accommodate changes in submissions that have been confirmed by FDA for review. Therefore, the interim final rule does not provide for amendments.

4. ''How Do You Submit a Product Identity Amendment or an Arrival Update to a Prior Notice?'' (Proposed § 1.292)

The proposed rule required that a product identity amendment or an arrival update to a prior notice may be submitted only in the same manner as an initial prior notice; that is, electronically to FDA through the FDA PN System Interface.

(Comments) A comment asks that the agency examine means by which communication to the agency of any unexpected change in this information can be provided by the entity that is actually knowledgeable about a change in the date of arrival, for example, by the ocean or air carrier. Several comments suggest that the carrier that is the party with the most accurate information on arrival time and can therefore provide the most efficient communication to FDA. Other comments raise concerns about providing unlimited discretion to carriers to make substantive changes to submissions, but note that the need for carriers to make ''updates'' is essential. One comment indicates that alternative mechanisms for the carrier to submit updates, such as touch-tone telephones, should be explored.

(Response) Although requirements for amendments to product identity information and arrival updates have been deleted from the interim final rule, FDA recognized that several entities might have critical information concerning required prior notice information. Therefore, the interim final rule does not limit who can submit prior notice information. The interim final rule continues to require electronic submission of prior notice to FDA.

5. ''What Are the Consequences if You Do Not Submit a Product Identity Amendment to Your Prior Notice?'' (Proposed § 1.293)

FDA proposed that if a U.S. importer or U.S. purchaser, or their U.S. agent, informed FDA in a prior notice that the submission would be amended, but subsequently did not amend it appropriately and within the applicable timeframe, then the prior notice would be inadequate for the purposes of proposed § 1.278(a). FDA clarified that the consequences of inadequate prior notice are the same as the consequences for failing to provide prior notice, *e.g.*, the food is subject to refusal if admission. FDA explained that the indication that a prior notice would be amended tells us that the prior notice is incomplete. FDA noted that without complete product identity, the agency could not adequately determine whether to inspect or take other action when the food arrives in the United States.

(Comments) Some comments object to the proposed provision that, if the submitter of a prior notice indicates that an amendment to the product identity will be submitted, but subsequently fails to do so, the original prior notice will be deemed inadequate and the product would not be allowed to enter. Some point out that FDA should not penalize a submitter for anticipating an amendment and then not amending the prior notice.

(Response) For the reasons set forth previously, FDA has eliminated the requirement to provide product identity amendments.

6. ''What Must You Do if the Anticipated Arrival Information (Required Under Proposed § 1.288(k)(1)) Submitted in Your Prior Notice Changes?'' (Proposed as § 1.294)

FDA proposed to require the submitter to update anticipated arrival information submitted in a prior notice, if the anticipated information changes after the submission. FDA proposed 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, the time of arrival must be updated. FDA proposed that updates to the arrival information must be submitted 2 hours before arrival (proposed § 1.294).

a. *General.* (Comments) Many comments indicate that the window of time for arrival updates is too small. Several comments suggest changing the requirements for submitting updates for arrival information. Suggested changes included expanding the window for arrival to 2 hours and 6 hours before the anticipated arrival time and 6, 7, 8, and 18 hours after the anticipated arrival time. A few comments state that notification of the day of arrival, not the time, should be sufficient. Some comments state that updates to arrival information should be allowed upon arrival at the border. One comment objects to allowing only one update to arrival information. The comment complains that this is very restrictive and that submitters must be allowed to keep updating the ''prior notice of arrival'' without worrying about the form being rejected.

Some comments point out that the owner, importer, and U.S. agent often do not know the actual port of entry for a ship or airplane, the time of entry, or changes in this information. For example, an air shipment of seafood may be switched to a different plane, which arrives at the U.S. port outside the anticipated arrival window. This may occur during nonbusiness hours, before notification of the change can be provided.

One comment suggests that exporters who choose to report to specific border crossings identified by FDA, should not be required to provide updates due to lateness in the time of arrival at the border.

One comment states that ambiguity on when updates can be submitted might lead to confusion and inconsistent application of these provisions. The comment expresses concern that some ports may take the position that the update must be provided within the 4-hour window so FDA will be informed that the shipment will not be arriving when originally anticipated. Yet other ports may take the position that the update requirements are satisfied as long as the update is received at least 2 hours before arrival, regardless of how many hours or days it arrives after the originally identified arrival time.

Some question how notifications that need to be amended and subsequent amendments for numerous entries could assist FDA in scheduling of inspections.

Some point out that carriers should continue to be able to change ports of arrival, as necessary, to find a more expeditious route, based on weather and/or traffic conditions. One comment states that exporters/importers should be able to declare up to three possible ports of entry that all fall under the jurisdiction of a single FDA regional office for administrative and inspection purposes.

One comment suggests that a requirement to update the port of entry could be viewed as limiting the port of entry, which is prohibited by the statute.

One comment points out that the proposed rule is silent on changes to border crossings, unlike changes in arrival time and suggested that FDA clarify whether it needs to be notified of a change to the anticipated border crossing or if any border crossing is acceptable.

b. *Water.* (Comments) One comment asks for a wider margin of variability for the arrival of ocean-going vessels. Some comments state that for ocean-going shipments, an update should not be required if the actual arrival at the port of entry is not more than 24 hours before or after the anticipated time of arrival specified in the prior notice. One comment notes that because of the logistics and unpredictability of ocean transport, it is not possible to accurately predict arrival time of a carrier within the 4-hour window provided. One comment notes that such tight time frames would increase the cost of the prior notice process because the submitter will be forced to continuously check on the status of the shipment to ensure that the arrival time is correct all the way up to 2 hours before delivery. For ocean imports, vessel arrival times may vary widely depending upon weather conditions, scheduling, and loading changes. Vessels can be held or delayed at various ports en route and importers are unlikely to be informed of these changes. Some comments state that it is unrealistic for a sea vessel to have to individually update hundreds or thousands of notices when the vessel is delayed. Comments ask that FDA allow a single update from a carrier to automatically update each prior notice associated with food products on that vessel.

c. *Air.* (Comments) One comment states that the 2 hours for updates is not practical for air shipments because air carriers often do not inform importers of changes in arrival time until the cargo is close to its destination. One comment notes that because of current air and travel security procedures, arrivals are rarely at their scheduled times.

d. *Land/road.* (Comments) A few comments indicate that with respect to trucks, there will be circumstances where a driver cannot contact a dispatcher to submit an arrival update, *e.g.*, 2 a.m. The comments note that a large amount of border truck traffic flows in the early morning/mid-to-late evening to avoid rush-hour traffic in major centers. However, shippers do not have a mechanism for submitting updates at these times when there are unforeseen delays that prevent arrival outside of the anticipated window. Comments state that FDA should provide flexibility in the rule for these and similar circumstances where, for legitimate reasons, it is not possible to provide an update.

Some comments express concern about current delays for trucks at ports of entry, which may vary from a few minutes to 12 hours. The comments note that, because it is necessary to submit updates when a truck is outside the proposed time range for arrival, many trucks might be forced to sit idly on the side of the road waiting for their proper window when FDA will allow entry. Comments express concern that if a shipment were to miss the original arrival time, they would be forced to file an update and wait 2 hours to rejoin the line.

e. *Land/rail.* (Comments) For rail cargo, arrival times may vary depending on scheduling and loading changes. Often, multiple rail cars on one entry can be located at multiple locations across the rail yard. Actual crossing times for those cars can vary widely depending on that location and the ability of the rail to load and cross them. In these cases, linking prior notice into the manifest could also allow the carrier to provide electronic updates.

(Response) FDA agrees that there may be factors such as business practices, weather, and traffic congestion that may impact the accurate representation of the port, date, and time of arrival. Although the interim final rule will continue to require submission of the anticipated place, date, and time of arrival that is known to the submitter, the interim final rule does not require an update to that information, and prior notice will not be deemed inadequate if

the information changes after FDA has confirmed the prior notice for review.

In sum, FDA has removed from the interim final rule all proposed sections related to product identity amendments and arrival updates (proposed §§ 1.289 through 1.294) because of the following situations:

- The timeframes are shortened substantially;
- The timeframes provide us with very little leeway in the time we have to ''receive, review and respond'' to the prior notice submissions. Thus, we can no longer permit changes to prior notice without restarting the clock. FDA believes that the information required by the interim final rule for prior notice should be sufficiently fixed to be submitted within these new, shorter timeframes;
- FDA has revised the required information in the interim final rule, including the requirement to provide the estimated quantity;
- If the estimated quantity, the anticipated arrival information, or the planned shipment information change, the interim final rule does not require that the prior notice be resubmitted; and
- Under the interim final rule, prior notice can be submitted through ABI/ACS. The proposed provisions for amendments and updates to a submission through ABI/ACS are not feasible after the submissions have been electronically transmitted to OASIS and confirmed by FDA for review.

(Summary of the interim final rule) FDA has removed from the interim final rule all proposed sections related to product identity amendments and arrival updates (proposed §§ 1.289 through 1.294).

J. ''What Happens to Food That Is Imported or Offered for Import Without Adequate Prior Notice?'' (Section 1.283) and ''What are the Other Consequences of Failing to Submit Adequate Prior Notice or Otherwise Failing to Comply With This Subpart?'' (§ 1.284 Proposed as § 1.278)

1. Inadequate Prior Notice (No Prior Notice, Inaccurate Prior Notice, or Untimely Prior Notice) (§ 1.283(a) Proposed as § 1.278(a))

FDA proposed in § 1.278(a) that if an article of food is imported or offered for import with no prior notice or inadequate prior notice, the food shall be refused admission, as set out in under section 801(m)(1) of the FD&C Act. Proposed examples of inadequacy were untimely, inaccurate, or incomplete prior notice.

(Comments) Comments ask for clarification on what would cause a prior notice to be incomplete or inadequate. Some comments express concern that clerical errors or failure to provide minor information or optional information could result in a refusal. Some comments suggest that inadequate prior notice should be confined to material omissions or major errors that would seriously impede the agency's ability to review and appropriately respond to the notice. Comments ask whether they would be notified about such deficiencies and given a chance to correct them. Some comments object to not receiving feedback, before reaching the port, when the prior notice is inadequate.

(Response) A prior notice is not complete if the required information, as set forth in § 1.281, has not been provided. However, FDA agrees that feedback during the transmission process to reduce mistakes and omissions that could result in unnecessary holdups or refusals is a good idea. As explained earlier, both systems will review and validate required information to minimize the likelihood that clerical or typographical errors will result in an incomplete or inaccurate prior notice. The systems will tell transmitters which required information is still lacking or is recognized by the initial validation as facially incorrect, to allow transmitters to make corrections quickly. Moreover, the systems will not provide a confirmation until required information is complete and facially valid. Thus, if the initial incorrect information is not corrected and submitted, the transmitter will not receive a prior notice confirmation. FDA believes that this initial review/validation process will help ensure that transmitters will not make inadvertent errors that could result in a refusal. We advise, however, that this initial review/validation process will not be capable of identifying all possible errors. Thus, submitters and transmitters should understand that confirmation does not mean that FDA has determined that the prior notice is accurate in all respects.

If FDA determines that the prior notice is inaccurate after the systems provide a confirmation, the article of food is subject to refusal under § 1.283(a)(1)(ii). FDA has the option of issuing the refusal notice to the transmitter under § 1.283(a)(1)(ii) before arrival, assuming that FDA determines that the prior notice is inaccurate before arrival and before the time period for the prior notice has expired. If this happens, the transmitter must resubmit an accurate prior notice in accordance with § 1.282. This will remove the refusal, although it will ''restart the clock'' in terms of when prior notice must be submitted to FDA. Until we have had some experience with prior notice review, we do not know how often we will be able to determine prior notice inaccuracy before food arrives. However, in certain situations, inaccuracy of prior notice cannot be determined until the article of food is examined upon arrival.

(Comments) Comments suggest the regulation provide a waiver or other mechanism to release foods that are safe, although the electronic paperwork is not complete. Comments also suggest that the regulation provide that, unless FDA has credible evidence or information that an article of food presents a threat of serious adverse health consequences or death to humans or animals, that FDA would not refuse the article if the prior notice is incomplete or inadequate.

(Response) FDA does not agree that the regulation should provide a waiver for refusal when some, but not all required, information has been submitted. Given that the purpose of prior notice is to provide FDA with better information sooner about food imports, including such a waiver in the rule would seem to be antithetical to the provision. The reference to the credible evidence standard in section 801(m) of the FD&C Act, which appears in the part of section 801(m) that deals with FDA review of prior notice after refusal, does not suggest otherwise. Section 801(m)(2)(B)(ii) of the FD&C Act states that, when FDA reviews a prior notice that has been submitted for a refused article of food, FDA ''shall determine whether there is in the possession of [FDA] any credible evidence or information indicating that such article presents a threat of serious adverse heath consequences or death to humans or animals.'' FDA does not agree that this provision means that FDA should not refuse food with an inadequate prior notice under section 801(m)(1) of the FD&C Act when FDA has no such credible evidence or information. If that is what Congress intended, it would not have provided for refusal of an article of food without adequate prior notice, as it did in section 801(m)(1) of the FD&C Act.

(Comments) Comments note that the proposed rule did not set out procedures for notifications regarding refusals and holds. Comments ask who would be notified of refusal and when. Comments state that FDA should notify importers, purchasers, or manufacturers that an article is being held. One comment notes that carriers would have no way of determining if prior notice had been satisfied until they arrived at

the border, but that they would be responsible. A comment also states that FDA should engage the manufacturer or processor when the situation involves a bioterrorism threat or event.

(Response) FDA and CBP have determined that the most appropriate notification point is the carrier. When an article of food arrives at the border without adequate prior notice (*i.e.*, none, inaccurate, or untimely), the carrier is the clearest immediate point of contact that FDA and CBP staff at the border have. Thus, FDA or CBP intend to notify the carrier that the article of food is refused due to inadequate prior notice when the food is presented for CBP processing. It will be up to the carrier to communicate the prior notice refusal to other persons or firms. Neither FDA nor CBP currently has sufficient capability at the border to communicate these refusals to other persons and still process arrivals and examinations in a reasonable amount of time. We recognize that this will affect carriers. We will be exploring ways to provide notice to the transmitter and others, as well. FDA notes that if carriers want to ensure, for any food they are transporting, that prior notice has been submitted to FDA and confirmed for review, they can ask that a copy of the PN confirmation be provided to them. Indeed, under § 1.279(g), for prior notices transmitted through the FDA PN System Interface, the carrier must present the PN confirmation number to CBP or FDA upon arrival.

We do not agree that FDA should provide routine advance notice that it intends to refuse, examine, or hold food or has asked CBP to do so. Although FDA and CBP are structuring implementation to ensure that changes in ports and arrival times will not mean that food which should be refused, held, or examined at the port of arrival slips past us, we believe that routine advance notice could make it easier for the unscrupulous to evade FDA requirements and import unsafe food. Finally, whether we contact importers or manufacturers when there is a bioterrorism threat or other food-related emergency will depend on the particular circumstances.

(Comments) Some comments state that inconsistency in time and changes in the port of arrival should not result in refusal of the article. One comment asks whether a shipment that arrives one-half hour late will be treated the same as one that arrives 12 hours late.

(Response) As explained elsewhere, changes in the anticipated arrival information or planned shipment information will not be a basis for a refusal under section 801(m)(1) of the FD&C Act if FDA wants to examine the shipment; however, these changes may mean waiting while FDA is notified by CBP and arranges to examine the shipment. This is more likely to be the case with changes in ports and in arrivals that are much later than the anticipated time.

When it comes to changes in arrival time, what matters is whether the prior notice time was submitted sufficiently in advance of arrival, in accordance with the timeframes set out in § 1.279(a) of the interim final rule. These timeframes are what FDA has determined are necessary, as a general matter, to ensure that FDA has enough time to receive, review, and respond to each prior notice appropriately. However, § 1.283(a)(1)(iii) of the interim final rule does provide that if an article of food arrives early, before the prior notice time has elapsed, its arrival will not be considered untimely if FDA has already reviewed the prior notice, determined its response to the prior notice, and advised CBP of that response. FDA believes there is no need to make the food wait if the agency has been able to accomplish its prior notice review sooner than anticipated.

(Comments) One comment asks for clarification on whether the article would be refused if the classification of goods under the HTS code has been changed by Customs officials after the shipment arrives.

(Response) If the FDA Product Code is accurate, then the article will not be refused if the HTS code provided is later changed by CBP during its review of the entry for CBP purposes.

(Comments) One comment asks whether there would be a penalty for canceling and resubmitting a prior notice when the changes that need to be made to the prior notice cannot be made by an amendment or an update.

(Response) FDA has removed the provisions relating to amendments and updates. If required information (with the exception of estimated quantity, anticipated arrival information, and planned shipment information) changes, *e.g.*, the manufacturer is different than the one originally submitted or the complete FDA product code is not accurate, you should cancel the prior notice and must resubmit prior notice (if you still plan to import or offer for import the article of food into the United States). The timeframes set out in § 1.279(a) of the interim final rule will start to run again from the time the new prior notice is confirmed for review by FDA.

a. *Status and movement of refused foods (§ 1.283(a)(2)).* FDA proposed in § 1.278(b) that if an article of food is imported or offered for import is refused under section 801(m)(1) of the FD&C Act, the food shall be held at the port unless directed to a secure facility under proposed § 1.278(c). Proposed § 1.278(d) provided that the person submitting prior notice was responsible for arranging for movement of refused food. Proposed § 1.278(e)(2) stated that refused food could not be delivered under bond to the importer, owner, or consignee. In the preamble to the proposed rule (68 FR 5432), we explained that the provisions in title 19 of the U.S. Code relating to imports for which entry cannot be made would apply.

i. *General order status (§ 1.283(a)(2)(i)).* (Comments) One comment asks for confirmation that the provisions in title 19 of the U.S. Code that apply to unentered merchandise would apply to articles of food that have been refused under section 801(m)(1) of the FD&C Act.

(Response) FDA and CBP generally agree with this comment. However, we have concluded that the interim final rule should specify that these provisions will apply immediately upon refusal under section 801(m)(1) of the FD&C Act because entry of an article of food refused under section 801(m)(1) cannot be made for want of proper documents or other cause, as described in section 490(a)(1)(C) of the Tariff Act of 1930, as amended (19 U.S.C. 1490(a)(1)(C)). Accordingly, § 1.283(a)(2)(i) of the interim final rule specifies that an article of food that has been refused under section 801(m)(1) of the FD&C Act shall be considered general order. Thus, an article of food refused under section 801(m)(1) meets the criteria of general order and must be handled in accordance with sections 490 and 491 of the Tariff Act (19 U.S.C. 1490 and 1491) and CBP's implementing regulations at 19 CFR part 127 except as otherwise specified in 21 CFR part 1, subpart I.

ii. *Locations for holding refused food (§ 1.283(a)(2)(ii)).*

(Comment) One comment suggests using the existing system where shipments may be held in place at the port for 14 days after which they must be moved to general order.

(Response) After merchandise has arrived in the United States, the Customs regulations prescribe a 15-calendar day period during which entry must be made. If entry is not made during this time, the merchandise then must be sent to general order inasmuch as entry has not been completed (see 19 CFR 4.37, 122.50, or 123.10). However, as described previously, this 15-calendar day period is not applicable to articles refused under section 801(m)(1)

of the FD&C Act. Articles that are refused for inadequate prior notice cannot be entered under any form of Customs entry. Those articles may only be entered after adequate prior notice has been given.

(Comments) Several comments express concern about the impact of refusal and holding at the port or secure storage on the quality, value, and marketability of perishable fresh and frozen foods.

(Response) FDA expects that the changes in the interim final rule, in particular the shortened timeframes, will mean fewer refusals. In addition, since FDA will make every effort to review prior notices for refused articles within these same timeframes, those responsible for submitting prior notice have the ability to have the refusal removed in a matter of a few hours. This, too, significantly reduces the impact of the interim final rule on perishables. Finally, FDA also intends to provide guidance to its staff on implementing and enforcing the prior notice requirements, both during the initial transition period and after that period ends.

FDA agrees that appropriate storage and holding conditions must be considered for perishable and frozen foods refused for inadequate prior notice. This means that if the article of food arrives in frozen condition and has been transported under frozen conditions, the facility used for holding the product must provide adequate frozen conditions.

(Comments) Some comments express concern that there are insufficient facilities at the U.S./Mexico ports to handle the potential refusals during the produce season. One commenter disagrees with FDA's statement in the preamble to the proposed rule that ''U.S. Customs has identified a well-established network of storage facilities that are secure.'' The comment pointed out that there is no infrastructure of secure facilities at all ports. A comment noted that there are few facilities at remote East and West ports along the U.S./Canadian border that have temperature controlled environments and are available around the clock. Another comment noted that there generally is a lack of bonded cold storage facilities at borders and at airports. One comment asks for information on the infrastructure of storage facilities that would provide sanitation and temperature controls, as well as security controls, including security against theft and accidents. Some comments ask that FDA publish a list of the secure facilities and the costs that FDA authorizes for the refused food.

(Response) FDA expects that the changes in the interim final rule, in particular the shortened timeframes, will mean fewer refusals and thus less need for storage for refused articles of food. Nevertheless, FDA and CBP agree that the different ranges of storage available at different ports need to be addressed. However, this issue needs to be addressed in light of the determination, reflected in § 1.283(a)(2)(i), that food refused under section 801(m)(1) of the FD&C Act has ''general order'' status. Under customs laws and regulations, general order merchandise must generally be held in a general order warehouse (19 CFR 127.1). Customs regulations also empower the port director, if merchandise requires specialized storage facilities that are unavailable in a bonded facility, to direct the storage of the merchandise by the carrier or by any other appropriate means (see 19 CFR 4.37(f), 122.50(f), or 123.10(f)). Additionally, fruit and other perishables may be held by the port director in a bonded cold-storage warehouse for a reasonable period, if it is probable that entry will be made at an early date (19 CFR 127.28(c)).

FDA and CBP believe that general order storage qualifies as secure facilities for purposes of the Bioterrorism Act, as it is subject to the requirements set out at 19 CFR part 19. In particular, 19 CFR 19.9 contains controls that will ensure that refused food will be adequately controlled while in storage and will not be released from general order storage without CBP authorization.

(Comments) Several comments ask for clarification on secure facilities. Comments ask whether a general-purpose warehouse in a FTZ or a secure facility operated by the importer of record would be considered a secure facility under the rule. Another comment suggests that a clear chain of custody and fiduciary responsibility is required when products are impounded. The comment recommends that appropriate and sufficient impound storage facilities must be available before enforcement begins.

(Response) As set out previously, food refused under section 801(m)(1) of the FD&C Act must be held in accordance with CBP's regulations on general order merchandise.

(Comments) One comment suggests that if there is a failure to submit adequate prior notice, the goods should be allowed to move to the port of destination.

(Response) The prior notice is required to be submitted to and confirmed by FDA before the article of food arrives at the port of arrival. Food refused because of inadequate prior notice must be held within the port of entry for the article unless directed by CBP or FDA. Thus, refused food may be permitted to move to the port of destination.

iii. *Movement of refused food (§ 1.283(a)(2)(iii)).* (Comments) One comment objects to making the carrier responsible by regulation for movement of refused food. One comment suggested that FDA should be responsible for movement of refused foods.

(Response) As set out in the preamble to the proposed rule (68 FR 5431 to 5432), we do not believe that section 801(m) of the FD&C Act mandates that the government take physical control of refused food. Rather, it limits the locations where refused food can be held and to whom it can be delivered. Accordingly, FDA proposed that the carrier or the person who submitted the prior notice arrange for the movement of the refused food. FDA has decided to remove this limitation in the interim final rule. Since we have removed limitations on who can submit, submitters may now be foreign firms that may have difficulty arranging to move food from overseas. We have concluded that we should not impose any limitations on who may arrange for the movement of refused foods. The interim final rule, § 1.283(a)(2)(iii), does maintain the requirement that movement of refused food occur under the appropriate CBP custodial bond. The interim final rule further provides that refused food must be taken directly to the designated facility, shall not be entered, and shall not be delivered to any importer, owner, or ultimate consignee. Failure to observe these conditions will be a violation of the bond and may result in the imposition of liquidated damages.

b. *Segregation of refused foods (§ 1.283(a)(3)).* (Comments) Some comments state that FDA should release to the owner or importer all of the other food or nonfood items in the shipment that are not affected by the inadequate prior notice, in mixed or consolidated shipments, if one or more food items has been refused because of inadequate prior notice. One comment points out that shipments might contain sealed containers of different foods from different sources. One comment asks for clarification on how refused products will be segregated from products that may continue when the products are on a truck or in a rail car. The comment points out that this is a concern for less-

than-truckload (LTL) carriers and small package carriers, who may have thousands of overnight or expedited shipments on one trailer. The comments express concern that importers and carriers of nonfood items and of compliant food items would be unfairly penalized because of a noncompliant entry. A comment states that Customs' regulations authorize different portions of merchandise imported in a single shipment and consigned to a single consignee to be cleared under separate consumption entries (19 CFR 141.52). The Customs regulation in 19 CFR 141.52 also authorizes separate entries for any portions of a shipment that will be covered by different types of entry, such as a bonded warehouse entry.

(Response) FDA agrees. In the preamble to the proposed rule, FDA recognized that food refused under section 801(m)(1) of the FD&C Act may be located in the same container or truck with nonfood items or food that is not refused under section 801(m). However, when mixed or consolidated imported freight contains refused articles of food that must be held, those articles that have been refused must be dealt with in a manner that is consistent with the limitations in section 801(m) of the FD&C Act. Therefore, FDA has added § 1.283(a)(3) to the interim final rule to state that if the article of food that is refused is part of a shipment that contains articles that have not been refused under section 801(m)(1) of the FD&C Act, the refused article(s) may be segregated from the rest of the shipment. This segregation must take place within the port of arrival or where the article is held, if different and may be supervised by FDA or CBP.

c. *Costs (§ 1.283(a)(4)).* (Comments) Several comments ask who would be responsible for storage and transportation costs. One comment notes that the private parties to the importing transaction should be liable for storage and transportation costs when food was refused. One comment stated that the person submitting prior notice should be responsible for these costs. Another comment asks FDA to include a provision in the interim final rule that allows carriers to recover removal, storage, or dispositions costs from the owner, purchaser, or consignee.

(Response) Inasmuch as articles for which adequate prior notice has not been received are considered general order merchandise, the expenses of transportation and storage will be the responsibility of those parties who are responsible under the general order statutes and regulations. FDA has thus decided it is not necessary to include a provision in the interim final rule that specifies which private parties should be responsible for costs associated with refusal. However, we have added § 1.283(a)(4) to the interim final rule to clarify that the U.S. Government is not responsible for these costs.

(Comments) Some comments ask that the regulation establish a damage claim system for losses that occur when perishable foods are detained for administrative reasons. Some comments suggest that FDA should provide compensation for losses, including transportation and storage fees, if the agency mistakenly holds imported product because of an oversight in the government's processing of a prior notice.

(Response) FDA disagrees. The interim final rule provides in § 1.283(a)(4) that neither FDA nor CBP will be responsible for transportation, storage, or other expenses resulting from refusal. FDA notes that it has never assumed responsibility for expenses associated with refusal under the FD&C Act. Any claim against the government arising under these activities shall be governed by the Federal Tort Claims Act.

3. *Post-refusal submissions and resubmissions (§ 1.283(c)).* (Comment) Comments ask FDA to clarify how inadequate notice could be corrected and what steps must be taken to have the product released. One comment suggests that the regulation should state that a shipment with inadequate prior notice would be held only until the prior notice is corrected and that the correction should be required within 24 hours. One comment suggests that food should be held for 24 hours and then deemed released if FDA has not notified the person submitting the notice that the food will be examined.

(Response) FDA agrees that the rule should specify procedures for submitting or resubmitting a prior notice after refusal. These are set out in § 1.283(c)(i) and (c)(ii) in the interim final rule. FDA does not believe it is necessary to impose any limit on how long a person has to submit or correct a prior notice for refused foods since an article of food refused under section 801(m)(1) of the FD&C Act is considered general order merchandise. If no adequate prior notice is received within the timeframes set out in 19 CFR part 127, title in the refused food will vest in the United States and the refused food will be eligible for general order sale or other disposition. Also note that fruit, perishables, or merchandise liable to depreciation, may be characterized as ''special merchandise'' per 19 CFR 127.28. Alternate disposition, consistent with the general order statutes, is then provided for.

The rules governing general order merchandise should be familiar to those in the business of importing food, as they are rules of long standing that are applied by CBP when no entry is made for food. FDA believes that it is up to the persons involved in importing the food into the United States to determine how quickly prior notice should be submitted or resubmitted for food refused under section 801(m)(1) of the FD&C Act.

FDA does not agree that the refusal should be deemed removed if the transmitter does not hear from FDA within 24 hours that FDA will be examining the product. Section 801(m)(2)(B)(i) of the FD&C Act states that refused food may not be released until prior notice has been submitted, reviewed by FDA, and determined by FDA to be adequate.

(Comments) Many comments state that the regulation should set limits on the time FDA has to determine the adequacy of a prior notice submitted after a food has been refused in order to ensure quick release of refused food. One comment explains that such language would be consistent with congressional intent as stated in the Conference Report:

> if an article of food were offered for import without providing the required prior notice, the article of food would be held at the port of entry until the Secretary has determined that notice is complete, but it would not be held longer than the unelapsed period of prior notice unless there is other basis for doing so.

(Conf. Rept. at H2858.)

(Response) FDA agrees in part. The rule provides in § 1.283(c)(iii) that once the prior notice or corrections to a prior notice have been submitted and confirmed by FDA for review, FDA will make every effort to review and respond to the prior notice submission within the timeframes set out in § 1.279(a).

d. *Export after refusal (§ 1.283(a)(5)).* Although export under the general order provisions of the title 19 of the U.S. Code was discussed in the preamble to the proposed rule (68 FR 5432), the proposed rule did not address exportation of food refused under section 801(m) of the FD&C Act.

(Comment) One comment asks whether export would be required for food refused under section 801(m)(1) of the FD&C Act.

(Response) Export is not required for an article of food refused under section 801(m)(1) of the FD&C Act; it is, however, an option for an article of food refused under § 1.283(a) and as permitted under CBP's general order

provisions unless FDA or CBP were to seize or administratively detain the food under other authority. We have added § 1.283(a)(5) to the interim final rule to make this clear. If an article of food that has been refused admission under section 801(m)(1) of the FD&C Act is exported, the prior notice should be cancelled within 5 calendar days of exportation. FDA and CBP note that any time an article of food leaves the country after arriving at the port of arrival, it is considered an export for CBP purposes, and the applicable line or entry is deleted and, if prior notice was transmitted with the entry via ACS, the prior notice will be cancelled as well. This is true regardless of whether the intent is to re-import the article, even if the re-import occurs after a brief period of time.

To import that article of food, the prior notice must be re-submitted, and a new entry must be made, and the new prior notice will have the effect of ''restarting the clock'' in terms of when the prior notice has been submitted to FDA. If prior notice had been transmitted via the FDA Prior Notice System Interface, the prior notice is not automatically canceled when the article of food is exported. The only way to cancel a prior notice that was transmitted via the FDA Prior Notice System Interface is to use that system to explicitly cancel the prior notice.

e. *Abandoned merchandise (§ 1.283(a)(6)).* (Comment) One comment states that the regulation should address what happens if refused food is not claimed by the owner, purchaser, or consignee.

(Response) The interim final rule, in § 1.283(a)(6), provides that if no prior notice or correction is received in a timely fashion or export has not occurred, the food shall be dealt with as set forth in CBP regulations relating to be general order merchandise, except that it may only be sold for export or destroyed as agreed to by CBP and FDA.

5. International Mail (§ 1.283(e))

Although the proposed rule applied to food imported or offered for import by mail, *see, e.g.*, 68 FR 5436, there were no proposed provisions specific to refusal of food arriving by international mail.

(Comments) No comments submitted comments specific to refusal of food arriving by international mail were submitted.

(Response) FDA believes that separate refusal procedures are necessary for food arriving by mail given differences between mail and cargo. FDA believes that these procedures are authorized under section 701(b) of the FD&C Act because they are necessary to ensure that the refusal provisions of section 801(m)(1) of the FD&C Act can be efficiently and effectively applied to food that arrives by mail. The interim final rule thus provides in § 1.283(e) that in the case of food arriving by international mail with inadequate prior notice, the parcel will be held by CBP for 72 hours for FDA inspection and disposition. If the parcel is refused and there is a return address, the article may be returned to sender stamped ''No Prior Notice—FDA Refused.'' If there is no return address or FDA determines that the articles of food in the shipment appear 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 will return the parcel to the sender or, if there is no return address, destroy the parcel, at FDA expense.

2. Food Carried by or Otherwise Accompanying an Individual (§ 1.283(b))

Although the proposed rule applied to food imported or offered for import in baggage that was not brought in by a traveler for personal use, there were no proposed provisions specific to refusal of food in baggage in the proposed rule.

(Comments) No comments submitted comments specific to refusal of food carried by or otherwise accompanying an individual.

(Response) FDA believes that separate refusal procedures are necessary for food carried by or otherwise accompanying an individual given differences between these kinds of imports and cargo. FDA believes that these separate procedures are authorized under section 701(b) of the FD&C Act because they are necessary to ensure that the refusal provisions of section 801(m)(1) of the FD&C Act can be efficiently and effectively applied to food carried by or otherwise arriving with an individual.

(Interim final rule) Section 1.279(f) provides that the individual who carries or is accompanied by food must have a copy of the confirmation of prior notice when arriving in the United States. Section 1.283(b) provides that if there is inadequate prior notice or the individual cannot provide FDA or CBP with a copy of the PN confirmation, the article of food is subject to refusal. If before leaving the port, the individual cannot arrange to have the refused food held at the port or exported, the article of food may be destroyed.

4. FDA Review After Refusal, § 1.283(d)

(Comments) Several commenters suggest there should be an efficient appeal mechanism in the event that the submitter, importer, owner, or consignee believes that food products have been inappropriately refused and held.

(Response) Although such a process is not required by § 801(m) of the FD&C Act, FDA agrees that having a review process designed to address prior notice issues is warranted. Section 1.283(d) of the interim final rule sets out parameters under which a request may be submitted to obtain FDA review of whether the article is subject to the requirements of this subpart under § 1.276(b)(5) (*i.e.*, meets the interim final rule's definition of food) or § 1.277 (*i.e.*, is within the scope of the interim final rule) or whether the contents of a prior notice submission were accurate. The interim final regulation provides that a request must be submitted within 5 days of refusal and that FDA will respond within 5 days. FDA notes that if the product is perishable, the sooner the request is submitted, the sooner FDA will respond. FDA chose these timeframes because they are consistent with the timeframes for perishables contemplated under the new administrative detention provisions at § 304(h) of the FD&C Act, 21 U.S.C. 334(h). After review, if FDA determines that the article is not subject to prior notice or that the prior notice submission is accurate, it will notify the requester, the transmitter, and CBP that the food is no longer subject to refusal under section 801(m)(1) of the FD&C Act.

5. Prohibition on Delivery Outside of the Port, § 1.283(f)

(Comments) One commenter suggests following existing procedures and allowing refused foods to be held at the importer's place of business, quarantined and considered to be undeliverable, but held for sampling and release. Another commenter asks for clarification on whether product could be shipped to the importer, purchaser, or consignee's facility, if prior notice is inadequate.

(Response) The statute explicitly states that an article of food that is refused under the provisions of section 801(m)(1) must be held and shall not be delivered to the importer, owner, or consignee. See § 801(m)(2)(B)(i). Thus, the provisions of the Bioterrorism Act specifically override certain existing procedures that apply when food is subject to refusal under § 801(a) of the FD&C Act. In accordance with the new procedures specified in the Bioterrorism Act, § 1.283(de) of the interim final rule provides that, notwithstanding § 801(b) of the FD&C Act, 21 U.S.C. 381(b), an

article of food refused under § 801(m)(1) may not be delivered to the importer, owner, or ultimate consignee or transferred by any person from the port or secure facility until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food no longer is subject to refusal of admission under § 801(m)(1) of the FD&C Act. After this notification, entry may be made in accordance with law and regulation.

6. Relationship to Admissibility (§ 1.283(g))

The proposed rule (§ 1.278(f)) differentiated between a refusal of admission under section 801(m)(1) of the FD&C Act (prior notice) and refusal of admission under section 801(a) of the FD&C Act or other U.S. laws. The proposed rule clarified that a determination that an article of food is no longer subject to refusal of admission under section 801(m)(1) of the FD&C Act does not mean that it will be admitted to the United States under other provisions of the law that apply to admissibility determinations.

(Comments) One comment asks for clarification on whether a shipment will have to remain at the port and be subject to inspection until after FDA receives and reviews the entry documentation through OASIS. The comment points out that in most cases, OASIS review occurs after the goods have at least been conditionally released. Other comments state FDA should conduct its review under section 801(a) of the FD&C Act at the same time it is doing its prior notice review. Another comment asks what would happen if a prior notice was determined to be inadequate as part of FDA's review under section 801(a) of the FD&C Act.

(Response) Section 1.283(g) provides that FDA's determination that an article of food is no longer refused under section 801(m)(1) of the FD&C Act is different than, and may come before, determinations of admissibility under other provisions of the FD&C Act or other U.S. laws. As a general matter, FDA intends to use prior notice information to determine what products should be inspected upon arrival; we do not intend to make admissibility decisions under section 801(a) of the FD&C Act until entry has been made. The refusal under section 801(m)(1) of the FD&C Act will be removed after prior notice has been received, reviewed, and responded to by FDA, and there will be no further requirement to hold at the port for purposes of section 801(m). As a general matter, at that point, the procedures under section 801(a) and (b) of the FD&C Act would apply. If FDA discovers that prior notice was inadequate after an article leaves the port of arrival but before it makes a decision to ''may proceed'' or release an article of food under section 801(a) of the FD&C Act, FDA may refuse the article under section 801(m)(1) and ask CBP to issue a notice of redelivery.

Interim Final Rule (§ 1.283)

FDA revised the proposed rule to provide for more specificity, clarify the status of refused food, and provide a mechanism for FDA review after refusal. In the interim final rule, FDA identifies the consequences and procedures for the following situations:

a. *Inadequate Prior Notice (No, inaccurate, or untimely prior notice) (§ 1.283(a)(1)).* The article is subject to refusal under section 801(m) and, if refused, unless immediately exported with CBP concurrence, must be held.

b. *Status and movement of refused food (§ 1.283(a)(2)).* A refused article of food shall not be delivered to the importer, owner, or ultimate consignee until FDA has examined the prior notice, determined the adequacy of the prior notice and notified the transmitter and CBP that the article of food covered by the prior notice is no longer refused. A refused food is considered general order merchandise under section 490 of the Tariff Act of 1939, as amended. The refused food must be moved under appropriate custodial bond. FDA must be notified of the location where the food has been or will be moved within 24 hours of refusal. The food must be taken directly to the designated location, shall not be entered, and shall not be delivered to any importer, owner, or ultimate consignee.

c. *Segregation (§ 1.283(a)(3)).* If a refused food is part of a shipment that contains other articles, the refused food may be segregated from the rest of the shipment within the port of arrival or where it is held, if different. FDA or CBP may supervise the segregation.

d. *Costs (§ 1.283(a)(4)).* Neither FDA nor CBP will be liable for transportation, storage, or other expenses resulting from refusal.

e. *Post-refusal submissions and resubmissions (§ 1.283(c)).* If an article of food is refused for no or inaccurate prior notice, the prior notice must be submitted to and confirmed by FDA for review.

f. *Export after refusal (§ 1.283(a)(5).* A refused food may be exported with CBP concurrence and supervision. If a refused food is exported, the prior notice should be cancelled within 5 days of exportation.

g. *No post refusal submission or request for review (§ 1.283(a)(6).* If no prior notice, correction, or request for FDA review is submitted in a timely fashion after an article of food is refused, the food will be dealt with as set forth in CBP regulations relating to general order merchandise. It may only be sold for export or destroyed as agreed to by CBP and FDA.

h. *International mail (§ 1.283(e)).* In the case of food arriving by international mail, if prior notice is inadequate, the article will be held by CBP for 72 hours for FDA inspection and disposition. If the article of food is refused and there is a return address, the parcel may be returned to sender. If there is no return address or the article of food in the parcel appears to present a hazard, FDA may dispose of or destroy it at FDA's expense. If FDA does not respond within 72 hours of the CBP hold, CBP will return the parcel back to the sender or, if there is no return address, may destroy the parcel at FDA's expense.

i. *Food carried by or otherwise accompanying an individual (§ 1.283(b)).* The individual must have a copy of the confirmation when entering the United States. If there is inadequate prior notice, the article will be refused entry and may be held at the port or exported. If arrangements for holding or export cannot be made, the food may be destroyed.

j. *FDA review after refusal (§ 1.283(d)).* After refusal, the submitter, importer, owner, or ultimate consignee may submit a written request asking FDA to review whether the article is subject to the requirements of this subpart under §§ 1.276(b)(5) and 1.277, or whether the prior notice submission is accurate. The interim final rule also sets out procedures and timeframes for this review process.

k. *Prohibition on delivery outside of the port (§ 1.283(f)).* A refused article of food may not be delivered to the importer, owner, or ultimate consignee until FDA has examined the prior notice, determined the adequacy of the prior notice and notified the transmitter and CBP that the article of food covered by the prior notice is no longer refused. When food that has been refused under section 801(m)(1) of the FD&C Act is held at the port or secure facility, it may not be transferred by any person from the port or secure facility until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified CBP

and the transmitter that the article of is food no longer refused.

l. *Relationship to admissibility (§ 1.283(g)).* A determination that an article of food is no longer subject to refusal under section 801(m)(1) of the FD&C Act is different than, and may come before, determinations of admissibility under other provisions of the FD&C Act or other U.S. laws. A determination that an article of food is no longer subject to refusal under section 801(m)(1) of the FD&C Act does not mean that it will be granted admission under other provisions of the FD&C Act or other U.S. laws.

6. What Are the Other Consequences of Failing To Submit Adequate Prior Notice or Otherwise Failing To Comply With This Subpart? (§ 1.284)

In accordance with section 301(ee) of the FD&C Act, the proposed rule (§ 1.278(g)) provided that it is a prohibited act to import or offer for import an article of food without complying with the requirements of section 801(m) of the FD&C Act, or otherwise to violate any requirement under section 801(m). In addition, the proposed rule provided that the United States can bring a civil action in Federal court to enjoin persons who commit prohibited acts and bring a criminal action in Federal court to prosecute persons who commit prohibited acts. In addition, under 21 U.S.C. 335a, FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States.

(Comments) Some comments ask that FDA provide a transition period for implementing the regulation, during which a submitter would not be prosecuted for providing inadequate or incomplete prior notice.

(Response) The requirements of the statute do not allow for this kind of a transition period. FDA will, however, provide guidance on enforcement to its staff containing the agency's policies on injunctions, prosecution, and debarment related to failure to provide timely and accurate prior notice, as well as the agency's policies regarding refusals under section 801(m)(1) of the FD&C Act and holds under section 801(l). FDA intends to include a transition period in this guidance, during which it will emphasize education to achieve compliance. While FDA will nonetheless be authorized to take various types of enforcement action for violations of the prior notice requirements, this planned transition period will allow FDA to focus its resources on the most appropriate circumstances. While this transition period is important, FDA also intends to provide guidance to its staff on enforcing the prior notice requirements after a transition period. These guidance documents will be made available to the public, and FDA will publish a notice of availability in the **Federal Register**.

This enforcement discretion with regard to refusals of foods under 801(m) and 801(l) will not impact FDA's ability to take other actions that may be necessary, such as conducting inspections for food safety and security concerns, determining whether an article of food is subject to refusal under section 801(a) of the FD&C Act at the port of entry, or taking any other action under the FD&C Act. FDA may consider the failure to provide prior notice as a factor in determining whether to examine the product at destination. In addition, it will not impact upon CBP's ability to assess penalties under 19 U.S.C. 1595a(b) or to take enforcement action under any other authority.

(Interim final rule) Section 1.284 of the interim final rule establishes a separate provision to cover the other consequences of failing to submit adequate prior notice or otherwise comply with 21 CFR part 1, subpart I. The interim final rule provides that the failure of a person who imports or offers for import an article of food to submit prior notice is a prohibited act under section 301(ee) of the FD&C Act (21 U.S.C. 331(ee)). The interim final rule also sets out the civil, criminal, and debarment actions that the United States may bring against persons who commit a prohibited act.

K. ''What Happens to Food That Is Imported or Offered for Import From Unregistered Facilities That Are Required To Register Under 21 CFR Part 1, Subpart H?'' (§ 1.285)

As set out in the preamble to the interim final rule on registration of food facilities under section 415 of the FD&C Act, FDA has decided to include in the prior notice interim final rule the provisions that address what happens when imports from unregistered foreign food facilities arrive at the port. FDA decided this course was most appropriate because, in the first instance, we will be using the prior notice review process to ensure that foreign food facilities are registered. Moreover, FDA believes that the procedures for dealing with food from unregistered foreign facilities should be, as they were in the proposed registration rule, identical in most respects to the prior notice procedures, and thus it makes sense to consolidate them in one regulation.

(Comments) Comments on the registration proposed rule are described in the preamble to the interim final registration rule, published elsewhere in this issue of the **Federal Register**.

(Response) Responses to comments on the registration proposed rule are described in the preamble to the interim final registration rule, published elsewhere in this issue of the **Federal Register**.

7. Interim Final Rule (§ 1.285)

FDA revised the proposed rule to provide for more specificity, to clarify the status of food under hold, and to provide a mechanism for FDA review after a hold is imposed.

a. *Failure to register (§ 1.285(a) and (b)).* If an article of food from a foreign manufacturer that is not registered as required under section 415 of the FD&C Act (21 U.S.C. 350d) and 21 CFR part 1, subpart H, is imported or offered for import into the United States, the food is subject to refusal of admission under section 801(m)(1) of the FD&C Act and 21 CFR 1.283(a) for failure to provide adequate prior notice. The failure to provide the correct registration number of any foreign manufacturer if registration is required under section 415 of the FD&C Act and 21 CFR part 1, subpart H, renders the identity of that facility incomplete.

If an article of food from a foreign facility that is not registered as required under section 415 of the FD&C Act and 21 CFR part 1, subpart H, is imported or offered for import, it is subject to a hold within the port of entry for the article unless directed by CBP or FDA under section 801(l) of the FD&C Act unless exported.

b. *Status and movement of held food.* An article of food under hold is considered general order merchandise under section 490(a) of the Tariff Act of 1930, as amended. The food must be moved under appropriate custodial bond. FDA must be notified of the location where the food has been or will be moved within 24 hours of the hold. It must be taken directly to the designated facility, shall not be entered, and shall not be delivered to any importer, owner, or ultimate consignee.

c. *Segregation (§ 1.285(d)).* If a food placed on hold is part of a shipment that contains other articles, the food may be segregated from the rest of the shipment within the port of arrival or where the article is held, if different.

d. *Costs (§ 1.285(e)).* Neither FDA nor CBP will be liable for transportation, storage, or other expenses resulting from a hold.

e. *FDA review after hold (§ 1.285(j)).* After an article of food has been placed

on hold, prior notice submitter, the importer, owner, or ultimate consignee may submit a written request asking FDA to review whether the foreign facility is subject to the requirements of section 415 of the FD&C Act. The interim final rule also sets out procedures and timeframes for this review process.

f. *Export after refusal (§ 1.285(f)).* A food under hold may be exported with CBP concurrence and supervision.

g. *No registration or request for review (§ 1.285(g)).* If no registration number is obtained from FDA or no request for FDA review is submitted in a timely fashion after a food is placed under hold, the food will be dealt with as set forth in CBP regulations relating to general order merchandise. It may only be sold for export or destroyed as agreed to by CBP and FDA.

h. *International mail (§ 1.285(k)).* In the case of food arriving by international mail, if required registration is lacking, the article will be held by CBP for 72 hours for FDA inspection and disposition. If the food is held and there is a return address, the parcel may be returned to sender. If there is no return address or the article of food in the parcel appears to present a hazard, the FDA may dispose of or destroy it, at FDA's expense. If FDA does not respond within 72 hours of the CBP hold, CBP may return the parcel to the sender or, if there is no return address, destroy the parcel at FDA's expense.

i. *Food carried by or otherwise accompanying an individual (§ 1.285(h)).* If placed on hold, the individual may arrange to have the food held at the port or exported. If such arrangements cannot be made, the food may be destroyed.

j. *Post-refusal and post-hold submissions (§ 1.285(i)).* To resolve a refusal if an article of food has been refused under § 1.285(a), the facility must be registered and a registration number obtained from FDA. The prior notice must then be submitted in accordance with § 1.283(c).

To resolve the hold if an article of food is held under § 1.285(b) the foreign facility must be registered and a registration number obtained from FDA. FDA must be notified of the applicable registration number in writing by mail, express courier, fax, or e-mail. The notification must provide the name and contact information for the person providing the registration information. The location for delivering this notification will be listed at *http://www.fda.gov*—see Food Facility Registration. If FDA determines that the food should no longer be held, it will notify the person providing the information and CBP the food is no longer subject to hold under section 801(l).

k. *Prohibition on delivery outside of the port (§ 1.285(l)).* An article of food under hold may not be delivered to the importer, owner, or ultimate consignee or transferred by any person from the port or the secure facility until registration is complete and FDA has notified CBP that the article of food is no longer under hold.

l. *Relationship to other admissibility provisions (§ 1.285(m)).* A determination that an article of food is no longer subject to hold under section 801(l) of the FD&C Act is different than, and may come before, determinations of admissibility under other provisions of the FD&C Act or other U.S. laws. A determination that an article of food is no longer subject to hold under section 801(l) does not mean that it will be granted admission under other provisions of the FD&C Act or other U.S. laws.

IV. Issuance of an Interim Final Rule and Effective Date; Comments

We are issuing this rule as an interim final rule, with an opportunity for public comment. Although we are seeking comment on this interim final rule, it will be in effect on December 12, 2003. Thus, its requirements will be in effect and have the force and effect of law from that date until they are modified by the issuance of a final rule. FDA will, however, provide guidance on enforcement to its staff containing the agency's policies on injunctions, prosecution, and debarment related to failure to provide timely and accurate prior notice, as well as the agency's policies regarding refusals under section 801(m)(1) of the FD&C Act and holds under section 801(l). FDA intends to include a transition period in this guidance, during which it will emphasize education to achieve compliance. While FDA will nonetheless be authorized to take various types of enforcement action for violations of the prior notice requirements, this planned transition period will allow FDA to focus its resources on the most appropriate circumstances.

The comment period on this interim final rule will open today for a period of 75 days. Moreover, to ensure that those that comment on this interim final rule have had the benefit of our 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. In addition, this date will coincide with the issuance of the plan by FDA and CBP relating to timeframes.

FDA invites public comment on this interim final rule. The agency will consider modifications to this interim final rule based on comments made during the comment period. Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) written or electronic comments regarding this interim final rule by [75 days after December 12, 2003.]. Two copies of any comments are to be submitted, except that individuals may submit one copy. Submit one electronic copy. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

As noted, this regulation is effective on December 12, 2003. FDA will address comments received and confirm or amend the interim final rule in a final rule. The agency, however, will not consider any comments that have been previously considered during this rulemaking.

V. Analysis of Economic Impacts

A. Final Regulatory Impact Analysis

FDA has examined the economic implications of this interim final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this interim final rule is a significant regulatory action as defined by Executive Order 12866.

Comments on the economic analysis of the proposed prior notice rule covered several major issues, including: The costs estimated to learn the rule, the costs to coordinate prior notice information, the costs of filing through a broker, and the costs of delayed arrival (including truck time costs and the costs

for lost value of products). We address all comments relevant to the economic analysis in detail as each issue appears in the analysis.

1. Need for Regulation

Section 307 of the Bioterrorism Act of 2002 requires prior notice of all food imported or offered for import into the United States. If FDA fails to issue a final regulation by December 12, 2003, section 307 of the Bioterrorism Act provides for a default minimum period of advance notice that is not fewer than 8 hours and not more than 5 days before an article of food is imported or offered for import into the United States. This regulation is needed to implement the statutory provisions.

2. Interim Final Rule Coverage

Unless excluded, this interim final rule applies to all FDA-regulated food for human and animal consumption that is imported or offered for import into the United States. This includes food that is imported for export, food transshipped through the United States to another country, and food for use in an FTZ. This interim final rule does not apply to food that is imported then exported from the port of arrival without leaving the port; meat, poultry, or egg products that are under the exclusive jurisdiction of USDA; food carried by or otherwise accompanying an individual when entering the United States for personal use. For the purpose of this rule, the definition of food does not include food contact substances (including food packaging), pesticide chemicals, or pesticide chemical residues.

As required by the Bioterrorism Act, the notification must provide the identity of the article, manufacturer, shipper, and grower (if known), the FDA Country of Production, the country from which the article is shipped, and the anticipated port of arrival. In addition, the notification must provide the identity of the person who submits and transmits the prior notice, the importer, the owner, the consignee, the carrier, the CBP entry identifier, anticipated time and date of arrival, anticipated shipment information, and, if the food has been refused admission and required to be held, the location where it is held.

For food shipments arriving in the United States through international mail, notification of the import must be sent before the article is mailed. Only the prior notice information that is relevant to that type of shipment must be submitted for articles of food arriving by international mail. Notification of mail entries will be received only through the FDA PN System Interface. For food carried by or otherwise accompanying an individual when entering the United States that is not for personal use, such as food for sale that is brought into the United States in baggage, prior notice must be submitted through the FDA PN System Interface.

a. *Number of establishments affected.* Using 2001 fiscal year information from OASIS (industry codes 02 through 52, 54, and 70 through 72), FDA has estimated that there are 77,427 importers and consignees who receive imported food shipments. Commenters were concerned that this importer number represented only importers of edible food products, and not such items as food packaging. These commenters concluded that FDA's estimate was too low. OASIS does include all importers of food, for both humans and animals, and food-related items and therefore does not underestimate the number of food importers. Also, because food contact substances, including food packaging, are excluded from interim final rule coverage, our estimate of importers should sufficiently account for food importers that might not have been formally captured by the OASIS data.

Comments also indicated that they wanted an expansion of the persons allowed to submit prior notice. The proposed rule had restricted the submission of prior notice to U.S. importers or U.S. purchasers (or their brokers). For the interim final rule, FDA has authorized the submission of prior notice by any person.

Using information from the OASIS system, FDA has determined that there are approximately 100,000 foreign manufacturers/processors of an article of food. We assume here that foreign manufacturer/processor costs associated with this interim final rule will be spread across the supply chain; we therefore do not directly address the distribution of costs. We think it probable, however, that most of the ongoing costs of this interim final rule will be borne by consumers in the form of higher retail food prices.

i. *New and closing importer establishments.* In addition to the U.S. importers currently operating, in future years some new import businesses will open and some existing import businesses will close. According to the Small Business Administration, in 2001 about 10 percent of all businesses were new and 10 percent of all businesses closed. These new importers will have to become familiar with the FDA prior notice system, and some may need to obtain computer equipment and Internet access to comply with prior notice requirements.

ii. *Baseline.* FDA considers the baseline for this analysis the state of the world before the Bioterrorism Act, and we assume this baseline has zero costs and benefits.

b. *Current state of the world.* The majority of the information that will be required by section 307 of the Bioterrorism Act now is supplied at the time of entry by a customs broker or self-filer, and usually is submitted electronically. Although importers already must notify CBP of entries, the Bioterrorism Act requires notification to FDA before the food shipment reaches the U.S. port of arrival. This requirement will change the current practice of notifying CBP and then subsequently FDA upon arrival (and as long as 15 days past arrival based on the time the consumption entry may be filed with CBP).

OASIS showed that approximately 2.9 million food entry lines were imported via sea and air transportation in fiscal year 2002. Information on food-importing practices indicates that importers bringing food products into the United States by vessel notify CBP and FDA before their arrival. Importers using vessels as their mode of transport for products can notify CBP well in advance of the actual shipping date, but CBP will not certify the entry until 5 days before the vessel is expected to dock at a U.S. port. FDA is notified of the shipment then, through CBP, as early as 5 days before the vessel's arrival at a U.S. port.

Importers bringing food products in by airplane can notify CBP of their intent to import food into the United States no more than 24 hours before the scheduled flight departure time, but cannot certify their cargo manifests with CBP until the airplane has taken off from the airport of the exporting country (''wheels-up''). FDA is notified after ''wheels up'', once the import entry has been filed and certified by CBP. CBP has informed FDA that they receive flight information for 87.6 percent of the flights at the time of ''wheels up.''

OASIS showed that around 2.3 million entry lines of food were imported into the United States via ground transportation in fiscal year 2002. The usual practice today for food brought in by truck or train (products coming directly from Canada or Mexico) is not to notify CBP until arrival. (Filers can certify their entry data up to 24 hours before arrival, but CBP does not give a ''screening response'' to the entry until actual arrival.) Even though these importers likely have the orders and invoices for these products in advance,

they do not currently notify CBP until the arrival of the food or thereafter.

The constraints prior notice places on those wishing to import food into the United States depend on: When the order for the product is placed, the minimum prior notice submission time, and the manufacturing/processing or other location where the product to be imported is held before importing into the United States. A longer prior notice submission time would change more business practices for food operations nearer to the U.S. border than for those farther away from the United States. For example, an 8-hour prior notice minimum timeframe will not significantly affect most food shipments imported from China, because they are likely to come by sea or by air and the length of the journey by either mode of transportation is longer than 8 hours. If the food to be imported is instead located in Mexico or Canada, and the prior notice submission timeframe is 8 hours, there is a greater likelihood that the food is located less than 8 hours driving time from the U.S. border, and transporting some shipments to the U.S. buyer of the product within a specified time would be much more difficult. Whereas there is no expectation that a product ordered from China will arrive in the United States in 8 hours, in the case of some products from Mexico or Canada, normal business practices do include the expectation of a quick or rushed delivery to a U.S. destination; this expectation may not be met for some prescribed minimum prior notice submission timeframes.

Given the standard importing business practices described in the previous paragraphs, and given the restraints that prior notice places on food importers using land transportation (and in some cases air transportation), we classify options for this analysis by minimum prior notice time based on costs for those shipments of imported food that arrive in the United States by ground and, in longer minimum submission time options, by air transportation as well. Therefore, while we include food shipments imported by vessel in the learning, coordinating, and submitting costs of each option considered, we do not calculate a lost product value or waiting time for products arriving by vessel because they are not constrained by the minimum prior notice timeframes considered in any of the options. Highly perishable food products are generally not imported to the United States by sea.

3. Regulatory Options Considered

Comments on the estimates used in the analysis of the proposed rule indicated that FDA should reexamine the following factors: (1) The time it takes to learn about the prior notice rule; (2) the time it takes to coordinate information for prior notice submission; (3) the number of entries expected yearly; (4) the lost value for perishable products; (5) the cost of carrier waiting time; and (6) the costs to current BRASS users. These comments have led FDA to assess additional options, and revise the estimated costs for other options.

We analyzed 12 options for a prior notice regulation. Each option covers all food subject to the interim final rule that is imported to the United States; the mode of transportation for the food is specifically addressed in options where minimum prior notice time constrains importation:

Option 1. Current state of the world, pre-Bioterrorism Act (baseline).

Option 2. Prior notice time of 1 hour (constrained by shipments arriving by land modes of transport); electronic submission of information. This option would require the persons responsible for all food imported or offered for import into the United States to notify FDA of their intent to import articles of food through an importer, customs broker, purchaser, or other agent. This option applies to all imported foods subject to the interim final rule. Submission of prior notice information must be electronic. Any change in prior notice information requires resubmission of corrected or new information.

Option 3. Require all components of option 2, but lengthen the minimum prior notice time to 2 hours (constrained by shipments arriving by land transportation modes).

Option 4. Require all components of option 2, but lengthen the minimum prior notice time to 4 hours (constrained by shipments arriving by air and land modes of transport); electronic submission of information.

Option 5. Require all components of option 2, including a 1-hour minimum prior notice time for vehicles, but lengthen the minimum prior notice time to 4 hours for articles of food arriving by train and by air, and 8 hours for articles of food arriving by vessel; electronic submission of information.

Option 6. Require all components of option 2, but lengthen the minimum prior notice time to 2 hours for articles of food arriving by vehicle, 4 hours for articles of food arriving by train and by air, and 8 hours for articles of food arriving by vessel; electronic submission of information (interim final rule).

Option 7. Require all components of option 4, but allow some prior notice information to be revised 1 hour before arrival at a U.S. port.

Option 8. Require all components of option 2, but lengthen the minimum prior notice time to 8 hours (statutory self-executing provision).

Option 9. Require all components of option 7, but allow some prior notice information to be revised 1 hour before arrival at a U.S. port.

Option 10. Require all components of option 2, but lengthen the prior notice time to 12 noon of the calendar day before crossing the U.S. border.

Option 11. Require all components of option 9, but allow some prior notice information to be revised 1 hour before arrival at a U.S. port.

Option 12. Require all components of option 9, but allow some prior notice information to be revised 2 hours before arrival at a U.S. port (proposed rule).

a. *Option 1: Current state of the world, pre-Bioterrorism Act*. Having no prior notice requirements is option 1 in our analysis. The Bioterrorism Act requires that FDA issue prior notice regulations or default times take effect, so this option is not legally viable. The OMB cost-benefit analysis guidelines recommend discussing statutory requirements that affect the selection of regulatory approaches. These guidelines also recommend analyzing the opportunity cost of legal constraints that prevent the selection of the regulatory action that best satisfies the philosophy and principles of Executive Order 12866. This option will serve as the baseline against which other options will be measured for assessing costs and benefits.

b. *Option 2: Minimum prior notice timeframe of 1 hour; electronic submission of information; any change in information requires resubmission*—i. *Costs*—(1) *Learning costs*. The party responsible for submitting prior notice to FDA will incur administrative and notification costs to comply with this regulation. The responsible party likely will become aware of the prior notice requirement through normal business activities: reading the trade press, reading industry news, FDA outreach, trade outreach, or conversations with other business operators who also must comply with prior notice. Once the submitter of the information becomes aware of the regulation, he or she will need to learn the requirements of the regulation, which will require finding a copy of the prior notice requirements and reading and understanding them.

In response to comments received, FDA has re-estimated the costs of learning about the prior notice regulation. Comments said that the FDA underestimated the learning costs in the

proposed rule, because of the large change in business practices. According to the comments, the importer, depending upon its size, will have at least two trained filers for CBP and FDA-related entries. Commenters also stated that it is quite likely that an entire brokerage staff, including supervisors, will need to understand the FDA prior notice system.

Some comments suggested that the estimated 1 and 2 hour learning time for the rule would in fact be an all day training event. Comments recalled having a daylong seminar to learn about OASIS when it was introduced. In response to the information these comments submitted, in this final analysis, FDA assumes that one manager and two subordinates from each importing business will attend an 8-hour training session on the prior notice regulation.

FDA used wage rates from the Bureau of Labor Statistics National Compensation Survey (Ref. 3), doubled to include overhead costs, to estimate the cost of the time to learn the prior notice requirement. For an administrative worker, the cost per hour is $25.10: for a manager, $56.74. FDA assumes that two administrative workers and one manager will be trained for 8 hours each on the prior notice requirements. As shown in table 1B of this document, total costs of this learning activity are about $66 million for the first year.

Given the 10 percent turnover in business reported by the Small Business Administration, FDA expects 10 percent of the total search costs to be incurred in each subsequent year after prior notice is in effect as new firms enter the industry. This cost is also shown in table 1B of this document.

TABLE 1B.—COST TO LEARN ABOUT THE PRIOR NOTICE REQUIREMENTS

	Manager cost	Administrative worker cost (two workers)
Number of firms	77,427	77,427
Wage rate per hour for manager and administrator Worker (including overhead)	$56.74	$25.10
1-day learning seminar	*8	*8
First year one time learning costs	$35,145,664	$31,094,684
Total first year learning costs		$66,240,000
Annual learning costs for new entrants		$6,624,000

*Hours.

(2) *Computer acquisition costs.* Both the Produce Marketing Association (PMA) and the National Food Processors Association (NFPA) submitted comments to FDA before FDA published the proposed rule that indicated that about 96 percent of the food industry has readily available Internet access. The American Feed Industry Association, which represents animal food manufacturers, also agreed with NFPA's estimate that 96 percent of the food industry has electronic transmitting capacity.

Since all prior notices must be submitted electronically, we estimate that there are 3,097 responsible parties without Internet access (4 percent of the 77,427 importers). These persons will have to purchase a computer and gain Internet access to transmit the information via a prior notice screen. This one-time computer cost and a recurring Internet access cost for these facilities are shown in table 2 of this document.

Again, given a 10 percent turnover rate for businesses in the import industry, we expect there to be new businesses in the future that may need to purchase electronic transmitting capabilities. With the passage of time, persons will likely purchase this computer equipment in the ordinary course of business, not solely to comply with prior notice. We include an estimate of this cost for new entrants to ensure that we do not underestimate the costs of electronic transmitting capacity.

A few comments indicated that they did not agree with the estimated cost for Internet access; they stated that the cost would be higher. Since FDA will be receiving most prior notices through ABI/ACS, which is an electronic submission system, and since the FDA PN System Interface will be used for mail and other non-ABI/ACS transmissions and is Web-based, FDA does not agree that Internet access rates should be estimated at a higher rate.

TABLE 2.—FACILITIES AND RESPONSIBLE PARTIES WITHOUT INITIAL INTERNET ACCESS

Number of facilities	3,097
Computer equipment cost per facility	$2,000
Annual cost of Internet access ($20 per month × 12)	$240
Search costs for equipment and access ($25.10 × 8 hours)	$201
Total First Year One Time Cost of Electronic Transmitting Capacity	$7,559,777
Annual one time cost of electronic transmitting capacity for firms entering industry in subsequent years	$755,978

(3) *Annual costs to submit prior notice entry lines.* FDA used OASIS information to determine that about 5.2 million entry lines of food were imported into the United States in fiscal year 2002, including formal mail and express carrier (*e.g.*, Federal Express) entries. An ''entry line'' is an FDA term used by OASIS, which refers to a line on an invoice that reflects a certain article specific to manufacturer/processor or packaging: *e.g.*, 100 cases containing 48, 6-oz cans of tuna.

Comments on the proposed rule were concerned that the FDA fiscal year 2001 OASIS entry line estimate (4.7 million lines) was too low. Some comments said that not all the food categories that will need to submit prior notice were included in the count; other comments said that the prior notice requirement would, because of the information required, increase the number of lines per entry by a significant amount.

According to FDA OASIS codes, all formal entries for human and animal food were included in the OASIS line count. This count included all food contact substances, including the bulk chemicals and polymers used to

produce food-packaging material. The OASIS line count also included the codes for beer and wine, but not distilled spirits (*e.g.*, bourbon, whiskey, gin, etc.).

The OASIS entry line totals do not include informal entries for mail or express carrier shipments, or for food brought into the United States as personal baggage, not for personal use, but intended for sale or other distribution use. Persons bringing food into the United States by these means, however, are required to submit prior notice to the FDA. Therefore, even though food contact substances, including food packaging, pesticide chemicals, and pesticide chemical residues are no longer subject to the interim final rule, we do not reduce the estimate of imported food entry lines in order to capture informal food lines and other imported food items that are not currently included in the OASIS line estimates. Rather than adjust the total line estimate downward to account for the exclusion of food packaging, pesticide chemicals, and pesticide chemical residues we adjust the estimate of lines upwards to capture food lines not in OASIS. The upward adjustment should be regarded as net of food contact substances and food packaging.

For the prior notice interim final rule, then, FDA has re-estimated the number of entry lines expected to be filed yearly for prior notice. The FDA PN System Interface and ABI/ACS are estimated to handle up to 25,000 prior notice submissions on a usual business day, for a projected yearly total of 6.5 million submissions. (FDA's prior notice system will operate 24 hours a day, 7 days a week; however, since most shipments enter the United States during a normal business work week, Monday through Friday, we estimate the projected prior notice line total as 25,000 daily submissions $\times$ 260 days = 6.5 million lines per year.) This updated total includes estimates for informal and other entries not currently captured by OASIS.

According to OASIS data, the average import entry contains 2.6 lines, which means that there are typically more than two different articles of food per import entry: *e.g.*, 100 cases of canned tuna and 50 cases of canned peaches in the same shipment. A prior notice must be filed for each of the lines in an entry.

FDA estimates that it will take, on average, 1 hour to submit an import entry of 2.6 lines. This time is an average; some entries will take longer than 1 hour to complete and other entries will take less than 1 hour to complete.

This 1-hour estimate includes 45 minutes of an administrative worker's time to gather information to initially complete the prior notice, and then 15 minutes of a manager's time to verify that the information is correct. Assuming that there is an average of 2.6 lines per entry, and each line requires a prior notice, then each line actually takes about 23 minutes to complete.

Comments on the prior notice proposed rule agreed with the FDA estimation for time to fill out the notice. Comments also agreed that once prior notice submitters were familiar with the information required, an hour was a reasonable time estimate. Some comments, however, suggested that the time to make amendments and updates to the prior notice had not been included or was not sufficient in the proposed rule. FDA believes the 1 hour estimate is appropriate for the following reasons: (1) The interim final rule does not contain update or amendment provisions as the reduced time for submitting a prior notice negated the need for them; (2) CBP Form 3461, (the entry document upon which information is provided to CBP) carries an estimated burden of 15.5 minutes and FDA Importer Entry Notice (as required by section 801 of the FD&C Act) carries an estimated burden of 8.5 minutes (Paperwork Reduction Act estimates); and (3) many comments agree with the hour estimate for submitting prior notice (23 minutes per line).

Comments were also concerned that FDA had not included costs to have a licensed customs broker file prior notice submissions in the costs estimated for the proposed rule. FDA specifically made no assumptions in its analysis of the proposed rule about who would file the prior notice. Our estimate covered anyone who was authorized to file a prior notice based on the anticipated number of entry lines. The analysis implicitly assumed that if an importer, owner, or consignee hired a customs broker to submit their prior notices, the broker would do so at the marginal cost. In the competitive market for broker services, this assumption is reasonable.

However, FDA prior notice may now be submitted through ABI/ACS for most importations, so the burden of prior notice submission will most likely be on the customs brokers that normally file with CBP. Some comments said that the current customs broker cost to file an entry with CBP is $110, with the additional filing of prior notice increasing these costs by up to 70 percent. Other comments also indicated that the additional costs to file prior notice would be between $50 or $100 or more for an entry.

Based on comments and FDA's own research on the broker costs, FDA agrees that the average costs to submit prior notice will be higher than the $33 per entry estimated in the proposed rule. For this interim final rule, FDA used information provided by commenters to estimate $75 as the cost to file prior notice. FDA believes that using a midrange estimate is appropriate for this cost since filing prior notice through ABI/ACS should efficiently combine transactions costs for brokers submitting information to both CBP and FDA.

Using the OASIS data indicating that the average imported entry contains 2.6 lines, we can then divide the expected yearly 6.5 million total lines by 2.6, which results in 2.5 million expected import entries. Table 3 of this document shows that the annual cost of prior notice submissions based on 2.5 million entries will be about $187.5 million.

TABLE 3.—COST TO FILL OUT PRIOR NOTICE SCREENS BY IMPORT ENTRY

[Must Be Electronic]

Broker cost per entry to submit prior notice	$75
OASIS entry total based on 6.5 million lines	2,500,000
Total Annual Costs (of all prior notice screens based on 2.6 lines per entry, including updates and amendments to the information)	$187,500,000

(4) *Information coordination costs.* As previously stated, FDA received numerous comments on the time it takes to file a prior notice for each line, with some comments agreeing that an entry will take an hour to complete once firms learn how to submit the information. However, comments were concerned that the preparation cost to coordinate the information needed for each prior notice had not been calculated.

In particular, comments said that firms will need to teach their suppliers, manufacturers/processors, customers, drivers, warehouses, growers, carriers, and shippers about the prior notice requirements regardless of whether each of the parties has filing responsibilities. FDA agrees. This new collection will necessitate some additional coordination of information among the parties involved in importing the article of food into the United States.

FDA assumes it takes about 2 business days (16 hours) for an administrative employee of the prior notice-submitting firm to coordinate with others to set up the new business practices required to receive the information needed for prior notice. We assume this set-up time will be sufficient to coordinate information for existing importing accounts. Table 4 of this document reports the costs of this information gathering and coordinating activity.

Because we expect some importing firms to enter and leave the industry every year, so do we expect importing firms to experience a turnover rate for their import accounts. FDA assumes that the turnover rate on these types of accounts is similar to the entry and exit rate of firms. We therefore assume that 10 percent of the firms' accounts each year are new accounts for which prior notice coordination of information is needed. This cost is also presented in table 4 of this document.

TABLE 4.—INFORMATION GATHERING AND COORDINATION FOR PRIOR NOTICE

Number of firms submitting notices	77,427
Administrative worker wage rate (doubled to include overhead)	$25.10
Time to coordinate existing accounts	16 hours
First year cost of coordination of information on current accounts	$31,094,683
Annual cost of coordination of information on new accounts	$3,109,468

ii. *FDA costs. Information Technology.* We assume that FDA's information technology (IT) costs for this option and each option hereafter are the costs of interfacing with ABI/ACS to receive prior notice through OASIS for most FDA-regulated food subject to this interim final rule. FDA is developing an FDA PN System Interface to receive prior notice information for import entries that cannot be accommodated through ABI/ACS, mainly mail and baggage entries, and prior notices for food refused under section 801(m) of the FD&C Act.

FDA has allocated $12.5 million for the development of the FDA prior notice system for fiscal year 2003. This total is broken down into $7,400,000 for infrastructure design, procurement, setup, operations, and maintenance of computer system hardware and system and database software and licensing, plus $5,100,000 for contractor services for the design, development, testing, and implementation of the FDA PN System Interface and the extensive enhancements required by OASIS to support prior notice. These costs are summarized in table 5 of this document. Also included in table 5 are the costs CBP has incurred to accommodate prior notice. CBP costs include modifying ABI/ACS, training, and outreach.

In the next few years, CBP plans to have its new system, ACE (Automated Commercial Environment), operational. The ACE system will replace the current ABI/ACS as well as combine other CBP entry functions and transactions. Prior Notice submission will be compatible with ACE. It is quite likely that importers will benefit from the enhanced functions of the new ACE system.

TABLE 5.—FDA PRIOR NOTICE SYSTEM COSTS

Infrastructure design and implementation	$7,400,000
Contractor services	$5,100,000
FDA system interface costs	$12,500,000
CBP ABI/ACS system modification costs	$500,000
Total prior notice system costs	$13,000,000

Human Resources. The implementation of prior notice does not specifically call for the hiring of additional FDA border or inspectional staff. However, even before the passage of the Bioterrorism Act, FDA hired 300 additional consumer safety officers to help with the inspection of articles of food. And with the implementation of the prior notice interim final rule, it is quite likely that FDA will need to concentrate even more of its human resources on enforcement activities. Currently, FDA is working on a memorandum of understanding with CBP that would allow FDA to commission CBP's help as needed for inspections and enforcement activities related to the prior notice rule.

Destruction of Foods. FDA will be responsible for the destruction of articles of food that come into the United States via international mail and whose prior notices are considered inadequate or refused. FDA does not have an estimate of these destruction costs. We expect these destruction costs to be minimal, however, based on the fact that these will be personal food shipments and that there were relatively few formal mail entries (38,000) for articles of food in the OASIS data for fiscal year 2002.

iii. *Current operating practices affected*—(1) *Food importers currently using BRASS.* In response to comments, FDA and CBP have agreed to allow prior notice information to be filed through ABI/ACS for most articles of food. By allowing prior notice to be submitted through ABI/ACS, FDA has eliminated the duplicative information collection that would have resulted from the proposed stand-alone FDA Web-based system. While combining agency efforts has eliminated duplicative submission of information for many food importers, the combined system will increase submission requirements for those food importers who use BRASS.

BRASS is a CBP program that allows expedited arrival processing for high-volume, repetitive shipments that have been judged by CBP to be low risk. BRASS processing is not compatible with the electronic submission of prior notice information because entry information for BRASS shipments is not filed until entry summary, long after the food has crossed the border. Therefore, those food importers who currently use BRASS and its expedited arrival process

will no longer be able to do so once prior notice submission is required.

Currently, importers who qualify to use BRASS show paperwork at the border. These importers then only have to submit an entry summary after arrival (up to 10 business days later). In contrast, non-BRASS importers must submit an entry and a later entry summary. Since prior notice is required before arrival, importers of FDA-regulated products will no longer be able to submit information to CBP using BRASS; they must submit both the entry information (which includes prior notice requirements) and then a later entry summary to CBP.

Data from CBP show that about 630,000 entry lines were submitted through BRASS for FDA-regulated products, including foods, in fiscal year 2002. We use this information to estimate the increased submission costs for these importers once they are no longer able to use BRASS to expedite entry of their products. Increased submission costs come in the form of having to make two submissions through CBP instead of the one summary entry after arrival in the United States. We calculated the cost of the one additional transmission of information, now required due to the prior notice information that is needed before arrival, in table 3 of this document. By using these same costs per import entry ($75), we can account for the extra costs for BRASS users. Table 6 shows that the extra submission of information by importers no longer able to use BRASS will be about $18 million per year.

Being able to use BRASS not only allows the condensing of the submission of required import information, but also allows the importer's carrier or transporter to spend less time crossing the border. BRASS users must stop at the border only long enough for a CBP official to ''wand'' the barcode information pertaining to their shipments and assign a CBP entry number to the shipment. Once food importers are no longer able to use BRASS, however, they must not only submit more information on the shipment than was previously required at arrival, but they also will no longer be able to cross the border as quickly. Because former BRASS entries will no longer be able to get through the border checkpoints as easily as they used to, we include here the cost of an extra half-hour of truck time per BRASS entry.

Using one comment's estimate of the cost of truck time, $250 per hour, we can calculate the yearly additional cost of wait time at the border for food importers who were former BRASS users. Table 6 of this document shows the cost of the additional truck time for BRASS users to be about $30 million annually.

TABLE 6.—ADDITIONAL COSTS FOR BRASS USERS

Additional Submission Costs:	
Total cost per import entry	$75
FY 2002 BRASS line total for FDA-regulated products	630,000
BRASS yearly entry total (2.6 lines per entry)	242,308
Additional annual costs of submissions for BRASS users	$18,173,100
Additional border wait time:	
Cost per half hour	$125
BRASS yearly entry total (2.6 lines per entry)	242,308
Additional annual border wait costs for former BRASS users	$30,288,500
Total annual additional food importing costs for BRASS users	$48,462,000

(2) *Loss of value for highly perishable products.* A 1-hour minimum prior notice requirement would be less likely to change current food importing practices than would a longer minimum time requirement for prior notice submission. Pre-proposal comments received from Canadian and Mexican perishable seafood processors and produce growers indicated they would prefer the minimum prior notice time to be set at 4 hours or less. The seafood processors and produce growers asked for the shorter minimum prior notice time because the source of these food products often is close to the U.S. border, and the products are perishable.

For example, Canadian fruit and vegetable producers said that such products as ''leafy vegetables, green onions, cabbage, cauliflower, new potatoes, sweet cherries, and berries are harvested within hours of arrival at the U.S. border and cannot withstand delays, especially during the extreme heat of summer and early fall when the products are in season.'' As another example, a produce company from Mexico commented that growers typically harvest produce in the morning, pack and cool the fruit in the afternoon, and then start the drive to the U.S. border during evening hours. Some, but not all, of the border ports are open in the evenings during the height of the Mexican produce season. If notice to FDA is required by 12 noon the calendar day before arrival at the border, as FDA proposed, it is unlikely that these produce products could be harvested in the morning in Mexico and then enter the United States by the same evening, because not all the information would be prepared in time to meet the submission deadline in the proposed rule, which was 12 noon the day before arrival in the United States.

Canadian seafood industry comments said that 90 percent of all fresh seafood sales are same day orders that are processed, sold, and shipped in the same day. They also commented that if buyers were required to submit seafood orders early (by 12 noon on the calendar day before arrival) because of prior notice requirements, they would tend to order short, rather than risk being left with a decomposing inventory. Comments also said that many perishable seafood contracts with shippers call for a variety of species to be delivered depending on what could be harvested that day; thus, species and the specific amount of fish in an import entry will be uncertain for longer prior notice timeframes.

From these comments, it is clear that at least in some industries, when the order for the shipment is received, when the prior notice is submitted, when the shipment is loaded, and the loaded shipment's location relative to a U.S. border all play roles in determining how the requirement for prior notice will affect current business operating practices.

FDA expects that there will be some imported shipments by vehicle for which the order was received just before the shipping time, some shipments for which the composition of the product has changed since the time when the prior notice was submitted, and some shipments for which other changes to the information on the prior notice must be made. Importers whose shipments fall into this ''changed'' category must

resubmit the prior notice or risk that their products will be refused admission into the United States and held if the notice is deemed inadequate.

FDA does not have information on the number of shipments that, under this option, would need to submit or resubmit prior notice information due to a late order or a change in the information provided on the original notice. We know that changes will occur for some percentage of all prior notices; comments did not indicate the percentage of notices that would have to be resubmitted.

Depending on the U.S. entry point, however, comments FDA received before publishing the proposal indicated that between 40 and 100 percent of shipments from Canada and Mexico are loaded less than 4 hours before arrival. Therefore FDA believes that it is this subset of importers, importing perishable products not far from the U.S. border, that will be most concerned with the prior notice submission timeframe. Based on this information, FDA bases its prior notice resubmission percentage rates and prior notice arrival time on the 4 hours required under option 4.

Option 4 is to have prior notice be required 4 hours before arrival, with the resubmission rate at 20 percent; one-half the comments' lower bound estimate of 40 percent. By using option 4 as the base option, we can then estimate resubmission rates for prior notice arrival times that are less than 4 hours. We assume, then, that for each hour reduction in required prior notice arrival time, the resubmission rate for importers of perishable produce and seafood (based on their location to the border and order placement) is cut in half. Thus, for a 3 hour prior notice timeframe, we assume the resubmission rate for notices will be 10 percent, for a 2 hour prior notice timeframe the resubmission rate for notices will be 5 percent, and for a 1 hour prior notice timeframe (this option) the resubmission rate for notices is 2.5 percent.

(3) *Loss of value for perishables.* The following paragraphs and tables outline how FDA calculated a loss in product value to account for the time that perishable produce and seafood from Canada and Mexico might have to wait to cross the border due to prior notice resubmission. This wait occurs if prior notice needs to be submitted or canceled and resubmitted due to shipment changes when the shipment is closer to the border than the 1 hour required; the transporter of the shipment must wait for the minimum prior notice time to elapse before crossing the border or risk being denied entry.

Comments from Canadian and Mexican perishable seafood and produce producers indicated that the mode of transport that causes the most concern for delays are shipments arriving in the United States by truck. Some comments, however, indicated that some perishable products might arrive via air transportation, and that air flights from Latin America and even potentially some countries in Europe could take less than 8 hours and in some cases less than 4 hours.

FDA has examined flight times to the countries suggested by comments. FDA does not believe that articles of food arriving in the United States on flights from South America or from Europe will be delayed by the prior notice requirement. However, FDA does believe that perishable products being flown in from Central America might experience some delay, and therefore lost product value, as a result of prior notice. We will begin to include the products from these countries in option 4, minimum prior notice time of 4 hours.

Information on perishable produce and seafood from Canada and Mexico used in this analysis represents yearly shipments of each product regardless of mode of transport. We assume most of these shipments arrive in the United States by truck or other ground transportation, given the proximity of Mexican and Canadian processors to the border, but it is possible that some shipments by air and sea are included in this count. These yearly all-inclusive totals should therefore be sufficient to account for any delay in time that importers of food shipments from Canada and Mexico may experience.

Table 7 of this document shows the volume of fresh, perishable produce imported into the United States from Mexico for the calendar year 2001 (Ref. 4). Produce was included in the count if it was considered 'highly or very highly perishable' (Ref. 5) and if the produce was not regulated under section 8e of the Agricultural Marketing Agreement Act of 1937 (AMAA). Products currently regulated by the AMAA (including, tomatoes, avocadoes, oranges, dates, hazelnuts, grapefruit, table grapes, kiwi fruit, limes, most olives, onions, Irish potatoes, plums, prunes, raisins, and walnuts), are required to notify USDA at least 1 day before arrival to make arrangements for inspection and certification of the product they are importing. These products therefore are not included in the count because they already have business practices in place that would accommodate the prior notice requirements provided in this option.

Several comments wanted products under the AMAA and products that are somewhat less perishable to be included in the perishability loss of value calculation. FDA has decided not to include these products in the lost value calculation; products under the AMAA already have operating practices in place to ensure they provide notice before arrival and those products that are less than highly perishable, such as potatoes, are not going to lose value because of the prior notice times presented in these options. FDA will expand its analysis to include the cost of additional truck time for longer submission times for all products being imported into the United States. FDA agrees with the comments that stated that the cost of truck time from a delay at the border is a real cost regardless of a product's perishability.

Multiplying the volume of Mexican produce that was imported into the United States in 2001 by the current U.S. border prices per pound (Ref. 6) for these products gives an estimate of wholesale revenue. Then we convert the wholesale revenue to retail revenue using the retail price mark-up on produce in the United States. We will increase the wholesale revenue by 100 percent in these estimates to represent a reasonable retail price mark-up rate across produce commodities in the United States (Ref. 7). Some comments did not agree with FDA's calculation of the spread between wholesale and retail prices for perishable products. We reexamine our choice of the 100 percent mark-up rate in a sensitivity analysis presented later in the costs section.

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Table 7.--Highly Perishable Produce Imported From Mexico

Perishable Produce From Mexico	Total Volume for 2001 (100,000 lb units)	Current Wholesale Price ($ per lb) (Sept. 2002)	Total Revenues Wholesale ($)
Cucumbers	6,491	0.29	188,239,000
Peppers (all varieties)	6,088	0.53	322,664,000
Squash	4,158	0.71	295,218,000
Mangoes	3,461	0.57	197,277,000
Papaya	1,587	0.45	71,415,000
Broccoli	1,138	0.65	73,970,000
Eggplant	887	0.40	35,480,000
Asparagus	856	1.29	110,424,000
Sweet corn	828	0.26	21,528,000
Strawberries	676	0.96	64,896,000
Beans	559	0.58	32,422,000
Radishes	516	0.31	15,996,000
Fruits-other	426	2.04	86,904,000
Vegetables-other	365	2.80	102,200,000
Greens	298	0.48	14,304,000
Spinach	197	1.375	27,087,500
Green peas	129	2.20	28,380,000
Okra	112	0.80	8,960,000
Berries-(miscellaneous)	78	1.67	13,026,000
Raspberries	32	4.40	14,080,000
Artichokes	23	1.50	3,450,000
Mushrooms	7	1.60	1,120,000
Endive	4	0.37	148,000
Escarole	2	0.37	74,000
Wholesale Value			$1,729,262,500
Retail Value			$3,458,525,000

We repeat the exercise outlined above in table 7 of this document for Canada, as shown in table 8 of this document. For these calculations we assume that Canadian produce growers use business practices that are similar to those used by Mexican growers; FDA did not receive any comments to the contrary. As with the Mexican produce, only Canadian produce that is highly or very highly perishable and did not fall under the purview of the AMAA is included in table 8 of this document.

Table 8.--Highly Perishable Produce Imported From Canada

Perishable Produce From Canada	Total Volume for 2001 (100,000 lb units)	Current Wholesale Price ($ per lb) (Sept. 2002)	Total Revenues Wholesale ($)
Peppers	753	0.30	22,590,000
Cucumbers	627	0.145	9,091,500
Blueberries	401	1.42	56,942,000
Mushrooms	373	1.55	57,815,000
Lettuce-other	243	0.50	12,150,000
Raspberries	89	2.78	24,742,000
Broccoli	88	0.72	6,336,000
Cherries	37	1.30	4,810,000
Sweet corn	36	0.22	792,000
Squash	27	0.17	459,000
Spinach	24	1.30	3,120,000
Radishes	11	0.50	550,000
Endive	9	0.17	153,000
Beans	7	0.50	350,000
Strawberries	5	0.575	287,500
Pears	4	0.39	156,000
Green peas	3	1.60	480,000
Greens	2	0.30	60,000
Eggplant	1	0.29	29,000
Wholesale Value			$200,913,000
Retail Value			$401,826,000

Assuming that perishable produce has an average life span of 7 days, we estimate the value of the time lost (1 hour) for 2.5 percent of the imports waiting to cross the border as a less than 1 percent loss in the product's value (1 hour out of 168 hours). Applying this 0.6 percent loss in value to 2.5 percent of the total retail revenue of imported Mexican fresh produce results in approximately a $519,000 loss in produce value. We calculate that same 0.6 percent loss in product value for 2.5 percent of the Canadian imported perishable produce. This loss in product value due to the 1-hour wait time totals approximately $60,000.

We used information from the annual imported seafood statistics published by the National Marine Fisheries Service (Ref. 8) to estimate the weight and wholesale value in dollars of all perishable seafood products imported from Mexico and Canada. As we did for perishable produce, we mark-up the wholesale price of the perishable seafood by 100 percent (Ref. 9) to represent the retail value of the products. Table 9 of this document shows the value of perishable seafood imports from Mexico; table 10 of this document shows the value of perishable seafood imports from Canada.

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Table 9.--Perishable Seafood Imported From Mexico

2001 Perishable Mexican Seafood Products	Pounds	Dollars
Atka mackerel, fresh	1,995	2,200
Bass, fresh	1,362	2,218
Clam live, fresh	245,498	274,942
Crab live, fresh	405,621	489,856
Crabmeat, fresh	287,531	1,540,130
Flatfish flounder, fresh	1,518	2,199
Flatfish fillet, fresh	1,705	3,100
Flatfish, fresh	678,768	781,883
Ground fish cod, fresh	4,000	2,400
Grouper, fresh	4,056,054	7,399,434
Lobster, live	8,584	50,474
Rock lobster live, fresh	794,224	5,859,260
Mackerel, fresh	147,334	127,873
Marine fish fillet, fresh	2,120,250	7,395,902
Marine fish, fresh	5,448,771	6,681,485
Marine fish scaled, fresh	162,105	125,346
Mollusks live, fresh	2,147	15,272
Octopus live, fresh	31,680	24,214
Oysters live, fresh	39,930	25,040
Salmon Atlantic fillet farmed, fresh	405	2,552
Sardine, sardinella, brisling, sprat, fresh	71,163	7,591
Scallops live, fresh	472,384	1,418,302
Sea urchin live, fresh	10,501	67,331
Sea urchin roe, fresh	464,946	4,641,659
Shark, fresh	1,500,877	711,349
Shrimp, shell-on, fresh	452,714	861,897
Snapper, fresh	5,835,775	9,254,300
Squid live, fresh	88,042	39,952
Swordfish, fresh	1,615,546	3,759,096
Trout, fresh	82,958	131,353
Rainbow trout farmed, fresh	80,384	161,526
Bigeye tuna, fresh	9,819	12,200
Bluefin tuna, fresh	82,471	332,250
Tuna, fresh	78,747	155,069
Yellowfin tuna, fresh	2,012,848	3,771,488
Whitefish fillet, fresh	3,590	7,560
Total Wholesale Value	27,302,246	56,138,703
Total Retail Value		$112,277,406

Table 10.--Perishable Seafood Imported From Canada

2001 Perishable Canadian Seafood Products	Pounds	Dollars
Bass, fresh	727,830	740,152
Caviar	20,189	272,770
Clam geoduck live, fresh	155,927	1,097,902
Clam live, fresh	9,144,304	22,064,683
Crab live, fresh	9,479,765	24,066,021
Crabmeat, fresh	27,601	80,431
Crustaceans live, fresh	148,925	574,989
Fish liver and roe, fresh	51,154	229,569
Flatfish flounder fillet, fresh	750,468	1,238,031
Flatfish flounder, fresh	6,264,346	4,367,780
Flatfish halibut Atlantic, fresh	1,948,791	7,542,598
Flatfish halibut Pacific, fresh	12,553,266	39,850,556
Flatfish fillet, fresh	853,224	3,536,120
Flatfish, fresh	1,693,516	796,383
Flatfish sole fillet, fresh	1,099,430	2,968,610
Flatfish sole, fresh	1,062,030	1,096,079
Flatfish turbot Greenland fillet, fresh	700,456	2,069,006
Flatfish turbot Greenland, fresh	862,211	3,146,300
Freshwater fish fillet, fresh	2,824,811	4,970,127
Freshwater fish, fresh	549,956	1,008,302
Groundfish cod Atlantic fillet, fresh	1,646,363	4,489,788
Groundfish cod Atlantic, fresh	4,904,368	5,199,471
Groundfish cod fillet, fresh	107,994	288,644
Groundfish cod, fresh	239,987	249,991
Groundfish cusk, fresh	8,281	22,060
Groundfish cusk, pollock fillet, fresh	218,854	362,293
Groundfish haddock fillet, fresh	708,261	2,109,607
Groundfish haddock, fresh	17,391,202	19,469,582
Groundfish hake fillet, fresh	160,972	93,941
Groundfish hake, fresh	14,070,217	9,182,974
Groundfish ocean perch fillet, fresh	5,415,106	10,029,520
Groundfish ocean perch, fresh	898,964	518,431
Groundfish pollock Atlantic, fresh	2,362,637	1,595,615
Groundfish pollock, fresh	161,121	130,308
Herring, fresh	4,009,469	671,338
Lingcod, fresh	612,093	812,597
Lobster, fresh	7,707	60,030
Lobster, live	49,200,925	244,567,173
Rock lobster live, fresh	196,858	1,133,246
Mackerel, fresh	943,155	595,937

Table 10.--Perishable Seafood Imported From Canada

2001 Perishable Canadian Seafood Products	Pounds	Dollars
Marine fish fillet, fresh	10,272,946	24,235,390
Marine fish, fresh	9,084,029	6,610,870
Mollusks live, fresh	809,461	907,048
Monkfish, fresh	89,861	154,267
Mussels live, fresh farmed	18,545,254	13,693,263
Mussels live, fresh wild	98,842	104,273
Oysters live, fresh farmed	2,918,098	4,378,548
Oysters live, fresh wild	579,011	1,236,868
Perch fillet, fresh	529,366	2,079,677
Perch, fresh	337,273	727,284
Pickerel fillet, fresh	850,256	3,715,248
Pickerel, fresh	1,682,743	3,500,552
Pike, fresh	214,390	395,706
Pike perch, yellow pike, fresh	125,114	197,396
Sablefish, fresh	21,648	48,845
Salmon Atlantic fillet, fresh farmed	28,972,418	97,270,694
Salmon Atlantic fillet, fresh wild	404,012	1,281,582
Atlantic Salmon, fresh farmed	107,101,696	248,809,617
Atlantic Salmon, fresh wild	68,732	84,035
Chinook Salmon, fresh farmed	5,752,197	10,614,163
Chinook Salmon, fresh wild	225,509	530,368
Salmon chum, fresh	1,651,221	1,133,029
Salmon coho, fresh farmed	1,382,572	1,963,499
Salmon coho, fresh wild	183,427	270,138
Salmon fillet, fresh	1,640,485	4,361,707
Salmon, fresh	2,820,957	5,430,272
Pink Salmon, fresh	79,981	60,403
Sockeye salmon, fresh	265,505	457,427
Salmonidae, fresh	57,787	149,760
Scallops live, fresh	6,955,476	31,688,064
Sea urchin live, fresh	5,053,710	4,367,434
Sea urchin roe, fresh	11,414	94,706
Dogfish shark, fresh	3,300,398	1,003,294
Shark, fresh	223,788	206,838
Shrimp peeled, fresh	5,401	27,934
Shrimp shell-on, fresh	479,483	1,478,634
Smelts, fresh	509,586	606,463
Snail live, fresh	46,174	121,239
Snapper, fresh	37,316	94,366
Swordfish, fresh	1,809,654	6,488,992

Table 10.--Perishable Seafood Imported From Canada

2001 Perishable Canadian Seafood Products	Pounds	Dollars
Trout, fresh	1,574,672	2,891,806
Rainbow trout, fresh farmed	361,121	608,347
Albacore tuna, fresh	25,859	70,076
Bigeye tuna, fresh	426,547	1,448,778
Bluefin tuna, fresh	288,361	2,464,619
Tuna, fresh	13,429	50,299
Yellowfin tuna, fresh	205,812	666,809
Whitefish fillet, fresh	988,816	1,864,542
Whitefish, fresh	8,224,484	11,262,979
Yellow perch fillet, fresh	1,174,798	6,401,844
Total Wholesale Value	382,663,829	931,608,947
Total Retail Value		$1,863,217,894

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We used the same logic for seafood as we did for produce to account for the possibility of having to resubmit prior notice: A change in the type of seafood in the shipment made after the original notice was submitted, less than 1 hour before scheduled arrival, would lead to a reduction in value. We use the reduction in the value of perishable imported seafood to account for the cost of a wait at the border while prior notice is resubmitted. Then, assuming that perishable seafood will keep for 2 days in a consumer's refrigerator (Ref. 10), we find that a 1-hour wait caused by the prior notice requirement for 2.5 percent of the products would result in a 2.1 percent loss in that seafood's value (1 hour out of 48 hours). The lost time would result in a $59,000 loss in value of Mexican perishable seafood imports and a $978,000 loss in value of Canadian perishable seafood imports.

Table 11 of this document shows the loss in value caused by the resubmitted prior notice information for the 2.5 percent of imported Mexican and Canadian fresh seafood and produce affected.

Table 11.--Loss in Value Caused by Resubmitted Prior Notice Under Option 2

Perishable Produce	
2001 Imported Mexican Produce Total Retail Value	$3,458,525,000
0.6% Reduction in value for 2.5% of Mexican produce	$519,000
2001 Imported Canadian Produce Total Retail Value	$401,826,000
0.6% Reduction in value for 2.5% of Canadian produce	$60,000
Total Lost Value for Produce	$579,000
Perishable Seafood	
2001 Imported Mexican Seafood Total Retail Value	$112,277,406
2.1% Reduction in value for 2.5% of Mexican seafood	$59,000
2001 Imported Canadian Seafood Total Retail Value	$1,863,217,894
2.1% Reduction in value for 2.5% of Canadian seafood	$978,000
Total Lost Value for Seafood	$1,037,000

Table 12 of this document presents a summary of the costs associated with option 2. Also presented in table 12 of this document are the present values of the costs associated with this option, calculated using the OMB-recommended discount rates of 3 and 7 percent.

The first 6 rows of the summary table are the same for options 2 through 9. The options differ only in the time set for prior notice and revisions; the differences in cost across options arise from differences in the lost value of produce and seafood, and in some options, the cost of truck time.

TABLE 12.—SUMMARY OF COSTS FOR OPTION 2 (1 HOUR PRIOR NOTICE SUBMISSION TIME)

	Dollars (thousands)
Learning costs	$66,240

TABLE 12.—SUMMARY OF COSTS FOR OPTION 2 (1 HOUR PRIOR NOTICE SUBMISSION TIME)—Continued

	Dollars (thousands)
Coordination costs	$31,095
Computer acquisition costs	$7,600
FDA prior notice system costs	$13,000
Annual costs to fill out prior notice screens	$187,500
Additional costs for BRASS users	$48,462
Lost value for Mexican produce	$519
Lost value for Canadian produce	$60
Lost value for Mexican seafood	$59
Lost value for Canadian seafood	$978
Total first year costs for Option 2	$355,513
Annual costs after first year	$249,372
Present value of costs at 7% for 20 years	$2,741,043
Present value of costs at 3% for 20 years	$3,813,068

c. *Option 3: Minimum prior notice time of 2 hours before arrival; electronic submission of information; any change in information requires resubmission.* Option 3 requires that prior notice be submitted 2 hours before arrival. If the prior notice time for submission is 2 hours instead of 1 hour, the probability of having to adjust and resubmit prior notice information will be greater. Now, instead of 2.5 percent of the importers of perishable products from Canada and Mexico having to cancel and resubmit their notices, we will assume that the 2-hour submission timetable means that 5 percent will have to resubmit their notices. FDA expects most orders to be placed well in advance of the 2-hour timeframe. Carriers of these products may not be able to cross the border for 2 hours instead of 1 hour, which affects 1.2 percent of the produce life span (2 hours out of 168 hours) and 4.2 percent of the seafood life span (2 hours out of 48 hours).

Table 13 of this document shows the loss in value caused by the resubmitted prior notice information for the 5 percent of imported Mexican and Canadian fresh seafood and produce affected.

TABLE 13.—LOSS IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION 3

Perishable Produce	
2001 Imported Mexican produce total retail value	$3,458,525,000
1.2% Reduction in value for 5% of Mexican produce	$2,075,115
2001 Imported Canadian produce total retail value	$401,826,000
1.2% Reduction in value for 5% of Canadian produce	$241,096
Total Lost Value for Produce	$2,316,000
Perishable Seafood	
2001 Imported Mexican seafood total retail value	$112,277,406
4.2% Reduction in value for 5% of Mexican seafood	$235,783
2001 Imported Canadian seafood total retail value	$1,863,217,894
4.2% Reduction in value for 5% of Canadian seafood	$3,912,758
Total Lost Value for Seafood	$4,149,000

We do not include the costs of truck time with this option, as the prior notice timeframe is relatively short and encompassed within the time many trucks currently spend at the borders.

Table 14 of this document presents a summary of the costs associated with option 3. Also presented in table 14 of this document are the present values of the costs associated with this option using the OMB-recommended discount rates of 3 and 7 percent.

TABLE 14.—SUMMARY OF COSTS FOR OPTION 3 (2 HOUR PRIOR NOTICE SUBMISSION TIME)

	Dollars (thousands)
Learning costs	$66,240
Coordination costs	$31,095
Computer acquisition costs	$7,600
FDA prior notice system costs	$13,000
Annual costs to fill out prior notice screens	$187,500
Additional costs for BRASS users	$48,462
Lost value for Mexican produce	$2,075
Lost value for Canadian produce	$241
Lost value for Mexican seafood	$236
Lost value for Canadian seafood	$3,913
Total first year costs for Option 3	$360,362
Annual costs after first year	$254,221
Present value of costs at 7% for 20 years	$2,792,413

TABLE 14.—SUMMARY OF COSTS FOR OPTION 3 (2 HOUR PRIOR NOTICE SUBMISSION TIME)—Continued

	Dollars (thousands)
Present value of costs at 3% for 20 years	$3,885,209

d. *Option 4: Minimum prior notice timeframe of 4 hours before arrival; electronic submission of information; any change in information requires resubmission.* Option 4 requires that prior notice be submitted 4 hours before arrival instead of 2 hours before arrival.

How much the business practices of importers, produce growers, and seafood processors will be affected by prior notice requirements again will depend on how early the orders are received compared with how early prior notice must be submitted. If the order for the product is placed more than 4 hours before the shipment is scheduled to arrive at the border, then there should be no delay in the importation of the product.

What is more likely to cause a wait before crossing the border is if the information on the prior notice changes after the prior notice has been submitted (*i.e.,* quantity shipped is greater than the quantity specified on the prior notice); this situation will be exacerbated if the exporting facility is located within 4 hours of the U.S. border. For example, if the prior notice is submitted for swordfish before the transport is loaded, and the fish to be loaded turns out to be shark instead of swordfish, the prior notice information submitted will not match the actual shipment. This is one way that information on a prior notice submission might change after the prior notice has already been submitted to FDA, thus requiring a cancellation of the prior notice and a resubmission of the corrected information.

Having to resubmit a prior notice to FDA may not cause any delay of the shipment if the original submission was placed early enough. However, it is likely that the necessary corrected prior notice information will be resubmitted not long before the article of food starts heading for the border. Therefore it is likely that some shipments may have to wait several hours before entering the United States.

If the prior notice time for submission is 4 hours before arrival instead of 2 hours, the probability of having to adjust and resubmit prior notice information will be greater. Now, instead of 5 percent of the importers of perishable products from Canada and Mexico having to resubmit their notices, we will assume that the 4-hour submission timetable means that 20 percent will have to resubmit their notices. Since pre-proposal comments asserted that 40 to 100 percent of trucks are loaded less than 4 hours before driving to the border, we will assume one-half of their lower-bound estimate as the percentage of articles of food that will have to have their prior notices resubmitted.

For this option, and other options where the minimum prior notice time for food arriving by airplane is 4 hours or longer, we include the lost value for highly and very highly perishable produce and seafood imported from Central American countries (including some Caribbean countries and Colombia), not subject to the AMAA. Perishable produce from Belize, Costa Rica, the Dominican Republic, Guatemala, Haiti, Jamaica, Honduras, Nicaragua, Panama, and Colombia can all be flown to Miami, FL in 2 to 4 hours, depending on the starting location. Perishable fish products from the Bahamas, Barbados, Costa Rica, the Dominican Republic, El Salvador, Guatemala, Haiti, Honduras, Jamaica, Nicaragua, Panama, and Colombia also can be flown to Miami, FL in 2 to 4 hours. Table 15 of this document shows the retail value of perishable produce imported from Central America to the United States for 2001. Table 16 of this document shows the retail value of perishable seafood imported from Central America for 2001.

BILLING CODE 4160–01–P

Table 15.--Perishable Produce From Central America

Perishable Produce From Central America	Total Volume for 2001 (100,000 lb units)	Current Wholesale Price ($ per lb) (Sept. 2002)	Total Revenues Wholesale ($ thousands)
Asparagus	37	1.29	4,773
Beans	11	0.58	638
Broccoli	1	0.65	65
Cherries	2	1.3	260
Cucumbers	363	0.29	10,527
Eggplant	61	0.4	2,440
Endive	13	0.37	481
Green peas	227	2.2	49,940
Mangoes	439	0.57	25,023
Berries (miscellaneous)	14	1.67	2,338
Okra	2	0.8	160
Papaya	107	0.45	4,815
Peppers	39	0.53	2,067
Squash	73	0.71	5,183
Total 2001 wholesale value			$108,710
Retail Value			$217,420

Table 16.--Perishable Seafood From Central America

2001 Perishable Seafood Products Flown From Central America	Pounds	Dollars
Atka mackerel, fresh	14,128	22,148
Conch live, fresh	2,474,956	5,884,962
Crab live, fresh	248,580	1,125,507
Eels, fresh	207	7,520
Fish liver and roe, fresh	78,606	112,066
Flatfish flounder, fresh	6,622	7,840
Freshwater fish, fresh	211,853	354,798
Groundfish cod, fresh	1,808	2,381
Grouper, fresh	1,077,703	2,092,349
Lingcod, fresh	5,020	8,804
Lobster (Homarus spp), fresh	104,689	1,007,256
Rock lobster, live	55,042	414,237
Mackerel, fresh	178,312	250,169
Marine fish fillet, fresh	5,840,824	12,442,031
Marine fish, fresh	21,284,450	32,628,025
Marine fish scaled, fresh	98,085	196,186
Molluscs live, fresh	7,372	14,739
Oysters live, fresh	4,629	10,380
Perch fillet, fresh	6,461	13,104
Salmon Atlantic fillet, fresh farmed	8,969	16,002
Salmon fillet, fresh	3,766	10,524
Shark, fresh	35,823	45,543
Shrimp peeled, fresh	58,384	177,434
Snapper, fresh	8,502,525	14,314,692
Squid live, fresh	5,914	2,575
Swordfish, fresh	2,272,257	6,626,692
Swordfish steaks, fresh	1,577	5,945
Tilapia fillet, fresh	11,053,830	28,080,704
Toothfish patagonian, fresh	5,636	15,574
Trout, fresh	67,795	130,844
Trout rainbow, fresh farmed	468,200	1,025,162
Tuna albacore, fresh	55,561	113,930
Tuna bigeye, fresh	2,924,770	8,348,825
Tuna bluefin, fresh	1,580	2,148
Tuna, fresh	1,070,384	2,735,066
Tuna yellowfin, fresh	2,542,404	7,652,086
Wholesale Value		$125,898,248
Retail Value		$251,796,496

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Importers of perishable products from Canada, Mexico, and Central America may not be able to cross the border for 4 hours, which is 2.4 percent of the produce life span (4 hours out of 168 hours) and 8.3 percent of the seafood life span (4 hours out of 48 hours).

Table 17 of this document shows the loss in value caused by the cancelled and resubmitted prior notice information for the 20 percent of imported Mexican, Canadian, and Central American perishable seafood and produce affected.

TABLE 17.—LOSS IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION 4

Perishable Produce	
2001 Imported Mexican produce total retail value	$3,458,525,000
2.4% Reduction in value for 20% of Mexican produce	$16,600,920
2001 Imported Canadian produce total retail value	$401,826,000
2.4% Reduction in value for 20% of Canadian produce	$1,928,765
2001 Imported Central American produce total retail value	$217,420,000
2.4% Reduction in value for 20% of Central American produce	$1,043,616
Total Lost Value for Produce	$19,574,000
Perishable Seafood	
2001 Imported Mexican seafood total retail value	$112,277,406
8.3% Reduction in value for 20% of Mexican seafood	$1,863,805
2001 Imported Canadian seafood total retail value	$1,863,217,894
8.3% Reduction in value for 20% of Canadian seafood	$30,929,417
2001 Imported Central American produce total retail value	$251,796,496
8.3% Reduction in value for 20% of Central American seafood	$4,179,822
Total Lost Value for Seafood	$36,973,000

For this 4-hour prior notice submission timeframe and for all subsequent options with longer timeframes for submission, we also begin to include some holding time costs paid to carriers of products to be imported. We add in this cost in response to the comments that indicated that at least 40 percent of food products being imported from Canada and Mexico are coming from locations located 4 hours or less from a U.S. border. For products located less than 4 hours from the U.S. border, it is quite possible that the carrier will have to be paid for additional waiting time over what had been established under the current business practices. Comments indicated that additional truck time was a real possibility for all food products being imported and not just perishable products. We therefore include a percentage of all products requiring prior notice in the cost estimate in table 18 of this document.

We do not have information on the number of import entries that may use additional truck time because of prior notice submission times. Therefore, we will assume that 20 percent of the 2.3 million lines that entered the United States by ground transportation in fiscal year 2002 (based on OASIS data) will pay for an additional 1 hour of truck time per entry. We use 20 percent as the percentage of trucks delayed to be consistent with our resubmission rate of 20 percent when the prior notice submission timeframe is 4 hours before arrival.

TABLE 18.—COST OF ADDITIONAL CARRIER TME FOR OPTION 4

2002 OASIS import entry lines by ground transportation (truck or train)	2,300,000
Average number of lines per entry	2.6
Total number of ground entries	884,615
20% of ground entries	176,923
Cost for 1 hour of carrier time ($250 per hour)	$250
Total cost of truck time	$44,231,000

Table 19 of this document presents a summary of the costs associated with option 4. Also presented in table 19 of this document are the present values of the costs associated with this option using the OMB-recommended discount rates of 3 and 7 percent.

TABLE 19.—SUMMARY OF COSTS FOR OPTION 4 (4 HOUR MINIMUM PRIOR NOTICE SUBMISSION TIME)

	Dollars (thousands)
Learning costs	$66,240
Coordination costs	$31,095
Computer acquisition costs	$7,600
FDA prior notice system cost	$13,000
Annual costs to fill out prior notice screens	$187,500
Additional Costs for BRASS users	$48,462
Lost value for Mexican produce	$16,601
Lost value for Canadian produce	$1,929
Lost value for Central American produce	$1,044
Lost value for Mexican seafood	$1,864
Lost value for Canadian seafood	$30,929
Lost value for Central American seafood	$4,180
Cost for truck time	$44,231
Total first year costs for Option 4	$454,675
Annual costs after first year	$348,534
Present value of costs at 7% for 20 years	$3,791,567
Present value of costs at 3% for 20 years	$5,288,348

e. *Option 5: Minimum prior notice time frame of 1 hour before arrival for vehicles, 4 hours before arrival for rail and air, and 8 hours before arrival for vessels; electronic submission of information; any change in information requires resubmission.* Option 5 requires that prior notice be submitted 1 hour before arrival for articles of food being imported by vehicle and 4 hours before arrival for articles of food being imported by rail or air modes of transportation. This option is a combination of the minimum prior notice times used in options 2, 4, and 8. By varying minimum prior notice times by conveyance type, option 5 provides flexibility for the importers where it is most needed.

Importers whose articles of food are transported by vehicle from Canada and Mexico are most constrained by facility proximity to the United States, so a 1-hour minimum prior notice time for these shipments is the least constraining possible while still allowing FDA the time needed to review the import information. Comments on shipments of food arriving in the United States by vehicle indicated that (specifically Mexican) food facilities are often close to the U.S. border, and thus requested that FDA require a minimum prior notice time of 2 hours rather than the proposed 12 noon the calendar day prior to arrival. A minimum prior notice time for vehicle traffic of 1 hour will be even less constraining on importers than the 2 hours requested by the majority of comments.

Importers whose shipments of food are flown in from the Caribbean, Central America, and Colombia, or importers whose food shipments are brought into the United States by train will be less constrained by minimum prior notice time than food shipments arriving by vehicle, but more constrained than food shipments arriving in the United States by vessel. Therefore, for this option, importers bringing food into the United States by airplane or by train are required to give prior notice a minimum 4 hours before arrival. This timeframe is sufficient for even shorter flights from Caribbean countries and Central American countries to the United States. For example, though the actual flying time of a direct flight from the Bahamas to Miami is only 2 hours, the airplane must be loaded, taxied to the runway, cleared for take-off, and on arrival landed, taxied from the runway, and unloaded. A 4-hour minimum prior notice time will therefore seldom be constraining. A 4-hour minimum prior notice time for flights could be constraining for rush orders of food from Canada and Mexico. However, OASIS fiscal year 2002 data shows that only about 10,000 food entry lines were flown in from Canada and only about 20,000 lines flown in from Mexico. This is a very small portion, less than 1 percent, of total shipments from Canada and Mexico.

Option 5 requires that prior notice be submitted 8 hours before arrival for articles of food being imported by vessel. We do not specifically address food importation by vessel in this option because this mode of transport will not be constrained by an 8 hour minimum prior notice timeframe. The costs of this option for vessels will be the same as in the previous option.

(i) *One-hour minimum prior notice time for food arriving by vehicle.* Importers of perishable products from Canada and Mexico, whose articles of food arrive in the United States by vehicle, will have to submit prior notice 1 hour before arrival. This short, minimum submission time should eliminate the probability of having to resubmit prior notice for all but 2.5 percent of those perishable products imported from Canada and Mexico.

OASIS data indicates that approximately 44 percent of all imported food shipments used land transportation to arrive in the United States for fiscal year 2002. These shipments must come from Canada and Mexico (or in some cases transshipped), as these are the countries that have land borders with the United States. OASIS data shows that only about 2 percent of imported food shipments arrived in the United States by rail in 2002, and less than 1 percent of shipments arrived from Canada and Mexico by air. Thus, at least 97 percent of all imported food shipments arriving from Canada and Mexico used vehicles as the mode of transport.

Using this 97 percent estimate, we calculate the proportion of the total retail value of highly perishable produce and seafood from Canada and Mexico that arrives in the United States by vehicle. We then use this new retail value, 97 percent of the total value, to calculate the lost product value (1 hour out of 168 hours for produce, 1 hour out of 48 hours for seafood) for the 2.5 percent of highly perishable produce and seafood from Canada and Mexico for which importers would have to resubmit the prior notice when the minimum submission time is 1 hour. Table 20 of this document shows the loss in value caused by the cancelled and resubmitted prior notice information for the 2.5 percent of imported Mexican and Canadian perishable seafood and produce affected.

We also do not include the cost of truck time with this option, because the minimum prior notice time for articles of food arriving by vehicle is only 1 hour. Given current border wait times and manufacturing/processing facility distance from the U.S. border, it is unlikely that articles of food will have to wait to enter the United States because of prior notice requirements.

TABLE 20.—LOSS IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION 5 FOR SHIPMENTS ARRIVING BY VEHICLE (1-HOUR MINIMUM NOTICE REQUIREMENT)

	Dollars
Perishable Produce:	
2001 Imported Mexican produce total retail value	$3,458,525,000
97% of Total retail value for Mexican produce	$3,354,769,000
0.6% Reduction in value for 2.5% of Mexican produce	$503,215
2001 Imported Canadian produce total retail value	$401,826,000
97% of Total retail value for Canadian produce	$389,771,000
0.6% Reduction in value for 2.5% of Canadian produce	$58,466
Total lost value for produce	$562,000
Perishable Seafood	
2001 Imported Mexican seafood total retail value	$112,277,000
97% of Total retail value for Mexican seafood	$108,909,000
2.1% Reduction in value for 2.5% of Mexican seafood	$57,177
2001 Imported Canadian seafood total retail value	$1,863,218,000

TABLE 20.—LOSS IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION 5 FOR SHIPMENTS ARRIVING BY VEHICLE (1-HOUR MINIMUM NOTICE REQUIREMENT)—Continued

	Dollars
97% of Total retail value for Canadian seafood	$1,807,321,000
2.1% Reduction in value for 2.5% of Canadian seafood	$948,844
Total lost value for seafood	$1,006,000

(ii) *Four-hour minimum prior notice time for food arriving by rail and air.* The 4-hour minimum submission time for prior notice applies to articles of food imported by rail and air modes of transportation. A 4-hour minimum prior notice time for these modes of transportation could be constraining for products arriving from the countries bordering the United States.

Since we are assuming that 97 percent of food imported from Canada and Mexico arrives by vehicle, we are left with 3 percent that is imported by rail or air. We adjust the total retail value of highly perishable produce and seafood from Canada and Mexico to account for this 3 percent. Table 21 of this document shows the lost value for the 20 percent of perishable products arriving by rail and air from Canada and Mexico that may have to resubmit prior notice when the minimum prior notice time is 4 hours.

For Central American countries, it is probable that most, if not all, of their perishable products are imported to the United States by air. Therefore, for the highly perishable produce and seafood coming from the Central American region, we assume that 97 percent of the perishable produce and seafood from Central America is shipped to the United States by air. We adjust the total retail value of the perishable products from Central America to reflect that 97 percent of the total value that arrives in the United States by air. Table 21 of this document shows the loss of value for those 20 percent of air shipments from Central America for which prior notice was resubmitted under option 5.

Table 21.--Loss in Value Caused by Resubmitted Prior Notice Under Option 5 for Shipments Arriving by Air and Rail (4-hour minimum notice requirement)

Perishable Produce	Dollars
2001 Imported Mexican produce total retail value	$3,458,525,000
3% of Total retail value for Mexican produce	$103,756,000
2.4% Reduction in value for 20% of Mexican produce	$498,000
2001 Imported Canadian produce total retail value	$401,826,000
3% of Total retail value for Canadian produce	$12,055,000
2.4% Reduction in value for 20% of Canadian produce	$58,000
2001 Imported Central American produce total retail value	$217,420,000
97% of Total retail value for Central American produce	$210,897,000
2.4% Reduction in value for 20% of Central American produce	$1,012,000
Total lost value for produce	$1,568,000
Perishable Seafood	
2001 Imported Mexican seafood total retail value	$112,277,000
3% of Total retail value for Mexican seafood	$3,368,000
8.3% Reduction in value for 20% of Mexican seafood	$56,000
2001 Imported Canadian seafood total retail value	$1,863,218,000
3% of Total retail value for Canadian seafood	$55,897,000
8.3% Reduction in value for 20% of Canadian seafood	$928,000
2001 Imported Central American seafood total retail value	$251,796,000
97% of Total retail value for Central American seafood	$244,242,000
8.3% Reduction in value for 20% of Central American seafood	$4,054,000
Total lost value for seafood	$5,038,000

Table 22 of this document presents a summary of the costs associated with option 5, including the costs of the option at the OMB-recommended discount rates of 3 and 7 percent.

Table 22.--Summary of Costs for Option 5

	Dollars ($ thousands)
Learning costs	$66,240
Coordination costs	$31,095
Computer acquisition costs	$7,600
FDA prior notice system cost	$13,000
Annual costs to fill out prior notice screens	$187,500
Additional costs for BRASS users	$48,462
Lost value for produce	$2,130
Lost value for seafood	$6,044
Cost for truck time	$0
Total first year costs for option 5	$362,071
Annual costs after first year	$255,929
Present value of costs at 7% for 20 years	$2,810,515
Present value of costs at 3% for 20 years	$3,910,630

e. *Option 6: Minimum prior notice timeframe of 2 hours before arrival for vehicles, 4 hours before arrival for rail and air, and 8 hours before arrival for vessels; electronic submission of information; any change in information requires resubmission (interim final rule).* Option 6 requires that prior notice be submitted 2 hours before arrival for articles of food being imported by vehicle and 4 hours before arrival for articles of food being imported by rail or air modes of transportation.

Option 6 requires that prior notice be submitted 8 hours before arrival for articles of food being imported by vessel. We do not specifically address food import by vessel in this option because this mode of transport will not be constrained by an 8-hour minimum prior notice timeframe. The costs of this option for vessels will be the same as in the previous options.

i. *Two-hour minimum prior notice time for food arriving by vehicle.* Importers of perishable products from Canada and Mexico, whose articles of food arrive in the United States by vehicle, will have to submit prior notice 2 hours before arrival. This short, minimum submission time frame should eliminate the probability of having to resubmit prior notice for all but 5 percent of those perishable products imported from Canada and Mexico.

OASIS data indicates that approximately 44 percent of all imported food shipments used land transportation to arrive in the United States for fiscal year 2002. These shipments must come from Canada and Mexico (or in some cases transshipped), as these are the countries that have land borders with the United States. OASIS data shows that only about 2 percent of imported food shipments arrived in the United States by rail in 2002, and less than 1 percent of shipments arrived from Canada and Mexico by air. Thus, at least 97 percent of all imported food shipments arriving from Canada and Mexico used vehicles as the mode of transport.

Using this 97 percent estimate, we calculate the proportion of the total retail value of highly perishable produce and seafood from Canada and Mexico that arrives in the United States by vehicle. This new retail value, 97 percent of the total value, is then used to calculate the lost product value for the 5 percent of highly perishable produce and seafood from Canada and Mexico for which importers would have to resubmit the prior notice when the minimum submission time is 2 hours. Table 23 of this document shows the loss in value caused by the cancelled and resubmitted prior notice information for the 5 percent of imported Mexican and Canadian perishable seafood and produce affected.

We do not include the lost value for perishable seafood and produce imported from Central America in table 23 of this document since perishable products from Central America are most likely flown into the United States. We also do not include the cost of truck time with this option since the minimum prior notice time for articles of food arriving by vehicle is only 2 hours. Given current border wait times and manufacturing/processing facility distance from the U.S. border, it is unlikely that trucks will have to wait to enter the United States because of prior notice requirements. We expect that some delays will occur, but that they will be relatively rare and will impose little additional cost compared with a 1-hour minimum prior notice time. We therefore do not include any additional truck time costs for this option.

Table 23.--Loss in Value Caused by Resubmitted Prior Notice Under Option 6 for Shipments Arriving by Vehicle (2 hour minimum notice requirement)

Perishable Produce	Dollars
2001 Imported Mexican produce total retail value	$3,458,525,000
97% of Total retail value for Mexican produce	$3,354,769,000
1.2% Reduction in value for 5% of Mexican produce	$2,013,000
2001 Imported Canadian produce total retail value	$401,826,000
97% of Total retail value for Canadian produce	$389,771,000
1.2% Reduction in value for 5% of Canadian produce	$234,000
Total Lost Value for Produce	$2,247,000
Perishable Seafood	
2001 Imported Mexican seafood total retail value	$112,277,000
97% of Total retail value for Mexican seafood	$108,909,000
4.2% Reduction in value for 5% of Mexican seafood	$229,000
2001 Imported Canadian seafood total retail value	$1,863,218,000
97% of total retail value for Canadian seafood	$1,807,321,000
4.2% Reduction in value for 5% of Canadian seafood	$3,795,000
Total Lost Value for Seafood	$4,024,000

ii. *Four-hour minimum prior notice time for food arriving by rail and air.* The 4-hour minimum submission time for prior notice applies to articles of food imported by rail and air modes of transportation. A 4-hour minimum prior notice timeframe for these modes of transportation could be constraining for products arriving from the countries bordering the United States.

Since we are assuming that 97 percent of food imported from Canada and Mexico arrives by vehicle, we are left with 3 percent that is imported by rail or air. We adjust the total retail value of highly perishable produce and seafood from Canada and Mexico to account for this 3 percent. Table 24 of this document shows the lost value for the 20 percent of perishable products arriving by rail and air from Canada and Mexico that may have to resubmit prior notice when the minimum prior notice timeframe is 4 hours.

For Central American countries, it is probable that most, if not all, of their perishable products are imported to the United States by air. Therefore, for the highly perishable produce and seafood coming from the Central American region, we assume that 97 percent of the perishable produce and seafood from Central America is shipped to the United States by air. We adjust the total retail value of the perishable products from Central America to reflect that 97 percent of the total value that arrives in the United States by air. Table 24 of this document shows the loss of value for those 20 percent of air shipments from Central America for which prior notice was resubmitted under option 6.

Table 24.--Loss in Value Caused by Resubmitted Prior Notice Under Option 6 for Shipments Arriving by Air and Rail (4 hour minimum notice requirement)

Perishable Produce	Dollars
2001 Imported Mexican produce total retail value	$3,458,525,000
3% of Total retail value for Mexican produce	$103,756,000
2.4% Reduction in value for 20% of Mexican produce	$498,000
2001 Imported Canadian produce total retail value	$401,826,000
3% of Total retail value for Canadian produce	$12,055,000
2.4% Reduction in value for 20% of Canadian produce	$58,000
2001 Imported Central American produce total retail value	$217,420,000
97% of Total retail value for Central American produce	$210,897,000
2.4% Reduction in value for 20% of Central American produce	$1,012,000
Total Lost Value for Produce	$1,568,000
Perishable Seafood	
2001 Imported Mexican seafood total retail value	$112,277,000
3% of Total retail value for Mexican seafood	$3,368,000
8.3% Reduction in value for 20% of Mexican seafood	$56,000
2001 Imported Canadian seafood total retail value	$1,863,218,000
3% of Total retail value for Canadian seafood	$55,897,000
8.3% Reduction in value for 20% of Canadian seafood	$928,000
2001 Imported Central American seafood total retail value	$251,796,000
97% of Total retail value for Central American seafood	$244,242,000
8.3% Reduction in value for 20% of Central American seafood	$4,054,000
Total Lost Value for Seafood	$5,038,000

Table 25 of this document presents a summary of the costs associated with option 6, including the costs of the option at the OMB-recommended discount rates of 3 and 7 percent.

Table 25.--Summary of Costs for Option 6--Interim Final Rule

	Dollars (thousands)
Learning costs	$66,240
Coordination costs	$31,095
Computer acquisition costs	$7,600
FDA prior notice system cost	$13,000
Annual costs to fill out prior notice screens	$187,500
Additional costs for BRASS users	$48,462
Lost value for produce	$3,815
Lost value for seafood	$9,062
Cost for truck time	$0
Total first year costs for Option 6	$366,744
Annual costs after first year	$260,633
Present value of costs at 7% for 20 years	$2,860,342
Present value of costs at 3% for 20 years	$3,980,603

f. *Option 7: Prior notice required 4 hours before arrival; electronic submission of information; allow changes to the prior notice submission up to 1 hour before arrival.* We now take the estimates in option 4 and adjust them to account for the effects of allowing changes to the prior notice submission without requiring resubmission. Although the original submission time of 4 hours before arrival is relatively short, allowing changes to the original submission, in the form of electronic amendments and updates, would improve the flow of import traffic by reducing the notice resubmission rate. The smaller resubmission rate would reduce the loss of value for perishable foods that might otherwise have to wait extra time before crossing the U.S. border.

Prior notice requires that certain information about each imported food product be relayed to FDA before

arrival. A more flexible entry screen that allows for updates and amendments to some notice information would reduce the likelihood that the original notice would have to be resubmitted by importers, thus lessening the time burden, and therefore the costs of prior notice. Even a 1 hour amendment and updates to prior notice would provide some flexibility for importers in industries where certain information, such as the type of the product being imported and the quantity of the article to be imported, may change or is not known until just before shipping.

It is also important to note here that we assume that the 1 hour time FDA has estimated that it takes to fill out each prior notice is sufficient for this option, even with the opportunity of amending prior notice information. This time is sufficient because amending or updating a particular item in the prior notice submission should only take a few seconds to a few minutes in time.

If prior notice can be amended and updated, fewer resubmissions would occur. For this option, then, with amendment and updates, we will assume that the number of prior notice resubmissions necessitated by changes in information on the notice would be reduced from 20 percent (as in option 4) to 2.5 percent. FDA believes that the resubmission rate for a 4-hour prior notice time with 1-hour amendment will result in about the same resubmission rate as option 2 (a straight, 1 hour before arrival, prior notice timeframe). FDA believes these two timeframes will cause about the same resubmission rate, because both arrival timeframes are relatively short and both are within the timeframe of 4 hours that was suggested by Canadian and Mexican perishable products importers.

Compared with option 4 (4 hours prior notice with no amendments or updates), option 7 would save 4 hours wait time per prior notice submission that can be amended or updated. Prior notice submissions that cannot be amended or updated, however, would lead to waits of 4 hours. Those 2.5 percent of shipments for which prior notice cannot be amended or updated would wait an extra 4 hours before being able to cross the border. This wait translates into 2.4 percent of the perishable produce life span (4 hours out of 168 hours) and 8.3 percent of the perishable seafood life span (4 hours out of 48 hours). Table 26 of this document shows the costs of submitting prior notice for a 4-hour minimum time before arrival, with a 1-hour timeframe before arrival for submitting amendment and updates, for Canadian, Mexican, and Central American perishable produce and seafood.

Table 26.--Loss in Value Caused by Resubmitted Prior Notice Under Option 7

Perishable Produce	Dollars
2001 Imported Mexican produce total retail value	$3,458,525,000
2.4% Reduction in value for 2.5% of Mexican produce	$2,075,115
2001 Imported Canadian produce total retail value	$401,826,000
2.4% Reduction in value for 2.5% of Canadian produce	$241,096
2001 Imported Central American produce total retail value	$217,420,000
2.4% Reduction in value for 2.5% of Central American produce	$130,452
Total Lost Value for Produce	$2,446,000
Perishable Seafood	
2001 Imported Mexican seafood total retail value	$112,277,406
8.3% Reduction in value for 2.5% of Mexican seafood	$232,976
2001 Imported Canadian seafood total retail value	$1,863,217,894
8.3% Reduction in value for 2.5% of Canadian seafood	$3,866,177
2001 Imported Central American seafood total retail value	$251,796,496
8.3% Reduction in value for 2.5% of Central American seafood	$522,478
Total Lost Value for Seafood	$4,621,000

Table 27 of this document compares the reduction in the costs of this interim final rule if amendments and updates to prior notice are allowed (option 7), as opposed to the no-amendment 4-hour option 4.

Table 27.--Comparison of Option 4 With Option 7--Lost Value for Perishables

Perishable Mexican Produce Value Loss	
Option 4--4 hour minimum notice	$16,601,000
Option 7--4 hour notice with changes	$2,075,000
Savings with amendment and update	$14,526,000
Perishable Canadian Produce Value Loss	
Option 4--4 hour minimum notice	$1,929,000
Option 7--4 hour notice with changes	$241,000
Savings with amendment and update	$1,688,000
Perishable Central American Produce Value Loss	
Option 4--4 hour minimum notice	$1,044,000
Option 7--4 hour notice with changes	$130,000
Savings with amendment and update	$914,000
Perishable Mexican Seafood Value Loss	
Option 4--4 hour minimum notice	$1,864,000
Option 7--4 hour notice with changes	$233,000
Savings with amendment and update	$1,631,000
Perishable Canadian Seafood Value Loss	
Option 4--4 hour minimum notice	$30,929,000
Option 7--4 hour notice with changes	$3,866,000
Savings with amendment and update	$27,063,000
Perishable Central American Seafood Value Loss	
Option 4--4 hour minimum notice	$4,180,000
Option 7--4 hour notice with changes	$522,000
Savings with amendment and update	$3,658,000

Although submitters can amend prior notice information with this option, we assume that those 2.5 percent of prior notice submissions that cannot use the amendment, but instead have to wait an additional 4 hours to cross the border, would incur at least some truck costs as a result of this wait time. Therefore, we will assume that 2.5 percent of the 2.3 million lines that entered the United States by ground transportation in fiscal year 2002 (based on OASIS data) would pay for an additional 4 hours of truck time per line. We use 2.5 percent as the percentage of trucks delayed to be consistent with our resubmission rate of 2.5 percent when the prior notice submission timeframe is 4 hours before arrival with a 1-hour amendment option. Table 28 of this document shows the costs of truck time associated with those prior notices that cannot be amended.

TABLE 28.—COST OF ADDITIONAL CARRIER TIME FOR OPTION 7

2002 OASIS import entry lines by ground transportation (truck or train)	2,300,000
Average number of lines per entry	2.6
Total number of ground entries	884,615
2.5% of ground entries	22,115
Cost for 4 hours of carrier time ($250 per hour)	$1,000
Total cost of truck time	$22,115,000

Table 29 of this document presents a summary of the costs associated with option 7. Also presented in table 29 of this document are the present values of the costs associated with this option using the OMB-recommended discount rates of 3 and 7 percent.

Table 29.--Summary of Costs for Option 7 (4 hour minimum submission time, 1 hour amendment)

	Dollars (thousands)
Learning costs	$66,420
Coordination costs	$31,095
Computer acquisition costs	$7,600
FDA prior notice system cost	$13,000
Annual costs to fill out prior notice screens	$187,500
Additional costs for BRASS users	$48,462
Lost value for Mexican produce	$2,075
Lost value for Canadian produce	$241
Lost value for Central American produce	$130
Lost value for Mexican seafood	$233
Lost value for Canadian seafood	$3,866
Lost value for Central American seafood	$522
Cost for truck time	$22,115
Total first year costs for Option 7	$383,079
Annual costs after first year	$276,938
Present value of costs at 7% for 20 years	$3,033,077
Present value of costs at 3% for 20 years	$4,223,181

g. *Option 8: Minimum prior notice timeframe of 8 hours before arrival; electronic submission of information; any change in information requires resubmission (statutory default option).* Option 8 is to issue an interim final rule that incorporates the default minimum timeframe for prior notices as provided in the Bioterrorism Act. Pre-proposal information and comments on the proposed rule indicated that Canadian and Mexican produce growers and seafood processors are concerned that the longer the minimum time required for the prior notice, the less fresh their products will be when they reach U.S. customers. Less-than-optimal fresh (*i.e.*, lower quality) products would result in a lower price paid for the imported produce or seafood shipments, or possibly even the loss of a customer's business to a domestic producer.

For importers of perishable products such as seafood and produce, the 8-hour minimum time for prior notice is expected to change business practices. How much importer, produce grower, and seafood processor business practices will be affected by prior notice requirements will depend on how early the orders are received compared with how early prior notice must be submitted. Also, as the prior notice submission time increases, the location of the exporter in relation to the U.S. border becomes a more important factor in determining whether changes in business practices are needed.

If the prior notice time for submission is 8 hours instead of 4 hours, the probability of having to resubmit prior notice information will be greater. Now, instead of 20 percent of the importers of perishable products from Canada, Mexico, and Central America having to resubmit their notices, we will assume that the 8-hour submission timetable means that 30 percent will have to resubmit their notices.

As explained in option 2, we based the resubmission rate percentages for perishable products coming from Canada and Mexico on comments FDA received indicating that 40 to 100 percent of the products from these two countries are shipped from locations no more than 4 hours from the border. For shorter prior notice timeframes, starting with the 4-hour option and moving downward in minimum prior notice time, we halved the resubmission rate because every hour decrease in required prior notice submission time will eliminate a significant number of prior notice resubmissions for those facilities close to the border. For options with longer timeframes, however, instead of doubling the resubmission rate, we begin to add an additional 10 percent resubmission rate for each additional 4 hours of required prior notice minimum submission time. We do this because, aside from perishable products and rush orders, most foods are ordered in advance of shipping and the quantities of such foods are easily identifiable; these are orders that will not change and thus will not require resubmission of prior notice.

Carriers of products requiring prior notice may not be able to cross the border for 8 hours or longer, instead of 4 hours. This time for prior notice represents 4.8 percent of the produce life span (8 hours out of 168 hours) and 16.7 percent of the seafood life span (8 hours out of 48 hours). Table 30 of this document shows the loss in value caused by the resubmitted prior notice information for the 30 percent of imported Mexican, Canadian, and Central American perishable seafood and produce affected.

Table 30.--Loss in Value Caused by Resubmitted Prior Notice Under Option 8

Perishable Produce	Dollars
2001 Imported Mexican produce total retail value	$3,458,525,000
4.8% Reduction in value for 30% of Mexican produce	$49,802,760
2001 Imported Canadian produce total retail value	$401,826,000
4.8% Reduction in value for 30% of Canadian produce	$5,786,294
2001 Imported Central American produce total retail value	$217,420,000
4.8% Reduction in value for 30% of Central American produce	$3,130,848
Total Lost Value of Produce	$58,720,000
Perishable Seafood	
2001 Imported Mexican seafood total retail value	$112,277,406
16.7% Reduction in value for 30% of Mexican seafood	$5,625,098
2001 Imported Canadian seafood total retail value	$1,863,217,894
16.7% Reduction in value for 30% of Canadian seafood	$93,347,216
2001 Imported Central American seafood total retail value	$251,796,496
16.7% Reduction in value for 30% of Central American seafood	$12,615,004
Total Lost Value for Seafood	$111,587,000

For this 8-hour prior notice submission timeframe, we include holding time costs paid to carriers of products to be imported. We add in this cost in response to comments indicating that for longer submission timeframes and for products located less than 8 hours from the U.S. border, it is quite possible that the carrier would have to be paid for additional waiting time over what had been established under the current business practices.

We do not have information on the number of import entries that may use additional truck time because of prior notice submission timeframes. We will assume that 30 percent of the 2.3 million lines that entered the United States by ground transportation in fiscal year 2002 (based on OASIS data) would pay for an additional 2 hours of truck time per entry. We use 30 percent as the percentage of trucks delayed to be consistent with our resubmission rate of 30 percent when the prior notice submission timeframe is 8 hours before arrival. These costs are summarized in table 31 of this document.

Table 31.--Cost of Additional Carrier Time for Option 8

2001 OASIS import entry lines by ground transportation (truck or train)	2,300,000
Average number of lines per entry	2.6
Total number of ground entries	884,615
30% of ground entries	265,385
Cost for 2 hours of carrier time ($250 per hour)	$500
Total cost of truck time	$132,692,500

Table 32 of this document presents a summary of the costs associated with option 8. Also presented in table 32 of this document are the present values of the costs associated with this option using the OMB-recommended discount rates of 3 and 7 percent.

Table 32.--Summary of Costs for Option 8
(8-hour minimum prior notice submission time)

	Dollars (thousands)
Learning costs	$66,420
Coordination costs	$31,095
Computer acquisition costs	$7,600
FDA prior notice system cost	$13,000
Annual costs to fill out prior notice screens	$187,500
Additional costs for BRASS users	$48,462
Lost value for Mexican produce	$49,803
Lost value for Canadian produce	$5,786
Lost value for Central American produce	$3,131
Lost value for Mexican seafood	$5,625
Lost value for Canadian seafood	$93,347
Lost value for Central American seafood	$12,615
Cost for truck time	$132,693
Total first year costs for Option 8	$656,897
Annual costs after first year	$550,756
Present value of costs at 7% for 20 years	$5,933,909
Present value of costs at 3% for 20 years	$8,296,901

h. *Option 9: Prior notice required 8 hours before arrival; electronic submission of information; allow changes to the prior notice submission up to 1 hour before arrival.* We now take the estimates in option 8 and adjust them to account for the effects of allowing changes to the prior notice submission. With an original submission time of 8 hours before arrival, it is likely that allowing changes to the original submission, in the form of electronic amendments and updates, would improve the flow of import traffic—especially since comments indicated that between 40 and 100 percent of products coming from Canada and Mexico are within 4 hours of a U.S. border. Regardless of when the order is placed, if the exporting facility of the product is located less than 8 hours from a U.S. border, allowing amendments and updates to prior notice would reduce the notice resubmission rate, and also reduce the loss of value for perishable foods that might otherwise have to wait extra time before crossing the U.S. border.

Again, we note with this option, we assume that the FDA 1-hour time estimate for filling out each prior notice is sufficient, even with the option of amending prior notice information. This time is sufficient because amending or updating a particular item in the prior notice submission should only take a few seconds to a few minutes in time.

For this option, with amendment and updates, we will assume that the number of prior notice resubmissions necessitated by changes in information on the notice will be reduced from 30 to 5 percent. Although the amendment will eliminate the need for notice resubmission for many entries, the uncertainty associated with some shipment information increases as the prior notice minimum submission timeframe increases. Thus, for an 8-hour original submission time frame, it is unlikely that the allowance of an amendment will reduce the prior notice resubmission rate to 2.5 percent as presented in option 7. Instead, we assume that an 8-hour prior notice submission timeframe with a 1-hour amendment will reduce the prior notice resubmission rate to 5 percent.

Option 9 saves 8 hours of wait time per entry for prior notices that can be amended or updated. The 5 percent of imports for which the prior notice cannot be amended, however, will end up waiting at the border or at the manufacturing/processing facility an additional 8 hours before arriving in the United States, which is 4.8 percent of the perishable produce life span (8 hours out of 168 hours) and 16.7 percent of the perishable seafood life span (8 hours out of 48 hours). Table 33 of this document shows the costs of submitting prior notice for an 8-hour minimum time, with a 1-hour amendment and updates, for Canadian, Mexican, and Central American perishable produce and seafood.

Table 33.--Loss in Value Caused by Resubmitted Prior Notice Under Option 8

Perishable Produce	Dollars
2001 Imported Mexican Produce total retail value	$3,458,525,000
4.8% Reduction in value for 5% of Mexican produce	$8,300,460
2001 Imported Canadian produce total retail value	$401,826,000
4.8% Reduction in value for 5% of Canadian produce	$964,382
2001 Imported Central American produce total retail value	$217,420,000
4.8% Reduction in value for 5% of Central American produce	$521,808
Lost Value for Produce	$9,786,000
Perishable Seafood	
2001 Imported Mexican seafood total retail value	$112,277,406
16.7% Reduction in value for 5% of Mexican seafood	$937,516
2001 Imported Canadian seafood total retail value	$1,863,217,894
16.7% Reduction in value for 5% of Canadian seafood	$15,557,869
2001 Imported Central American seafood total retail value	$251,796,496
16.7% Reduction in value for 5% of Central American seafood	$2,102,501
Total Lost Value for Seafood	$18,599,000

Table 34 of this document compares the reduction in the costs of this interim final rule if an amendment and update to prior notice is allowed (option 9) as opposed to the no-amendment option 8.

Table 34.--Comparison of Option 8 With Option 9--Lost Value for Perishables

Perishable Mexican Produce Value Loss	
Option 8--8 hour minimum notice	$41,502,000
Option 9--8 hour notice with changes	$8,300,000
Savings with amendment and update	$33,202,000
Perishable Canadian Produce Value Loss	
Option 8--8 hour minimum notice	$4,822,000
Option 9--8 hour notice with changes	$964,000
Savings with amendment and update	$3,858,000
Perishable Central American Produce Value Loss	
Option 8--8 hour minimum notice	$3,131,000
Option 9--8 hour notice with changes	$522,000
Savings with amendment and update	$2,609,000
Perishable Mexican Seafood Value Loss	
Option 8--8 hour minimum notice	$4,688,000
Option 9--8 hour notice with changes	$938,000
Savings with amendment and update	$3,750,000
Perishable Canadian Seafood Value Loss	
Option 8--8 hour minimum notice	$77,789,000
Option 9--8 hour notice with changes	$15,558,000
Savings with amendment and update	$62,231,000
Perishable Central American Seafood Value Loss	
Option 8--8 hour minimum notice	$12,615,000
Option 9--8 hour notice with changes	$2,103,000
Savings with amendment and update	$10,512,000

Although submitters can amend prior notice information with this option, we assume that those 5 percent of entries that cannot use the amendment, but instead have to wait an additional 8 hours before arriving in the United States would incur at least some truck costs as a result of this wait time. We will therefore assume that 5 percent of the 2.3 million lines that entered the United States by ground transportation in fiscal year 2002 (based on OASIS data) would pay for an additional 8 hours of truck time per prior notice submission. We use 5 percent as the percentage of trucks delayed to be consistent with our resubmission rate of 5 percent when the prior notice submission timeframe is 8 hours before arrival with a 1-hour amendment option. Table 35 shows the costs of truck time associated with those prior notices that cannot be amended.

Table 35.--Cost of Additional Carrier Time for Option 9

2002 OASIS import entry lines by ground transportation (truck or train)	2,300,000
Average number of lines per entry	2.6
Total number of ground entries	884,615
5% of ground entries	44,231
Cost for 8 hours of carrier time ($250 per hour)	$2,000
Total cost of truck time	$88,462,000

Table 36 of this document presents a summary of the costs associated with option 9. Also presented in table 36 of this document are the present values of the costs associated with this option using the OMB-recommended discount rates of 3 and 7 percent.

Table 36.--Summary of Costs for Option 9
(8-hour prior notice minimum submission time, 1-hour amendment)

	Dollars (thousands)
Learning costs	$66,420
Coordination costs	$31,095
Computer acquisition costs	$7,600
FDA prior notice system cost	$13,000
Annual costs to fill out prior notice screens	$187,500
Additional costs for BRASS users	$48,462
Lost value for Mexican produce	$8,300
Lost value for Canadian produce	$964
Lost value for Central American produce	$522
Lost value for Mexican seafood	$938
Lost value for Canadian seafood	$15,558
Lost value for Central American seafood	$2,103
Cost for truck time	$88,462
Total first year costs for Option 9	$470,744
Annual costs after first year	$364,603
Present value of costs at 7% for 20 years	$3,961,802
Present value of costs at 3% for 20 years	$5,527,415

i. *Option 10: Prior notice received by 12 noon of the calendar day before arrival; electronic submission of information; any change in information requires resubmission.* This option requires that prior notice be submitted no later than 12 noon of the calendar day before the expected day of arrival. Under this option, prior notice submitters will have to let FDA know of the incoming food shipment at least 12 hours before the shipment reaches the U.S. port of arrival. This option would likely cause a change in importer business practices and the business practices of their clients in much the same way as option 8, but the potential loss of product value is higher because the minimum prior notice time has increased.

Again, how business practices would be affected by prior notice requirements depends on how early the invoice orders are received, when the truck is loaded, and when prior notice is submitted.

As before, we assume that as the minimum notice time increases, the likelihood of a resubmission also increases. Instead of 30 percent of the importers of perishable products from Canada and Mexico having to cancel their original prior notices and resubmit, we will assume that the 12-hour submission timetable means that 40 percent will have to cancel and resubmit their notices.

We increase the percentage of resubmission this time by 10 percent because as the prior notice time frame increases relative to the time of arrival, it becomes more likely that the prior notice information will change after the notice is submitted to FDA, thus requiring resubmission of the notice. The transporters of products with resubmitted prior notices may then have to wait as long as 12 hours, which affects 7.1 percent of the produce life span (12 hours out of 168 hours) and 25 percent of the seafood life span (12 hours out of 48 hours).

Table 37 of this document shows the loss in value caused by the resubmitted prior notice information for the 40 percent of imported Mexican, Canadian, and Central American perishable seafood and produce that might be affected.

Table 37.--Loss in Value Caused by Resubmitted Prior Notice Under Option 10

Perishable Produce	Dollars
2001 Imported Mexican produce total retail value	$3,458,525,000
7.1% Reduction in value for 40% of Mexican produce	$98,222,110
2001 Imported Canadian produce total retail value	$401,826,000
7.1% Reduction in value for 40% of Canadian produce	$11,411,858
2001 Imported Central American produce total retail value	$217,420,000
7.1% Reduction in value for 40% of Central American produce	$6,174,728
Total Lost Value for Produce	$115,809,000
Perishable Seafood	
2001 Imported Mexican seafood total retail value	$112,277,406
25% Reduction in value for 40% of Mexican seafood	$11,227,741
2001 Imported Canadian Seafood total retail value	$1,863,217,894
25% Reduction in value for 40% of Canadian seafood	$186,321,789
2001 Imported Central American seafood total retail value	$251,796,496
25% Reduction in value for 40% of Central American seafood	$25,179,650
Total Lost Value for Seafood	$222,730,000

For option 10, we also include the costs of additional carrier time that may be necessary due to the longer minimum prior notice submission timeframe. For option 8 we had included the cost of an additional 2 hours of truck time for 30 percent of ground-based import entry lines; for this option we will include the cost of an additional 4 hours of truck time for 40 percent of ground-based import entry lines. We expect the percentage of imported shipments that need extra truck time, and the truck time itself, to increase as the prior notice submission timeframe increases. These costs are summarized in table 38 of this document.

Table 38.--Cost of Additional Carrier Time for Option 10

2001 OASIS import entry lines by ground transportation (truck or train)	2,300,000
Average number of lines per entry	2.6
Total number of ground entries	884,615
40% of ground entries	353,846
Cost for 4 hours of carrier time ($250 per hour)	$1,000
Total cost of truck time	$353,846,000

Table 39 of this document presents a summary of the costs associated with option 10. Also presented in table 39 of this document are the present values of the costs associated with this option using the OMB-recommended discount rates of 3 and 7 percent.

Table 39.--Summary of Costs for Option 10
(12 noon the calendar day before arrival minimum submission time)

	Dollars (thousands)
Learning costs	$66,420
Coordination costs	$31,095
Computer acquisition costs	$7,600
FDA prior notice system cost	$13,000
Annual costs to fill out prior notice screens	$187,500
Additional costs for BRASS users	$48,462
Lost value for Mexican produce	$98,222
Lost value for Canadian produce	$11,412
Lost value for Central American produce	$6,175
Lost value for Mexican seafood	$11,228
Lost value for Canadian seafood	$186,322
Lost value for Central American seafood	$25,180
Cost for truck time	$353,846
Total first year costs for Option 10	$1,046,282
Annual costs after first year	$940,141
Present value of costs at 7% for 20 years	$10,059,060
Present value of costs at 3% for 20 years	$14,089,967

j. *Option 11: Prior notice received by 12 noon of the calendar day before arrival; electronic submission of information; allow changes to the prior notice submission up to 1 hour before arrival.* We now take the estimates in option 10 and adjust them to account for the effects of allowing changes to the prior notice submission. Since prior notice must be submitted by 12 noon on the calendar day before arrival, it is reasonable to expect that not all the information required on a prior notice would be final.

The prior notice requires the addresses of the submitter, importer, owner, and consignee, as well as the carrier, manufacturer, and grower if known. Required information also includes the identity of the article of food, its FDA Country of Production, the country from which the food is shipped, its CBP entry identifier, the date, time, and anticipated port of arrival, and planned shipment information.

Increasing the number of required fields that can be changed in the prior notice before arrival reduces the likelihood that the information would have to be completely resubmitted by importers. This change would lessen the time burden, and therefore, the cost of having to submit prior notice. Allowing a 1-hour amendment and updates to prior notice would provide some flexibility for importers in industries where some of the required information, such as the specific type of food (*i.e.*, codfish instead of fish) of the product being imported, may change or is not known until just before shipping. Again we note that we assume that 1-hour time FDA estimates that it takes to fill out each prior notice is sufficient, even with the option of amending prior notice information. This time is sufficient because amending or updating a particular item in the prior notice submission should only take a few seconds to a few minutes.

For this option with amendment and updates, we assume that the number of prior notice resubmissions necessitated by changes in information on the notice would be reduced from 40 percent (as in option 10) to 10 percent. The notice resubmission rate for this option is expected to be higher than previous options with amendments because the original submission must be given by 12 noon on the calendar day before arrival. The lengthening of the minimum prior notice time period from 8 hours with amendment (option 9) to 12 noon the calendar day before arrival with amendment (this option) suggests that there would be significantly more prior notices initially submitted for which all required information has not been completely determined. Less-than-final information on original prior notice submissions increases the likelihood that the notice will require revision, either in the form of an amendment or in the form of a total resubmission of the original prior notice.

Option 11 saves 12 hours wait time per entry line that can be amended or updated for the prior notice over the time used in option 9. Those shipments, whose prior notice must be completely resubmitted, would wait an additional 12 hours at the manufacturing/processing facility or at the U.S. border; 7.1 percent of the perishable produce life span (12 hours out of 168 hours) and 25 percent of the perishable seafood life span (12 hours out of 48 hours). Table 40 of this document shows the costs of submitting prior notice for a 12-hour minimum time, with a 1-hour timeframe for amendment and updates before arrival, for Canadian, Central American, and Mexican perishable produce and seafood.

Table 40.--Loss in Value Caused by Resubmitted Prior Notice Under Option 11

Perishable Produce	Dollars
2001 Imported Mexican produce total retail value	$3,458,525,000
7.1% Reduction in value for 10% of Mexican produce	$24,555,528
2001 Imported Canadian produce total retail value	$401,826,000
7.1% Reduction in value for 10% of Canadian produce	$2,852,965
2001 Imported Central American produce total retail value	$217,420,000
7.1% Reduction in value for 10% of Central American produce	$1,543,682
Total Lost Value for Produce	$28,953,000
Perishable Seafood	
2001 Imported Mexican seafood total retail value	$112,277,406
25% Reduction in value for 10% of Mexican seafood	$2,806,935
2001 Imported Canadian seafood total retail value	$1,863,217,894
25% Reduction in value for 10% of Canadian seafood	$46,580,447
2001 Imported Central American seafood total retail value	$251,796,496
25% Reduction in value for 10% of Central American seafood	$6,294,912
Total Lost Value for Seafood	$55,682,000

Table 41 of this document compares the reduction in the costs of this rule if an amendment and update to prior notice is allowed (option 11) as opposed to the no-amendment option 10.

Table 41.--Comparison of Lost Value for Perishables Between Option 10 With Option 11

Perishable Mexican Produce Value Loss	
Option 10--12 hour minimum notice	$98,222,000
Option 11--12 hour notice with changes	$24,556,000
Savings with amendment and update	$73,666,000
Perishable Canadian Produce Value Loss	
Option 10--12 hour minimum notice	$11,412,000
Option 11--12 hour notice with changes	$2,853,000
Savings with amendment and update	$8,559,000
Perishable Central American Produce Value Loss	
Option 10--12 hour minimum notice	$6,175,000
Option 11--12 hour notice with changes	$1,544,000
Savings with amendment and update	$4,631,000
Perishable Mexican Seafood Value Loss	
Option 10--12 hour minimum notice	$11,228,000
Option 11--12 hour notice with changes	$2,807,000
Savings with amendment and update	$8,421,000
Perishable Canadian Seafood Value Loss	
Option 10--12 hour minimum notice	$186,322,000
Option 11--12 hour notice with changes	$46,580,000
Savings with amendment and update	$139,742,000
Perishable Central American Seafood Value Loss	
Option 10--12 hour minimum notice	$25,180,000
Option 11--12 hour notice with changes	$6,295,000
Savings with amendment and update	$18,885,000

Although submitters can amend prior notice information with this option, we assume that those 10 percent of entry lines that cannot be amended, but instead have to wait an additional 12 hours to arrive in the United States would incur at least some truck costs corresponding to this wait time. Therefore we will assume that 10 percent of the 2.3 million lines that entered the United States by ground transportation in fiscal year 2002 (based on OASIS data) would pay for an additional 12 hours of truck time per line. We use 10 percent as the percentage of trucks delayed to be consistent with our resubmission rate of 10 percent when the prior notice submission timeframe is noon the calendar day before arrival with a 1-hour amendment option. Table 42 of this document shows the costs of truck time associated with those prior notices that cannot be amended.

TABLE 42.—COST OF ADDITIONAL CARRIER TIME FOR OPTION 11

2002 OASIS import entry lines by ground transportation (truck or train)	2,300,000
Average number of lines per entry	2.6
Total number of ground entries	884,615
10% of ground entries	88,462
Cost for 12 hours of carrier time ($250 per hour)	$3,000
Total cost of truck time	$265,386,000

Table 43 of this document presents a summary of the costs associated with option 11. Also presented in table 43 of this document are the present values of the costs associated with this option using the OMB-recommended discount rates of 3 and 7 percent.

Table 43.--Summary of Costs for Option 11 (12 noon the calendar day before arrival minimum submission time with amendment option 1 hour before arrival)

	Dollars (thousands)
Learning costs	$66,420
Coordination costs	$31,095
Computer acquisition costs	$7,600
FDA prior notice system cost	$13,000
Annual costs to fill out prior notice screens	$187,500
Additional costs for BRASS users	$48,462
Lost value for Mexican produce	$24,556
Lost value for Canadian produce	$2,853
Lost value for Central American produce	$1,544
Lost value for Mexican seafood	$2,807
Lost value for Canadian seafood	$46,580
Lost value for Central American seafood	$6,295
Cost of truck time	$265,386
Total first year costs for Option 11	$703,918
Annual costs after first year	$597,777
Present value of costs at 7% for 20 years	$6,432,050
Present value of costs at 3% for 20 years	$8,996,455

k. *Option 12: Prior notice received by 12 noon of the calendar day before arrival; electronic submission of information; allow changes to the prior notice submission up to 2 hours before arrival (proposed rule).* Option 12 is the option that was originally proposed by FDA. This option requires prior notice submission by noon on the calendar day before arrival, with updates and amendments that can be submitted up to 2 hours before scheduled arrival at a U.S. port. We re-present the option here for comparison, as the costs attributable to each option have changed significantly since the proposed rule stage.

For this option with amendment and updates, we assume that the number of prior notice resubmissions necessitated by changes in information on the notice would be reduced from 40 percent (as in option 10) to 15 percent. The notice resubmission rate for this option is expected to be higher than previous options with amendments because the original submission must be given by 12 noon on the calendar day prior to arrival and the minimum amendment timeframe before arrival is now 2 hours instead of 1 hour.

Option 12 saves 12 hours wait time per entry line that can be amended or updated for the prior notice over the time used in option 10. Those shipments whose prior notice must be completely resubmitted however, would wait an additional 12 hours at the manufacturing/processing facility or at the U.S. border; 7.1 percent of the perishable produce life span (12 hours out of 168 hours) and 25 percent of the perishable seafood life span (12 hours out of 48 hours). Table 44 of this document shows the costs of submitting prior notice for a 12-hour minimum time, with a 2-hour timeframe for amendment and updates before arrival, for Canadian, Central American, and Mexican perishable produce and seafood.

Table 44.--Loss in Value Caused by Resubmitted Prior Notice Under Option 12

Perishable Produce	Dollars
2001 Imported Mexican produce total retail value	$3,458,525,000
7.1% Reduction in value for 15% of Mexican produce	$36,833,000
2001 Imported Canadian produce total retail value	$401,826,000
7.1% Reduction in value for 15% of Canadian produce	$4,279,000
2001 Imported Central American produce total retail value	$217,420,000
7.1% Reduction in value for 15% of Central American produce	$2,316,000
Total Lost Value for Produce	$43,428,000
Perishable Seafood	
2001 Imported Mexican seafood total retail value	$112,277,000
25% Reduction in value for 15% of Mexican seafood	$4,210,000
2001 Imported Canadian seafood total retail value	$1,863,218,000
25% Reduction in value for 15% of Canadian seafood	$69,871,000
2001 Imported Central American seafood total retail value	$251,796,000
25% Reduction in value for 15% of Central American seafood	$9,442,000
Total Lost Value for Seafood	$83,523,000

Although submitters can amend prior notice information with this option, we assume that those 15 percent of entry lines that cannot be amended, but instead have to wait an additional 12 hours to arrive in the United States would incur at least some truck costs corresponding to this wait time. Therefore we will assume that 15 percent of the 2.3 million lines that entered the U.S. by ground transportation in fiscal year 2002 (based on OASIS data) would pay for an additional 12 hours of truck time per line. We use 15 percent as the percentage of trucks delayed to be consistent with our resubmission rate of 15 percent when the prior notice submission timeframe is noon the calendar day before arrival with a 2-hour amendment option. Table 45 of this document shows the costs of truck time associated with those prior notices that cannot be amended.

Table 45.--Cost of Additional Carrier Time for Option 12

2002 OASIS import entry lines by ground transportation (truck or train)	2,300,000
Average number of lines per entry	2.6
Total number of ground entries	884,615
15% of ground entries	132,692
Cost for 12 hours of carrier time ($250 per hour)	$3000
Total cost of truck time	$398,076,000

Table 46 of this document presents a summary of the costs associated with option 12. Also presented in table 46 of this document are the present values of the costs associated with this option using the OMB-recommended discount rates of 3 and 7 percent.

Table 46.--Summary of Costs for Option 12 (12 noon the calendar day before arrival minimum submission time with amendment option 2 hours before arrival)

	Dollars (thousands)
Learning costs	$66,420
Coordination costs	$31,095
Computer acquisition costs	$7,600
FDA prior notice system cost	$13,000
Annual costs to fill out prior notice screens	$187,500
Additional costs for BRASS users	$48,462
Lost value for Mexican produce	$36,833
Lost value for Canadian produce	$4,279
Lost value for Central American produce	$2,316
Lost value for Mexican seafood	$4,210
Lost value for Canadian seafood	$69,871
Lost value for Central American seafood	$9,442
Cost of truck time	$398,076
Total first year costs for Option 12	$878,924
Annual costs after first year	$772,783
Present value of costs at 7% for 20 years	$8,286,066
Present value of costs at 3% for 20 years	$11,600,102

4. Summary of Options

Table 47 of this document gives a summary of the costs associated with the prior notice rule for each option presented. The costs associated with the prior notice requirements are included for each option for all modes of transportation. These costs include the following items: Learning the rule, coordinating the required information, acquiring computer equipment, and annual submission costs for all imported food shipments. The cost of lost value for perishable products is included in each option calculation depending on mode of transportation and minimum prior notice submission time. Lost truck time is included for options with longer timeframes.

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Table 47.—Summary of Costs Associated With Each Option

Costs	Description of Option											
	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6	Option 7	Option 8	Option 9	Option 10	Option 11	Option 12
	No regulation	Prior notice 1 hour before arrival	Prior notice 2 hours before arrival	Prior notice 4 hours before arrival	Prior notice 1 hour before arrival for vehicles, 4 hours for trains and planes	Prior notice 2 hours before arrival for vehicles, 4 hours for trains and planes (interim final rule)	Prior notice 4 hours before arrival with 1 hour amendment	Prior notice 8 hours before arrival	Prior notice 8 hours before arrival with 1 hour amendment	Prior notice 12 noon the calendar day before arrival	Prior notice 12 noon the calendar day before arrival with 1 hour amendment	Prior notice 12 noon the calendar day before arrival with 2 hour amendment (proposed rule)
	Dollars (thousands)											
Learning costs	0	66,420	66,420	66,420	66,420	66,420	66,420	66,420	66,420	66,420	66,420	66,420
Coordination costs	0	31,095	31,095	31,095	31,095	31,095	31,095	31,095	31,095	31,095	31,095	31,095
Computer acquisition costs	0	7,600	7,600	7,600	7,600	7,600	7,600	7,600	7,600	7,600	7,600	7,600
FDA prior notice system cost	0	13,000	13,000	13,000	13,000	13,000	13,000	13,000	13,000	13,000	13,000	13,000
Annual costs to fill out prior notice screens	0	187,500	187,500	187,500	187,500	187,500	187,500	187,500	187,500	187,500	187,500	187,500
Additional costs for BRASS users	0	48,462	48,462	48,462	48,462	48,462	48,462	48,462	48,462	48,462	48,462	48,462
Lost value for perishable foods	0	1,616	6,465	56,547	8,174	12,877	6,415	154,561	25,760	307,184	76,796	126,951
Cost for truck time	0	0	0	44,231	0	0	22,115	132,693	88,462	338,462	265,386	398,076
First year cost of each option	0	355,513	360,362	454,675	362,071	366,774	383,079	656,897	470,744	1,046,282	703,918	878,924
Annual cost of each option	0	249,372	254,221	348,534	255,929	260,633	276,938	550,756	364,603	940,141	597,777	772,783
Present value total cost of each option at 7% for 20 years	0	2,741,043	2,792,413	3,791,567	2,810,515	2,860,342	3,033,077	5,933,909	3,961,802	10,059,060	6,432,050	8,286,066
Present value total cost of each option at 3% for 20 years	0	3,813,068	3,885,209	5,288,348	3,910,630	3,980,603	4,223,181	8,296,901	5,527,415	14,089,967	8,996,455	11,600,102

Sensitivity analysis. We estimate that the costs of the interim final rule (option 6) will be about $367 million in the first year and $261 million in later years. At a 7 percent discount rate, the present value of the costs of the interim final rule, discounted 20 years into the future, would be about $3 billion; for a discount rate of 3 percent, the present value costs would be $4 billion. These estimates rely on several important assumptions:

- In option 6, for perishable products from Canada, Mexico, and Central America: 5 percent of prior notices will need to be resubmitted if the notice must be submitted 2 hours before arrival for vehicles; 20 percent of prior notices will need to be resubmitted if the notice must be submitted 4 hours before arrival for air and rail.
- The minimum entry time for food shipments imported over land and by air is a constraining factor for those importers who use these modes of transportation. The additional costs for shipments made over land and by air are greater for a specified minimum prior notice time, the closer the facility is to the U.S. border. Shipments arriving by sea are not likely to be affected by a specified minimum prior notice time.
- The retail value of imported fresh seafood and produce is 100 percent higher than its wholesale value.
- The number of entry lines requiring prior notice will not increase over time.
- Prior notice must be submitted for informal food entries, *i.e.*, international mail.
- BRASS is not compatible with submitting prior notice.

We now present a sensitivity analysis, which shows how our estimates of costs for the interim final rule change if we use different assumptions. We substitute the following assumptions for those used previously:

- In option 6 for perishable products from Canada, Mexico, and Central America: 10 percent of prior notices will need to be resubmitted when the prior notice time is 2 hours before arrival for vehicles; 40 percent of prior notices will need to be resubmitted if the prior notice must be submitted 4 hours before arrival for shipments arriving by rail and air.
- The retail value of imported fresh seafood and produce is 200 percent higher than its wholesale value.
- The number of entry lines requiring prior notice will increase 3 percent per year.
- Prior notice does not need to be submitted for informal food entries, *i.e.*, international mail.
- BRASS is compatible with submitting prior notice.

Tables 48 and 49 of this document show the results of the sensitivity analysis. The tables show that the estimated cost of the interim final rule is most sensitive to the assumed fraction of prior notices that will need to be changed. The present value of the interim final rule is most sensitive to the rate of discount.

Table 48.--Sensitivity Analysis for Assumptions Made for Option 6 (interim final rule)

Test	First Year Cost Under Base Assumption	First Year Cost Under Test Assumption	Change in First Year Cost (or value)	Percent Change in Cost
	($ millions)			
10 and 40% prior notices changed	$367	$380	$13	4
Retail value is 200% of wholesale value	$367	$380	$13	4
Prior notice entries increase 3%	$367	$372	$5	1
Informal entries do not submit prior notice	$367	$329	-$38	-10
BRASS is compatible with submitting prior notice	$367	$318	-$49	-13

Table 49.--Present Values for Sensitivity Analysis for Assumptions Made for Option 6 (interim final rule)

Test	Present Value of Total Cost ($ billions)	Present Value Under Test Assumption ($ billions)	Change in Present Value ($ billions)	Percent Change in Present Value
40% prior notices changed (7% present value)	$2.9	$4.3	$0.1	3
40% prior notices changed (3% present value)	$4	$4.2	$0.2	5
Retail value is 200% of wholesale value (7% present value)	$2.9	$3	$0.1	3
Retail value is 200% of wholesale value (3% present value)	$4	$4.2	$0.2	5
Prior notice entries increase 3% (7% present value)	$2.9	$2.9	$0	0
Prior notice entries increase 3% (3% present value)	$4	$4.1	$0.1	3
Informal entries no prior notice (7% present value)	$2.9	$2.5	-$0.4	-14
Informal entries no prior notice (3% present value)	$4	$3.4	-$0.4	-10
BRASS compatible with prior notice (7% present value)	$2.9	$2.3	-$0.6	-21
BRASS compatible with prior notice (3% present value)	$4	$3.3	-$0.7	-18

5. Benefits

The FDA prior notice system will provide FDA with enhanced knowledge of what articles of food are being imported or offered for import into the United States including the anticipated port of arrival, the country of production, and the specific product identity. Requiring prior notice of imported food shipments and defining the required data information will therefore improve FDA's ability to detect accidental and deliberate contamination of food and to deter deliberate contamination.

Currently, FDA does not receive much advance notice about food products entering the United States from foreign sources, or the location of the food's anticipated port of arrival. With the information required by this interim final rule, FDA will know in advance what articles of food are being imported or offered for import, before they arrive at the port. In the event of a credible threat for a specific product or a specific manufacturer/processor, for example, FDA will be able to mobilize and assist in the detention and removal of products that may be a serious health threat to human or animals.

FDA plans to review prior notices in a central location, on a 24/7 basis. These persons will decide on a case-by-case basis whether the article of food needs to be held. Because prior notice will be linked through ABI/ACS system in most instances, if FDA wishes to stop and hold a shipment for examination, inspection, sampling, or other purpose and does not have personnel at the needed location, pursuant to a Memorandum of Understanding between FDA and CBP, CBP will act on FDA's behalf until FDA personnel can reach the location. The prior notice system linked through ABI/ACS will allow FDA to send messages to the screens of individual CBP staff, ensuring that time sensitive information is received and acted upon by the appropriate persons. Having notice of an article of food imported or offered for import into the United States before it reaches a U.S. port will allow FDA personnel to be ready to respond to shipments that appear to pose a significant and immediate serious risk to public health.

Historical evidence suggests that a terrorist or other intentional strike on the food supply is a low-probability, but potentially high-cost event. FDA has conducted its own assessment of the vulnerability of the U.S. food supply and additionally has commissioned two threat assessments, one through the Battelle Memorial Institute and a second through the Institute of Food Technologists. These assessments determined the most serious risks of intentional contamination during various stages of food production and distribution. The results of these assessments are classified. We have also received intelligence information regarding threats to the food supply that are guiding our food security efforts. Nonetheless, FDA lacks data to estimate the likelihood of a strike occurring. Without knowing the likelihood of a strike occurring, we cannot quantitatively measure the reduction in probability of an event occurring.

We can, however, show the potential risk associated with contaminated imported foods. Many past outbreaks have been traced to imported foods (Refs. 12 and 13); table 50 of this document gives some examples. An intentional attack on the food supply that sought to disrupt the food supply and sicken many U.S. citizens could be much larger than the examples given in table 50.

The potential hazard associated with a single shipment of imported food is large. For example, a single line entry from OASIS for a truckload of imported cantaloupe (gross weight 1,000 lb) represents 510 lb (231,332 grams) (g) of edible food, or 1,652 (140 g) servings. If an entire line or shipment is contaminated, then that number of servings represents the potential

exposure to the hazard. The FDA prior notice system alone will not prevent such exposures, but by increasing the amount of information available and giving FDA notice in advance of arrival, an essential component of the barrier against accidental or deliberate contamination of food is formed. FDA is better able to integrate intelligence, vulnerability, and entry data to plan import surveillance activities as a result.

Table 50.--Examples of Outbreaks Resulting From Imported Foods

Pathogen	Location and Year	Vehicle	Number of Cases
Salmonella Poona	Western United States, 2001	Cantaloupe (from Mexico)	29 cases, 4 hospitalizations, 2 deaths
S. Lexington S. Java ETEC; E. coli O6:H16 and O25:NM Giardia	Cruise ship, 2000	Raw frozen shrimp cooked on board	224 cases, with 9 (possibly more) laboratory confirmed
Cyclospora cayaetanensis	United States and Canada, 1996	Raspberries (probably imported from Guatemala)	1,465 cases identified, fewer than 20 hospitalizations
Salmonella typhi, hepatitis A	Florida, 1996	Homemade cheese (from Mexico)	9 cases Salmonella, 14 cases Hepatitis A
Salmonella Stanley	17 States, 1995	Alfalfa sprouts (seeds from Netherlands)	242 cases
Shigella flexneri, type 6 (SF6)	Illinois, 1994	Green onions (Mexico suspected)	171 cases

We can examine the high costs of a potential terrorist event by comparing costs of responding to a terrorist event with and without the advantage of having the FDA prior notice system. For example, if U.S. officials or FDA receives intelligence concerning the possibility of an intentional contamination of an incoming food shipment, in absence of prior notice, even with information on the type of food product, officials would be unlikely to know when and where the food was expected to cross U.S. borders. In this case, it is likely that officials would slow down the movement of food shipments through the border ports or possibly even close down some ports of entry to prevent the contaminated articles from entering the United States.

Information on the west coast port lock-out during Fall 2002, indicated that the closing of 29 major west coast ports cost the U.S. economy $1 billion a day (Refs. 14 and 15). Given that there are 361 ports of entry for the entire United States, if U.S. officials had to close all ports to prevent contaminated food from entering the country, the U.S. economy could lose upwards of $12.5 billion each day the ports remain closed. This cost exceeds the first year costs ($367 million), the annual costs ($261 million), and the present value of costs ($3 billion at the 7 percent discount rate and $4 billion at the 3 percent discount rate) for the chosen option of this rule. Thus, having the FDA prior notice system does not eliminate, but may significantly reduce the costs of a terrorist attack on the food supply as compared to not having the system.

TABLE 51.—COST BENEFIT SUMMARY TABLE

	Annualized costs over 20 years at 7% discount rate ($ millions)	Annualized costs over 20 years at 3% discount rate ($ millions)
Option 5—2 hour prior notice for vehicle, 4 hour for rail and air, 8 hour vessels (interim final rule)	$272	$269
Benefits—FDA will know in advance what articles of food are being imported or offered for import, before they arrive at the port. In the event of a credible threat, FDA will be able to mobilize and assist in the detention and removal of specific products that may pose a serious health threat to human or animals.		

B. Small Entity Analysis (or Final Regulatory Flexibility Analysis)

FDA has examined the economic implications of this interim final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities consistent with statutory objectives. FDA finds that this interim final rule will have a significant economic impact on a substantial number of small entities.

1. Number of Establishments Affected

FDA finds that this interim final rule would affect 77,427 U.S. importers. Most of these importers have fewer than 500 employees, thus making them small

businesses as defined by the Small Business Administration. Because most of the importers affected are small, all options considered in the Benefit-Cost Analysis in section IV.A of this document are regulatory relief options.

A few comments stated that FDA's analysis of the impact of prior notice on small businesses was inadequate. The comments also wished to see a breakdown of costs of the rule per small business by industry sector. Unfortunately, FDA does not have detailed information on which businesses subject to this interim final rule are small, nor did comments provide such information. Therefore, FDA cannot perform a detailed analysis of the costs per small business by industry sector. With limited data, FDA can estimate an average cost per importer for some of the prior notice cost categories, estimate some costs of the rule per retail establishment, and provide an average estimate of cost per establishment if the costs of the rule were evenly distributed across the supply chain.

2. Costs per Entity

This interim final rule requires FDA be notified of incoming products electronically before the food arrives at a U.S. port. The annual cost of doing so is about $2,400 per submitter (based on $187.5 million in notification costs/77,427 U.S. importers). This calculation is presented in table 52 of this document. Also presented in table 52 is the cost per importer to learn about the prior notice interim final rule and to coordinate the information that needs to be submitted; the costs per importer of these two activities are about $850 and $400, respectively.

As discussed and shown in tables 1B and 2 of this document, about 3,100 U.S. importers are estimated to not have electronic transmitting capacity and will have to obtain computer equipment (at a cost of about $2,000 per importer) and Internet access (at a cost of about $240 annually) in order to comply with this interim final rule. FDA could not provide flexibility for those importers who do not have electronic transmitting capacity, because paper notices could not be submitted in the prior notice timeframe and would therefore actually be more burdensome to importers, and because FDA would not be able to receive, review, and respond to paper prior notices that are submitted on a routine basis.

This interim final rule will cause some loss of product value if the prior notice requirement causes perishable products to have to wait any length of time before arriving at a U.S. port. The costs of lost product value vary with the required notice time. FDA does not have information on the subset of importers who will be affected by these costs; therefore, we cannot calculate a cost per importer for these potential losses. We do discuss the various costs associated with this possibility in the options outlined previously.

Table 52 of this document shows the average costs per importer to learn the rule, coordinate information, and submit prior notice. Table 52 also shows the average costs to the importer to absorb the costs of not being able to use BRASS and to absorb costs of lost value of perishable products. Table 52 also shows these average costs per retail establishment and per establishment across the supply chain. Numbers for establishments come from the County Business Patterns, U.S. Census, and Non-Employer statistics. A complete discussion of these establishment numbers can be found in the FDA Registration of Food Facilities interim final rule (Ref. 20).

Table 52.--Costs per Importer and per Establishment

Activity	Total Costs	Cost per importer (n= 77,427)
Learning costs	$66,240,000	$856
Coordination costs	$31,095,000	$402
Annual costs to fill out prior notice screens	$187,500,000	$2,422
Costs for BRASS users	$48,462,000	$626
Lost value for perishables	$12,877,000	$166
Total estimated average costs per importer		$4,472
Total estimated average costs per retail establishment (n= 238,697)		$1,450
Total estimated average costs per establishment in the distribution chain (n= 454,968)		$761

3. Additional Flexibility Considered

Because of the requirements of the Bioterrorism Act, FDA is precluded from selecting some of the options that typically would be considered to lessen the economic effect of the interim final rule on small entities, including granting an exemption to small entities. FDA concludes that it would be inconsistent with section 307 of the Bioterrorism Act to allow small entities a later effective date, since the Bioterrorism Act establishes an effective date for prior notice that applies to FDA-regulated food imported or offered for import into the United States, whether or not FDA has issued a final rule by this deadline. Thus, FDA concludes that Congress intended for prior notice to apply to FDA-regulated food by the effective date established in the Bioterrorism Act.

C. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses before any rulemaking if the rule would include a ''Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' The current inflation-adjusted statutory threshold is $113 million. FDA has determined that this interim final rule is significant under the Unfunded Mandates Reform Act. FDA has carried out the cost-benefit analysis in preceding sections (*see* table 47 of this document for the total costs). The other requirements under the Unfunded Mandates Act of 1995 include assessing the rule's effects on the following factors:

- Future costs;
- Particular regions, communities, or industrial sectors;
- National productivity;
- Economic growth;
- Full employment;
- Job creation; and
- Exports.

The issues listed in the bullets are covered in detail in the cost benefit analysis of the preceding sections, with the exception of the trade effects of this interim final rule, which we will discuss here.

Although most of the information required for prior notice is already supplied to CBP when importing food products, this new notice requirement may cause a reduction of imports of certain food products into the United States. For example, food manufacturers, processors, or growers may choose to stop exporting food products to the United States if the additional costs of complying with the prior notice increase the price of the imported product (or perhaps decrease the quality of the product) to the point where they cannot compete with a domestically-grown or produced product. This may be the case for food products that are grown or produced in the United States with an elastic enough supply to meet consumer demand without large increases in price. For example, if Florida-grown and California-grown oranges meet the demand for the fruit in this country at or close to current prices, then it is unlikely that the United States will import many oranges from other countries, if the price of the imported product rises (or the product quality is lowered) because of the prior notice requirement.

On the other hand, for example, there are products for which substitutes, and more specifically, U.S. grown or produced substitutes, are not available. In these cases, and in cases where U.S. demand for the product greatly exceeds domestic supply, importers will pass along to the consumer any increase in price for the product brought about by the prior notice requirement (as long as the quality and other attributes of the product remain intact). For example, exotic fruits such as coconuts, mangoes, and papayas are not grown in significant quantities in the United States; if the demands for those fruits are relatively inelastic, there will not be a significant decrease in quantity demanded in the United States when the importers raise the price of the fruit to cover the costs of submitting prior notice.

D. SBREFA Major Rule

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with SBREFA, OMB has determined that this interim final rule is a major rule for the purpose of congressional review.

VI. Paperwork Reduction Act of 1995

This interim final rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual reporting burden. The estimate includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information, *i.e.,* each prior notice.

Title: Prior Notice of Imported Food.

A. Description

Section 801(m) of the FD&C Act (21 U.S.C. 381(m)) requires prior notice to the Secretary of Health and Human Services (the Secretary) of an article of food that is being imported or offered for import into the United States. Section 801(m)(1) of the FD&C Act states that the Secretary shall require submission of notice providing the identity of each of the following: The article of food; the manufacturer; the shipper; the grower, if known at the time of notification; the originating country; the shipping country; and the anticipated port of arrival. Section 801(m)(2)(A) of the FD&C Act states that the Secretary shall by regulation prescribe the time of submission of the notification in advance of importation or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed 5 days. FDA's prior notification of imported food shipments interim final rule implements these statutory provisions.

1. Comments on the Burden of Information Collection

Some comments on the proposed burden of information collection stated that the information collection would not be necessary if ABI/ACS could be used to submit the required information. Other comments stated that the information collection was unproductive and unduly burdensome for the benefits it would provide. Still other comments stated that FDA had underestimated the hours associated with the reporting burden.

FDA's agreement with CBP to allow most prior notices to be submitted through ABI/ACS will greatly reduce the burden of this new collection of information.

A few comments were concerned that FDA had underestimated the proposed burden because they did not understand that FDA had calculated the submitting burden based on import entries, not entry lines. For each import entry, the prior notice or notices are expected to take about an hour to file. The prior notice or notices for each import entry would cover approximately 2.6 lines, with each line representing a different article of food to be imported. For this interim final rule burden of information analysis, FDA has clarified how the estimates were calculated to allay the comments' concerns.

2. Information Collection Burden Estimate

FDA estimates the burden for this information collection as follows:

Table 53.--Estimated Annual Reporting Burden

21 CFR Section	No. Of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Capital Costs	Operating and Maintenance Costs	Total Hours
1.279-1.285[1]	77,427	1	77,427	40	$6,194,000	$743,000	3,097,080
1.279-1.285[1]	7,743	1	7,743	40	$620,000	$74,400	309,715
1.280-1.281[2]	77,427	84	6,500,000	0.384	$0	$0	2,500,000
1.282[2]	77,427	3.36	260,000	0.5	$0	$0	130,000
1.283(a)(2)(iv), 1.285(c)(4)[2]	77,427	0.168	13,000	0.25	$0	$0	3,250
1.283(a)(5)(ii)[2]	77,427	1.26	97,500	1	$0	$0	97,500
1.283(a)(7)[2]	77,427	0.105	8,125	0.25	$0	$0	2,031
1.283(a)(6)(i)-(a)(6)(iv), 1.285(f)(1)-(f)(4)[2]	77,427	0.168	13,000	8	$0	$0	104,000
Total one time burden hours							3,406,795
Total recurring burden hours							2,836,781

[1] One time burden.

[2] Recurring burden.

B. Hour Burden Estimate

1. Number of Establishments Affected

Using 2001 fiscal year information from OASIS (industry codes 02 through 52, 54, and 70 through 72), FDA has determined that there are approximately 77,427 importers and consignees who receive shipments of food imported or offered for import into the United States. FDA does not have specific information on who will submit prior notice since there are no restrictions on who can submit prior notice. Therefore, FDA estimates prior notice submission information based on the 77,427 importers of food in OASIS.

2. New and Closing Importers

In addition to the U.S. importers currently in existence, in future years new import businesses will open and some existing import businesses will close. These new submitters would have to become familiar with the FDA prior notice system and possibly obtain computer equipment and Internet access to comply with prior notice requirements.

According to the Small Business Administration Office of Advocacy, in 2001, about 10 percent of all businesses were new and 10 percent of businesses closed. Using the 10 percent opening and closing business statistic, and given that there are currently 77,427 U.S. importers, FDA assumes that on a yearly basis 7,743 importers will leave the market and 7,743 importers will enter the market.

3. Hour Burden Estimate Researching the Prior Notice Requirement

a. *Learning the interim final rule.* To become familiar with the requirements for this interim final rule, FDA estimates that one manager and two subordinates from each importing business will attend an 8-hour training session on the prior notice regulation. This one-time research burden for the existing importers is about 1,858,248 hours (3 people per firm × 8 hours × 77,427 importers). This portion of the estimate is for 21 CFR part 1, subpart I, 1.279 through 1.285 and is shown in row 1 of table 53 of this document.

In the years that follow the startup year for prior notice, it is reasonable to expect a certain percentage of importing firms to enter and leave the market. In addition to the first year burden to research prior notice, it is expected that 185,832 hours will be spent annually researching the prior notice requirement by the anticipated 7,743 new importers entering the market annually that must learn about prior notice (3 people per firm × 8 hours × 7,743 new importers). This portion of the estimate is for 21 CFR part 1, subpart I, 1.279 through 1.285 and is shown in row 2 of table 53 of this document.

b. *Coordinating the information.* FDA assumes it will take about 2 business days (16 hours) for an administrative employee of the prior notice-submitting firm to coordinate with others to establish new business practices required to receive the information needed for prior notice. We assume this set-up time is sufficient to coordinate information for existing importing accounts. The total hours needed to gather information for existing accounts is 1,238,832 (77,427 importing firms × 16 hours per firm). This portion of the estimate is for 21 CFR part 1, subpart I, 1.279 through 1.285 and is shown in row 1 of table 53 of this document. Thus, the total burden listed in row 1 is 1,858,248 hours + 1,238,832 hours = 3,097,080 one-time burden hours to learn the rule and coordinate information.

In addition to the first year coordination burden, we expect importing businesses to see a 10 percent turnover in their accounts. Thus, in future years, importing firms will spend 123,883 hours to gather information on their new accounts. This portion of the estimate is for 21 CFR part 1, subpart I, 1.276 through 1.285 and is shown in row 2 of table 53 of this document. Thus, the total burden listed in row 2 is 185,832 hours + 123,883 hours = 309,715 one-time burden hours for new firms to learn the rule and coordinate information.

4. Submitting Prior Notice

To estimate the repetitive effort of submitting a prior notice, FDA assumes the activity takes 1 hour each time an import entry is submitted. An import

entry, on average, constitutes 2.6 different articles of food; a prior notice must be submitted for each article of food. Therefore we estimate that submitting prior notice for each article of food will take 23 minutes to complete (23 minutes per line = 60 minutes/2.6 lines per entry). On an annual basis, submitting prior notice will take about 2.5 million hours (23 minutes (or 0.384 hours) per prior notice × 6.5 million notices). This estimate is for 21 CFR part 1, subpart I, 1.280 through 1.281 and is shown in row 3 of table 53 of this document.

FDA does not have information on how many prior notices will come from each of the 77,427 importers. However, we assume that 6.5 million prior notices will be submitted annually based on fiscal year 2002 OASIS information and estimates of prior notice capacity. We divide 6.5 million lines by the 77,427 importers to get an average annual response frequency per importer of 84 notices.

5. Changes to a Confirmed Prior Notice

The annual total number of changes made by importers to confirmed prior notices will vary depending on the minimum prior notice submission time required. For example, more confirmed prior notices will likely have to be changed if the minimum prior notice submission time is noon the calendar day before arrival as opposed to a minimum submission time of 2 hours before arrival. FDA's interim final rule requires a minimum prior notice submission time for each of the following situations: 2 hours before arrival for articles of food imported by vehicle, 4 hours before arrival for articles of food imported by rail and air, and 8 hours before arrival for articles of food imported by vessel.

By combining the percentages by mode of transport and taking into account the location of the exporting country, we assume that about 4 percent of all prior notices (260,000 notices) will have to be resubmitted after confirmation is received from FDA. We assume that changes in the prior notices will be minor adjustments; therefore, both the cancellation of the original notice and the resubmission of the new notice are estimated to take about 30 minutes. This estimate is for 21 CFR part 1, subpart I, 1.282 and is shown in row 4 of table 53 of this document.

6. Refused Admission

Although FDA at this time does not have enough information to estimate a percent of refusals under the new prior notice program, for the purposes of this analysis FDA estimates the reporting burden assuming a 2 percent refused admission rate.

An imported food product is subject to refusal under section 801(m)(1) of the FD&C Act if it arrives at the port of arrival with untimely, inaccurate, or no prior notice. FDA estimates that about 130,000 of the annual prior notices will be subject to refusal (2 percent of 6.5 million prior notices).

If an article of food is refused under section 801(m)(1) of the FD&C Act, the food must be held until the prior notice has been correctly submitted or until the product is exported. FDA must be notified of the location where the food has been or will be moved within 24 hours of refusal.

In many cases, the location notice will be given as part of a correction and resubmission, as described in the next section. FDA estimates that 13,000 out of the 130,000 annual refusals will give the location notice separately and that it will take about 15 minutes per prior notice to notify FDA of the shipment's location. This will result in about 3,250 hours (13,000 notices × 0.25 hours). This estimate is for 21 CFR part 1, subpart I, 1.283(a)(2)(iv) and 1.285(c)(4) and is shown in row 5 of table 53 of this document.

7. Correction and Resubmission of Prior Notice

FDA estimates that 97,500 out of the 130,000 annual refusals will be because of inaccurate prior notice requiring resubmission, or because no prior notice was submitted. FDA estimates that it will take an hour to cancel, correct, and resubmit, or submit (in the case of no notice) each of these 97,500 notices. This estimate is for 21 CFR part 1, subpart I, 1.283(a)(5)(ii) and is shown in row 6 of table 53 of this document.

8. Exportation of Products Refused Admission

Some importers of articles of food that have been refused admission into the United States will decide to export their product rather than try to submit or resubmit prior notice. FDA estimates that this will occur for only about 25 percent of the 130,000 articles refused admission for inaccurate, untimely, or no prior notice. If an article of food is refused admission under section 801(m)(1) of the FD&C Act and exported, FDA requests, but does not require, that prior notice be cancelled. FDA estimates that for these 32,500 articles of food, prior notice will be cancelled 25 percent of the time and that this cancellation will take 15 minutes per article. This estimate is for 21 CFR part 1, subpart I, 1.283(a)(7) and is shown in row 7 of table 53 of this document.

9. FDA Review Request

If an article of food to be imported is refused under section 801(m)(1) of the FD&C Act or placed under hold under section 801(1), a request may be submitted asking for an FDA review. FDA estimates that of the 130,000 articles of food that are refused admission under section 801(m)(1) of the FD&C Act or placed under hold under section 801(1) of the FD&C Act yearly, 10 percent will request an FDA review (13,000 reviews). FDA estimates that it will take the requestor about 8 hours to prepare the factual and legal information necessary to request a review. Thus, importers will spend about 104,000 hours on review requests annually. This estimate is for 21 CFR part 1, subpart I, 1.283(a)(6)(i) through (a)(6)(iv) and 1.285(f)(1) through (f)(4) and is shown in row 8 of table 53 of this document.

C. Capital Cost and Operating and Maintenance Cost Burden

Since all prior notices must be submitted electronically, we assume that the 3,097 responsible parties without Internet access (4 percent of the 77,427 importers) will have to purchase the appropriate computer equipment and gain Internet access to transmit the information. Assuming computer equipment costs each firm $2,000 and yearly Internet access costs each firm $240 ($20 per month for 12 months), this results in a one-time computer cost for these facilities of $6,194,000 and a recurring Internet access cost of $743,000. This estimate is for 21 CFR part 1, subpart I, 1.279 through 1.285 and is included in row 1 of table 53 of this document.

For the 7,743 new firms that enter the import market each year, we expect 310 of them to need to purchase computer equipment and obtain Internet access. On an annual basis we expect new importers to spend $620,000 on computers and $74,400 on Internet access to be able to submit their prior notice information. This estimate is for 21 CFR part 1, subpart I, 1.279 through 1.285 and is included in row 2 of table 53 of this document.

The information collection provisions of this interim final rule have been submitted to OMB for review.

Prior to the effective date of this interim final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this interim final rule. An agency may not conduct

or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VII. Analysis of Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Federalism

FDA has analyzed this interim final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. References

The following references have been placed on display in the Division of Dockets Management (*see* **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses, but is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.

1. Ruling NY G89921 (June 12, 2001), U.S. Bureau of Customs and Border Protection, *http://rulings.customs.gov.*

2. Bureau of Economic Analysis, *http://www.bea.doc.gov.*

3. U.S. Department of Labor, Bureau of Labor Statistics, ''National Compensation Survey: Occupation Wages in the United States, 2000, Summary 01–04,'' available at *http://www.bls.gov/ncs/ocs/sp/ncbl0354.pdf.*

4. USDA Agricultural Marketing Service, March 2002, ''Fresh Fruits and Vegetable Shipments,'' *http://www.ams.usda.gov.*

5. Kasmire, Dr. Robert F., Vegetable Marketing Specialist, *http://www.thepacker.com/rbcs/handbookarticles/properis.htm,* accessed on 9.16.02.

6. USDA Agricultural Marketing Service produce point price reports for various border crossings for the dates September 12, 2002, and September 16, 2002, *http://www.ams.usda.gov.*

7. Florida Department of Agriculture and Consumer Services (FDACS), *http://www.ffva.com/rps.htm.*

8. National Marine Fisheries Service, Fisheries Statistics and Economics Division, *http://www.st.nmfs.gov,* accessed September 2002.

9. Florida Department of Agriculture and Consumer Services, *http://doacs.state.fl.us/press/1999/090999.html* and *http://www.ffva.com/rps.htm.*

10. Center for Food Safety and Applied Nutrition, *http://www.cfsan.fda.gov/~dms/qa-sto8.html.*

11. Small Business Administration Office of Advocacy, ''Small Business by the Numbers'', May 2002, *http://www.sba.gov/advo/.*

12. Herwaldt B.L., M.L. Ackers, and Cyclospora Working Group, ''An Outbreak in 1996 of Cyclosporiasis Associated With Imported Raspberries,'' *New England Journal of Medicine,* May 29, 1997, 1548–1556.

13. Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable, GAO Publication, April 1998, *http://www.gao.gov.*

14. ''Port Lockout Could Harm U.S. Economy,'' *http://www.firstcoastnews.net/news/2002–10–01/usw_portlockout.asp.*

15. ''Transportation official says strike at U.S. port would ripple across globe,'' *http://www.govexec.com/dailyfed/0202/022702gsn1.htm.*

16. ''The Informal Sector in El Salvador,'' Embassy of the United States of America in El Salvador, *http://sansalvador.usembassy.gov/* Select Economic Info (left column), then select the first option ''Economic and Commercial Reports, Updates,'' at next screen under Socio-Economic Reports, select the last article ''The Informal Sector in El Salvador, 1999,'' and Import Alert 1A1211, FDA Guidance, March 1998, *http://www.fda.gov/ora/_import_ia1211.html.*

17. Guidance for Industry, Importers and Filers, Food Security Preventive Measures Guidance, FDA Publication, March 2003.

18. Investigations Operations Manual, FDA Publication, page 179.

19. FDA Registration of Food Facilities interim final rule, published elsewhere in the issue of the **Federal Register**.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1 is amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for 21 CFR part 1 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. Subpart I, consisting of §§ 1.276 through 1.285, is added to part 1 to read as follows:

Subpart I—Prior Notice of Imported Food

General Provisions

Requirements to Submit Prior Notice of Imported Food

Consequences

General Provisions

§ 1.276 What definitions apply to this subpart?

(a) *The act* means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms in section 201 of the act (21 U.S.C. 321) apply when the terms are used in this subpart, unless defined below.

(1) *Calendar day* means every day shown on the calendar.

(2) *Country from which the article originates* means FDA Country of Production.

(3) *Country from which the article is shipped* means the country in which the article of food is loaded onto the conveyance that brings it to the United States or, in the case of food sent by international mail, the country in which the article will be mail.

(4) *FDA Country of Production* means:

(i) For an article of food that is in its natural state, the country where the article of food was grown, including harvested or collected and readied for shipment to the United States. If an article of food is wild fish, including seafood that was caught or harvested outside the waters of the United States by a vessel that is not registered in the United States, the FDA Country of Production is the country in which the vessel is registered. If an article of food that is in its natural state was grown,

including harvested or collected and readied for shipment, in a Territory, the FDA Country of Production is the United States.

(ii) For an article of food that is no longer in its natural state, the country where the article was made; except that, if an article of food is made from wild fish, including seafood, aboard a vessel, the FDA Country of Production is the country in which the vessel is registered. If an article of food that is no longer in its natural state was made in a Territory, the FDA Country of Production is the United States.

(5) *Food* has the meaning given in section 201(f) of the act,

(i) Except for purposes of this subpart, it does not include:

(A) Food contact substances as defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)); or

(B) Pesticides as defined in 7 U.S.C. 136(u).

(ii) Examples of food 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.

(6) *Grower* means a person who engages in growing and harvesting or collecting crops (including botanicals), raising animals (including fish, which includes seafood), or both.

(7) *International mail* means foreign national mail services. International mail does not include express carriers, express consignment operators, or other private delivery services.

(8) *No longer in its natural state* means that an article of food has been made from one or more ingredients or synthesized, prepared, treated, modified, or manipulated. Examples of activities that render food no longer in its natural state are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. Crops that have been cleaned (*e.g.*, dusted, washed), trimmed, or cooled attendant to harvest or collection or treated against pests, waxed, or polished are still in their natural state for purposes of this subpart. Whole fish headed, eviscerated, or frozen attendant to harvest are still in their natural state for purposes of this subpart.

(9) *Port of arrival* means the water, air, or land port at which the article of food is imported or offered for import into the United States, *i.e.*, the port where the article of food first arrives in the United States. This port may be different than the port where consumption or warehouse entry or foreign trade zone admission documentation is presented to the United States Bureau of Customs and Border Protection (CBP).

(10) *Port of entry*, in sections 801(m) and 801(l) of the act, means the port of entry as defined in 19 CFR 101.1.

(11) *Registration number* refers to the registration number assigned by FDA under section 415 of the act (21 U.S.C. 350d) and 21 CFR part 1, subpart H.

(12) *Shipper* means the owner or exporter of the article of food who consigns and ships the article from a foreign country or the person who sends an article of food by international mail to the United States.

(13) *United States* means the Customs territory of the United States (*i.e.*, the 50 states, the District of Columbia, and the Commonwealth of Puerto Rico), but not the Territories.

(14) *You* means the person submitting the prior notice, *i.e.*, the submitter, or the person transmitting prior notice information on behalf of the submitter, *i.e.*, the transmitter.

§ 1.277 What is the scope of this subpart?

(a) This subpart applies to 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.

(b) Notwithstanding paragraph (a), this subpart does not apply to:

(1) Food for an individual's personal use when it is carried by or otherwise accompanies the individual when arriving in the United States;

(2) 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;

(3) Food that is imported then exported without leaving the port of arrival until export;

(4) Meat food products that at the time of importation are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*);

(5) Poultry products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*); and

(6) Egg products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

Requirements To Submit Prior Notice of Imported Food

§ 1.278 Who is authorized to submit prior notice?

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

§ 1.279 When must prior notice be submitted to FDA?

(a) Except as provided in paragraph (c) of this section, you must submit the prior notice to FDA and the prior notice submission must be confirmed by FDA for review as follows:

(1) If the article of food is arriving by land by road, no less than 2 hours before arriving at the port of arrival;

(2) If the article of food is arriving by land by rail, no less than 4 hours before arriving at the port of arrival;

(3) If the article of food is arriving by air, no less than 4 hours before arriving at the port of arrival; or

(4) If the article of food is arriving by water, no less than 8 hours before arriving at the port of arrival.

(b) Except in the case of an article of food imported or offered for import 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.

(c) Notwithstanding paragraphs (a) and (b) of this section, if the article of food is arriving by international mail, you must submit the prior notice before the article of food is sent to the United States.

(d) FDA will notify you that your prior notice has been confirmed for review with a reply message that contains a Prior Notice (PN) Confirmation Number. Your prior notice will be considered submitted and the prior notice time will start when FDA has confirmed your prior notice for review.

(e) The PN Confirmation Number must accompany any article of food

arriving by international mail. The PN Confirmation Number must appear on the Customs Declaration that accompanies the package.

(f) A copy of the confirmation including the PN Confirmation Number, must accompany any article of food that is subject to this subpart when it is carried by or otherwise accompanies an individual when arriving in the United States. The copy of the confirmation must be provided to CBP or FDA upon arrival.

(g) The PN Confirmation Number must accompany any article of food for which the prior notice was submitted through the FDA Prior Notice System Interface (FDA PN System Interface) when the article arrives in the United States and must be provided to CBP or FDA upon arrival.

§ 1.280 How must you submit prior notice?

(a) You must submit the prior notice electronically to FDA. 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. Unless paragraph (d) of this section applies, you must submit prior notice through:

(1) The CBP Automated Broker Interface of the Automated Commercial System (ABI/ACS); or

(2) The FDA PN System Interface at *http://www.access.fda.gov*. You must submit prior notice through the FDA PN System Interface for articles of food imported or offered for import by international mail, other transaction types that cannot be made through ABI/ACS, and articles of food that have been refused under section 801(m)(1) of the act and this subpart.

(b) If a custom broker's or self-filer's system is not working or if the ABI/ACS interface is not working, prior notice must be submitted through the FDA PN System Interface.

(c) If FDA determines that FDA PN System Interface is not working, FDA will issue notification at *http://www.access.fda.gov* and FDA Web site at *http://www.fda.gov* —see Prior Notice. Once FDA issues this notification, if you intended to use the FDA PN System Interface to submit a prior notice, you must submit prior notice information by e-mail or by fax to FDA. The location for receipt of submission by e-mail or fax is listed at *http://www.fda.gov*—see Prior Notice—PN System Interface.

(d) If FDA determines that the Operational and Administration System for Import Support (OASIS) is not working, FDA will issue notification at *http://www.access.fda.gov*, on the FDA Web site at *http://www.fda.gov*, and through messages in ABI/ACS. Once FDA issues this notification, all prior notices must be submitted to FDA by e-mail or by fax. The location for receipt of submission by e-mail or fax is listed at *http://www.fda.gov*—see Prior Notice.

(e) Prior notice information will only be accepted at the listed e-mail or fax locations if FDA determines that the FDA PN System Interface or OASIS is not working.

§ 1.281 What information must be in a prior notice?

(a) *General.* For each article of food that is imported or offered for import into the United States, except by international mail, you must submit the information for the article that is required in this paragraph.

(1) The name of the individual submitting the prior notice and his/her business address, and phone number, fax number, and e-mail address, and the name and address of the submitting firm, if applicable. If a registration number is provided, city and country may be provided instead of the full address;

(2) If different from the submitter, the name of the individual and firm, if applicable, transmitting the prior notice on behalf of the submitter and his/her business address, and phone number, fax number, and e-mail address. If a registration number is provided, city and country may be provided instead of the full address;

(3) The entry type;

(4) The CBP entry identifier (*e.g.*, CBP entry number or in-bond number), if available;

(5) The identity of the article of food being imported or offered for import, as follows:

(i) The complete FDA product code;

(ii) The common or usual name or market name;

(iii) The estimated quantity of food that will be shipped, described from largest container to smallest package size; and

(iv) The lot or code numbers or other identifier of the food if required by the act or FDA regulations, *e.g.*, low acid canned foods, by 21 CFR 113.60(c); acidified foods, by 21 CFR 114.80(b); and infant formula, by 21 CFR 106.90;

(6) For an article of food that is no longer in its natural state, the name and address of the manufacturer and the registration number assigned to the facility that is associated with the article of food. A registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage, and export, or further manipulation and export. If the article of food is sent by an individual as a personal gift (*i.e.*, for nonbusiness reasons) to an individual in the United States, you may provide the name and address of the firm that appears on the label under 21 CFR 101.5 instead of the name, address, and registration number of the manufacturer. If a registration number is provided, city and country may be provided instead of the full address;

(7) For an article of food that is in its natural state, the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower or, if the article has been consolidated, the identity of any of the growers, you may provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations;

(8) The FDA Country of Production;

(9) The name and address of the shipper and, if the shipper is required to register under 21 CFR part 1, subpart H, the registration number assigned to the shipper's facility that is associated with the article of food. A registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage, and export, or further manipulation and export. If a registration number is provided, city and country may be provided instead of the full address;

(10) The country from which the article is shipped;

(11) Anticipated arrival information about the article of food being imported or offered for import, as follows:

(i) The anticipated port of arrival and, if the anticipated port of arrival has more than one border crossing, the specific anticipated border crossing where the food will be brought into the United States;

(ii) The anticipated date on which the article of food will arrive at the anticipated port of arrival; and

(iii) The anticipated time of that arrival;

(12) The name and address of the importer. If a registration number is provided, city and country may be provided instead of the full address. The identity of the owner is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(13) The name and address of the owner if different from the importer or ultimate consignee. If a registration

number is provided, city and country may be provided instead of the full address. The identity of the importer is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(14) The name and address of the ultimate consignee. If a registration number is provided, city and country may be provided instead of the full address. The identity of the ultimate consignee is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(15) The mode of transportation;

(16) The Standard Carrier Abbreviation Code (SCAC) or International Air Transportation Association (IATA) code of the carrier which is, or will be, carrying the article of food from the country from which the article is shipped to the United States, or if codes are not applicable, then the name and country of the carrier;

(17) Planned shipment information, as applicable:

(i) The Airway Bill number(s) or Bill of Lading number(s). This information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States;

(ii) For food arriving by ocean vessel, the vessel name and voyage number;

(iii) For food arriving by air carrier, the flight number;

(iv) For food arriving by truck, bus, or rail, the trip number;

(v) For food arriving as containerized cargo by water, air, or land, the container number(s). This information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States;

(vi) For food arriving by rail, the car number. This information is not required for an article of food when carried by or otherwise accompanying an individual;

(vii) For food arriving by privately owned vehicle, the license plate number and State or province; and

(viii) The 6-digit Harmonized Tariff Schedule (HTS) code.

(b) Articles arriving by international mail. For each article of food that is imported or offered for import into the United States by international mail, you must submit the information for the article that is required in this paragraph.

(1) The name of the individual submitting the prior notice and his/her business address, and phone number, fax number, and e-mail address, and the name and address of the submitting firm, if applicable. If a registration number is provided, city and country may be provided instead of the full address;

(2) If different from the submitter, the name of the individual and firm, if applicable, transmitting the prior notice on behalf of the submitter and his/her business address and phone number, fax number, and e-mail address. If a registration number is provided, city and country may be provided instead of the full address;

(3) The entry type (which will be a mail entry);

(4) The identity of the article of food being imported or offered for import, as follows:

(i) The complete FDA product code;

(ii) The common or usual name or market name;

(iii) The estimated quantity of food that will be shipped, described from largest container to smallest package size; and

(iv) The lot or code numbers or other identifier of the food if required by the act or FDA regulations, *e.g.*, low acid canned foods, by 21 CFR 113.60(c); acidified foods, by 21 CFR 114.80(b); and infant formula, 21 CFR 106.90;

(5) For an article of food that is no longer in its natural state, the name and address of the manufacturer and the registration number assigned to the facility that is associated with the article of food. A registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage and export, or further manipulation and export. If the article of food is sent by an individual as a personal gift (*i.e.*, for non-business reasons) to an individual in the United States, you may provide the name and address of the firm that appears on the label under 21 CFR 101.5 instead of the name, address, and registration number of the manufacturer. If a registration number is provided, city and country may be provided instead of the full address;

(6) For an article of food that is in its natural state, the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower or, if the article has been consolidated, the identity of any of the growers, you may provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations;

(7) The FDA Country of Production;

(8) The name and address of the shipper and, if the shipper is required to register under 21 CFR part 1, subpart H, the registration number assigned to the shipper's facility that is associated with the article of food. A registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage and export, or further manipulation and export. If a registration number is provided, city and country may be provided instead of the full address;

(9) The country from which the article is shipped (*i.e.*, mailed);

(10) The anticipated date of mailing; and

(11) The name and address of the U.S. recipient.

(c) *Refused articles.* If the article of food has been refused under section 801(m)(1) of the act and this subpart, you must submit the information for the article that is required in this paragraph. However, if the refusal is based on § 1.283(a)(1)(iii) (Untimely Prior Notice), you do not have to re-submit any information previously submitted unless it has changed or the article has been exported and the original prior notice was submitted through ABI/ACS. If the refusal is based on § 1.283(a)(ii), you should cancel the previous submission per § 1.282(b) and (c).

(1) The name of the individual submitting the prior notice and his/her business address, and phone number, fax number, and e-mail address, and the name and address of the submitting firm, if applicable. If a registration number is provided, city and country may be provided instead of the full address;

(2) If different from the submitter, the name of the individual and firm, if applicable, transmitting the prior notice on behalf of the submitter and his/her business address, and phone number, fax number, and e-mail address. If the registration number is provided, city and country may be provided instead of the full address;

(3) The entry type;

(4) The CBP entry identifier (*e.g.*, CBP entry number or in-bond number), if available;

(5) The identity of the article of food being imported or offered for import, as follows:

(i) The complete FDA product code;

(ii) The common or usual name or market name;

(iii) The quantity of food that was shipped, described from largest container to smallest package size; and

(iv) The lot or code numbers or other identifier of the food if required by the act or FDA regulations, *e.g.*, low acid canned foods, by 21 CFR 113.60(c); acidified foods, by 21 CFR 114.80(b); and infant formula, by 21 CFR 106.90;

(6) For an article of food that is no longer in its natural state, the name and address of the manufacturer and the registration number assigned to the facility that is associated with the article of food. A registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage and export, or further manipulation and export. If the article of food is sent by an individual as a personal gift (*i.e.*, for non-business reasons) to an individual in the United States, you may provide the name and address of the firm that appears on the label under 21 CFR 101.5 instead of the name, address, and registration number of the manufacturer. If a registration number is provided, city and country may be provided instead of the full address;

(7) For an article of food that is in its natural state, the name and growing location address of the grower, if known. If the submitter does not know the identity of the grower or, if the article has been consolidated, any of the growers, you may provide the name and address of the firm that has consolidated the articles of food from different growers or different growing locations;

(8) The FDA Country of Production;

(9) The name and address of the shipper and, if the shipper is required to register under 21 CFR part 1, subpart H, the registration number assigned to the shipper's facility that is associated with the article of food. A registration number is not required for a facility associated with an article of food if the article is imported or offered for import for transshipment, storage and export, or further manipulation and export. If a registration number is provided, city and country may be provided instead of the full address;

(10) The country from which the article is shipped;

(11) The port of arrival;

(12) The name and address of the importer. If a registration number is provided, city and country may be provided instead of the full address. The identity of the importer is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(13) The name and address of the owner, if different from the owner or ultimate consignee. If a registration number is provided, city and country may be provided instead of the full address. The identity of the owner is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(14) The name and address of the ultimate consignee. If a registration number is provided, city and country may be provided instead of the full address. The identity of the ultimate consignee is not required for an article of food that is imported or offered for import for transshipment through the United States under a Transportation and Exportation entry;

(15) The mode of transportation;

(16) The Standard Carrier Abbreviation Code (SCAC) or International Air Transportation Association (IATA) code of the carrier which carried the article of food from the country from which the article is shipped to the United States, or if codes are not applicable, then the name and country of the carrier;

(17) Shipment information, as applicable:

(i) The Airway Bill number(s) or Bill of Lading number(s); however, this information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States;

(ii) For food that arrived by ocean vessel, the vessel name and voyage number;

(iii) For food that arrived by air carrier, the flight number;

(iv) For food that arrived by truck, bus, or rail, the trip number;

(v) For food that arrived as containerized cargo by water, air, or land, the container number(s); however, this information is not required for an article of food when carried by or otherwise accompanying an individual when entering the United States;

(vi) For food that arrived by rail, the car number; however, this information is not required for an article of food when carried by or otherwise accompanying an individual;

(vii) For food that arrived by privately owned vehicle, the license plate number and State or province;

(viii) The 6-digit HTS code; and

(18) The location and address where the article of refused food will be or is being held, the date the article has arrived or will arrive at that location, and identification of a contact at that location.

§ 1.282 What must you do if information changes after you have received confirmation of a prior notice from FDA?

(a)(1) If any of the information required in § 1.281(a) except the information required in:

(i) § 1.281(a)(5)(iii) (quantity),

(ii) § 1.281(a)(11) (anticipated arrival information), or

(iii) § 1.281(a)(17) (planned shipment information) changes after you receive notice that FDA has confirmed your prior notice submission for review, you must resubmit prior notice in accordance with this subpart unless the article of food will not be offered for import or imported into the United States.

(2) If any of the information required in § 1.281(b), except the information required in § 1.281(b)(10) (the anticipated date of mailing), changes after you receive notice that FDA has confirmed your prior notice submission for review, you must resubmit prior notice in accordance with this subpart, unless the article of food will not be offered for import or imported into the United States.

(b) If you submitted the prior notice via the FDA PN System Interface, you should cancel the prior notice via the FDA PN System Interface.

(c) If you submitted the prior notice via ABI/ACS, you should cancel the prior notice via ACS by requesting that CBP delete the entry.

Consequences

§ 1.283 What happens to food that is imported or offered for import without adequate prior notice?

(a) For each article of food that is imported or offered for import into the United States, except for food arriving by international mail or food carried by or otherwise accompanying an individual, the consequences are:

(1) *Inadequate prior notice*—(i) *No prior notice.* If an article of food arrives at the port of arrival and no prior notice has been submitted and confirmed by FDA for review, the food is subject to refusal of admission under section 801(m)(1) of the act (21 U.S.C. 381(m)(1)). If an article of food is refused for lack of prior notice, unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

(ii) *Inaccurate prior notice.* If prior notice has been submitted and confirmed by FDA for review, but upon review of the notice or examination of the article of food, the notice is determined to be inaccurate, the food is subject to refusal of admission under section 801(m)(1) of the act (21 U.S.C. 381(m)(1)). If the article of food is refused due to inaccurate prior notice, unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within

the port entry for the article unless directed by CBP or FDA.

(iii) *Untimely prior notice.* If prior notice has been submitted and confirmed by FDA for review, but the full time that applies under § 1.279 of this subpart for prior notice has not elapsed when the article of food arrives, the food is subject to refusal of admission under section 801(m)(1) of the act (21 U.S.C. 381(m)(1)), unless FDA has already reviewed the prior notice, determined its response to the prior notice, and advised CBP of that response. If the article of food is refused due to untimely prior notice, unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival under CBP supervision, it must be held within the port of entry for the article unless directed by CBP or FDA.

(2) *Status and movement of refused food.* (i) An article of food that has been refused under section 801(m)(1) of the act and paragraph (a) of this section shall be considered general order merchandise as described in section 490 of the Tariff Act of 1930, as amended, 19 U.S.C. 1490.

(ii) Refused food must be moved under appropriate custodial bond. FDA must be notified of the location where the food has been or will be moved, within 24 hours of refusal. The refused food shall not be entered and shall not be delivered to any importer, owner, or ultimate consignee. The food must be taken directly to the designated location.

(3) *Segregation of refused foods.* If an article of food that is refused is part of a shipment that contains articles of food that have not been placed underhold, the refused article of food may be segregated from the rest of the shipment. This segregation must take place within the port, of arrival or where the article is held, if different. FDA or CBP may supervise segregation. If FDA or CBP determines that supervision is necessary, segregation must not take place without supervision.

(4) *Costs.* Neither FDA nor CBP are liable for transportation, storage, or other expenses resulting from refusal.

(5) *Export after refusal.* An article of food that has been refused under § 1.283(a) may be exported with CBP concurrence and under CBP supervision unless it is seized or administratively detained by FDA or CBP under other authority. If an article of food that has been refused admission under § 1.283(a) is exported, the prior notice should be cancelled within 5 business days of exportation.

(6) *No post-refusal submission or request for review.* If an article of food is refused under section 801(m)(1) and no prior notice is submitted or resubmitted, no request for FDA review is submitted in a timely fashion, or export has not occurred in accordance with paragraph (a)(7) of this section, the article of food shall be dealt with as set forth in CBP regulations relating to general order merchandise (19 CFR part 127), except that the article may only be sold for export or destroyed as agreed to by CBP and FDA.

(b) *Food carried by or otherwise accompanying an individual.* If food carried by or otherwise accompanying an individual arriving in the United States is not for personal use and does not have adequate prior notice or the individual cannot provide FDA or CBP with a copy of the PN confirmation, the food is subject to refusal of admission under section 801(m)(1) of the act. If before leaving the port, the individual arrange to have the food held at the port or exported, the article of food shall be destroyed.

(c) Post-Refusal Prior Notice Submissions.

(1) If an article of food is refused under § 1.283(a)(1)(i) (no prior notice) and the food is not exported, prior notice must be submitted in accordance with §§ 1.280 and 1.281(c) of this subpart.

(2) If an article of food is refused under § 1.283(a)(1)(ii) (inaccurate prior notice) and the food is not exported, you should cancel the prior notice in accordance with § 1.282 and must resubmit prior notice in accordance with §§ 1.280 and 1.281(c).

(3) Once the prior notice has been submitted or resubmitted and confirmed by FDA for review, FDA will endeavor to review and respond to the prior notice submission within the timeframes set out in § 1.279.

(d) FDA Review After Refusal.

(1) If an article of food has been refused admission under section 801(m)(1) of the act, a request may be submitted asking FDA to review whether the article is subject to the requirements of this subpart under § 1.276(b)(4) or § 1.277, or whether the information submitted in a prior notice is accurate. A request for review may not be used to submit prior notice or to resubmit an inaccurate prior notice.

(2) A request may be submitted only by the submitter, importer, owner, or ultimate consignee. A request must identify which one the requester is.

(3) A request must be submitted in writing to FDA and delivered by mail, express courier, fax, or e-mail. The location for receipt of a request is listed at *http://www.fda.gov*—see Prior Notice. A request must include all factual and legal information necessary for FDA to conduct its review. Only one request for review may be submitted for each refused article.

(4) The request must be submitted within 5 calendar days of the refusal. FDA will review and respond within 5 calendar days of receiving the request.

(5) If FDA determines that the article is not subject to the requirements of this subpart under § 1.276(b)(5) or § 1.277 or that the prior notice submission is accurate, it will notify the requester, the transmitter, and CBP that the food is no longer subject to refusal under section 801(m)(1) of the act.

(e) International Mail. If an article of food arrives by international mail with inadequate prior notice or the PN confirmation number is not affixed as required, the parcel will be held by CBP for 72 hours for FDA inspection and disposition. If FDA refuses the article under section 801(m) of the act and there is a return address, the parcel may be returned to sender stamped ''No Prior Notice—FDA Refused.'' If the article is refused and there is no return address or FDA determines that the article of food in the parcel 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 to the sender or, if there is no return address, destroy the parcel, at FDA expense.

(f) *Prohibitions on delivery and transfer.*

(1) Notwithstanding section 801(b) of the act, an article of food refused under section 801(m)(1) of the act may not be delivered to the importer, owner, or ultimate consignee until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food is no longer refused admission under section 801(m)(1).

(2) During the time an article of food that has been refused under section 801(m)(1) of the act is held, the article may not be transferred by any person from the port or the secure facility until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food no longer is refused admission under section 801(m)(1). After this notification by FDA to CBP and transmitter, entry may be made in accordance with law and regulation.

(g) *Relationship to other admissibility decisions.* A determination that an

article of food is no longer refused under section 801(m)(1) of the act is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. A determination that an article of food is no longer refused under section 801(m)(1) does not mean that it will be granted admission under other provisions of the act or other U.S. laws.

§ 1.284 What are the other consequences of failing to submit adequate prior notice or otherwise failing to comply with this subpart?

(a) The importing or offering for import into the United States of an article of food in violation of the requirements of section 801(m), including the requirements of this subpart, is a prohibited act under section 301(ee) of the act (21 U.S.C. 331(ee)).

(b) Section 301 of the act (21 U.S.C. 331) prohibits the doing of certain acts or causing such acts to be done.

(1) Under section 302 of the act (21 U.S.C. 332), the United States can bring a civil action in federal court to enjoin persons who commit a prohibited act.

(2) Under section 303 of the act (21 U.S.C. 333), the United States can bring a criminal action in Federal court to prosecute persons who are responsible for the commission of a prohibited act.

(c) Under section 306 of the act (21 U.S.C. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States or any person who has engaged in a pattern of importing or offering adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

§ 1.285 What happens to food that is imported or offered for import from unregistered facilities that are required to register under 21 CFR part 1, subpart H?

(a) If an article of food from a foreign manufacturer that is not registered as required under section 415 of the act (21 U.S.C. 350d) and subpart H is imported or offered for import into the United States, the food is subject to refusal of admission under section 801(m)(1) of the act and § 1.283 for failure to provide adequate prior notice. The failure to provide the correct registration number of the foreign manufacturer, if registration is required under section 415 of the act and 21 CFR part 1, subpart H, renders the identity of that facility incomplete for purposes of prior notice.

(b) Unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival, if an article of food is imported or offered for import from a foreign facility that is not registered as required under section 415 of the act and is placed under hold, it must be held within the port of entry for the article unless directed by CBP or FDA.

(c) *Status and movement of held food.* (1) An article of food that has been placed under hold under section 801(l) of the act shall be considered general order merchandise as described in section 490 of the Tariff Act of 1930, as amended (19 U.S.C. 1490).

(2) Food under hold under section 801(l) must be moved under appropriate custodial bond. FDA must be notified of the location where the food has been or will be moved, within 24 hours of the hold. The food subject to hold shall not be entered and shall not be delivered to any importer, owner, or ultimate consignee. The food must be taken directly to the designated facility.

(d) *Segregation of refused foods.* If an article of food that has been placed under hold under section 801(l) is part of a shipment that contains articles that have not been placed under hold of the act, the food under hold may be segregated from the rest of the shipment. This segregation must take place within the port of arrival where the article is held, if different. FDA or CBP may supervise segregation. If FDA or CBP determine that supervision is necessary, segregation must not take place without supervision.

(e) *Costs.* Neither FDA nor CBP will be liable for transportation, storage, or other expenses resulting from any hold.

(f) *Export after refusal.* An article of food that has been placed under hold under section 801(l) of the act may be exported with CBP concurrence and under CBP supervision unless it is seized or administratively detained by FDA or CBP under other authority.

(g) *No Registration or Request for Review.* If an article of food is placed under hold under section 801(l) of the act and no registration or request for FDA review is submitted in a timely fashion or export has not occurred in accordance with subsection (g), the food shall be dealt with as set forth in CBP regulations relating to general order merchandise, except that the article may only be sold for export or destroyed as agreed to by CBP and FDA.

(h) *Food carried by or otherwise accompanying an individual.* If an article of food carried by or otherwise accompanying an individual arriving in the United States is placed under hold under section 801(l) of the act because it is from a foreign facility that is not registered as required under section 415 of the act, 21 U.S.C. 350d, and subpart H, the individual may arrange to have the food held at the port or exported. If such arrangements cannot be made, the article of food may be destroyed.

(i) *Post-refusal and post-hold submissions.* (1) Post-refusal. To resolve the refusal if an article of food is refused under § 1.283(a) because the facility is not registered, the facility must be registered and a registration number has been obtained, you should cancel the prior notice and must resubmit the prior notice in accordance with § 1.283(c).

(2) Post-hold. To resolve a hold, if an article of food is held under § 1.285(b) because it is from a foreign facility that is not registered, the facility must be registered and a registration number must be obtained.

(i) FDA must be notified of the applicable registration number in writing. The notification must provide the name and contact information for the person submitting the information. The notification may be delivered to FDA by mail, express courier, fax, or e-mail. The location for receipt of a notification of registration number associated with an article of food under hold is listed at *http://www.fda.gov*—see Food Facility Registration. The notification should include the applicable CBP identifier.

(ii) If FDA determines that the article is no longer subject to hold, it will notify the person who provided the registration information and CBP that the food is no longer subject to hold under section 801(l) of the act.

(j) *FDA review after hold.* (1) If an article of food has been placed under hold under section 801(l), a request may be submitted asking FDA to review whether the facility associated with the article is subject to the requirements of section 415 of the act. A request for review may not be submitted to obtain a registration number.

(2) A request may be submitted only by the prior notice submitter, importer, owner, or ultimate consignee of the article. A request must identify which one the requestor is.

(3) A request must be submitted in writing to FDA and delivered by mail, express courier, fax or e-mail. The location for receipt of a request is listed at *http://www.fda.gov*—see Prior Notice. A request must include all factual and legal information necessary for FDA to conduct its review. Only one request for review may be submitted for each article under hold.

(4) The request must be submitted within 5 calendar days of the hold. FDA will review and respond within 5 calendar days of receiving the request.

(5) If FDA determines that the article is not from a facility subject to the requirements of section 415, it will

notify the requestor and CBP that the food is no longer subject to hold under section 801(l) of the act.

(k) *International mail.* If an article of food is that arrives by international mail is from a foreign facility that is not registered as required under section 415 of the act (21 U.S.C. 350d) and subpart H, the parcel will be held by CBP for 72 hours for FDA inspection and disposition. If the article is held under section 801(1) of the act and there is a return address, the parcel may be returned to sender stamped ''No Registration—No Admission Permitted.'' If the article is under hold and there is no return address or FDA determines that the article of food is in the parcel 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 to the sender stamped ''No Registration—No Admission Permitted'' or, if there is no return address, destroy the parcel, at FDA expense.

(l) *Prohibitions on delivery and transfer.* (1) Notwithstanding section 801(b) of the act (21 U.S.C. 381(b)), an article of food that has been refused under section 801(m)(1) of the act may not be delivered to the importer, owner, or ultimate consignee until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food is no longer refused admission under section 801(m)(1) of the act.

(2) During the time an article of food that has been refused under section 801(m)(1) of the act is held, the article may not be transferred by any person from the port or the secure facility location until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food is no longer refused admission under section 801(m)(1) of the act. After this notification by FDA to CBP and transmitter, entry may be made in accordance with law and regulation.

(m) *Relationship to other admissibility provisions.* A determination that an article of food is no longer subject to hold under section 801(l) of the act is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. A determination that an article of food is no longer under hold under section 801(l) does not mean that it will be granted admission under other provisions of the act or other U.S. laws.

Dated: October 2, 2003.

Tommy G. Thompson,

Secretary of Health and Human Services.

Dated: October 8, 2003.

Tom Ridge,

Secretary of Homeland Security.

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