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 × 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.

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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