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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 02N–0278]

RIN 0910–AC41

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is proposing a regulation that would require U.S. purchasers or U.S. importers or their agents to submit to FDA prior notice of the importation of food. The proposed regulation implements ~~of~~ Section 307 the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which requires prior notification of imported food to begin by December 12, 2003. The Bioterrorism Act requires FDA to issue final regulations that specify the period of advance notice by this date or a statutory notice provision requiring not less than 8 hours prior notice and not more than 5 days prior notice will take effect until a final rule is issued.

DATES: Submit written or electronic comments by [*insert date 60 days after date of publication in the* **Federal Register**]. Submit written or electronic comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, ATTN: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Mary Ayling, Center for Food Safety and Applied Nutrition (HFS–32), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2428.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background and Legal Authority
II. Preliminary Stakeholder Comments
III. The Proposed Regulation

A. Highlights of This Rule
B. General Provisions
1. What Imported Food is Subject to This Subpart? (Proposed § 1.276)
2. What Definitions Apply to This Subpart? (Proposed § 1.277)
3. What Are The Consequences of Failing to Submit Adequate Prior Notice or Otherwise Failing to Comply With This Subpart? (Proposed § 1.278)
C. Requirements to Submit Prior Notice of Imported Food
1. Who is Authorized to Submit Prior Notice for an Article of Food That is Imported or Offered for Import Into the United States? (Proposed § 1.285)

2. When Must the Prior Notice be Submitted to FDA? (Proposed § 1.286)
3. How Must You Submit the Prior Notice? (Proposed § 1.287)
4. What Information Must be Submitted in a Prior Notice? (Proposed § 1.288)
5. What Changes are Allowed to a Prior Notice After it Has Been Submitted to FDA? (Proposed § 1.289)
6. Under What Circumstances Must You Submit a Product Identity Amendment to Your Prior Notice After You Have Submitted it to FDA? (Proposed § 1.290)
7. What is the Deadline for Product Identity Amendments Under § 1.290? (Proposed § 1.291)
8. How Do You Submit a Product Identity Amendment or an Arrival Update to a Prior Notice? (Proposed § 1.292)
9. What Are the Consequences if You Do Not Submit a Product Identity Amendment to Your Prior Notice? (Proposed § 1.293)
10. What Must You Do if the Anticipated Arrival Information (Required Under § 1.288(k)(1)) Submitted in Your Prior Notice Changes? (Proposed § 1.294)

IV. Analysis of Economic Impacts

A. Preliminary Regulatory Impact Analysis
1. Need for Regulation
2. The Reason for the Regulation
3. Proposed Rule Coverage
4. Regulatory Options Considered
B. Small Entity Analysis (for Initial Regulatory Flexibility Analysis)
1. Number of Establishments Affected
2. Costs per Entity
3. Additional Flexibility Considered
C. Unfunded Mandates

per p. 91

U.S. Customs authorities, entry of the merchandise must be made within 15 days after importation.

U.S. Customs regulations provide for different kinds of entries. Commonly, merchandise is the subject of an entry for consumption (i.e., unrestricted, general use) under a basic importation and entry bond at the first port of arrival, but U.S. Customs authorities also allow for the entry of merchandise for transportation under a custodial bond from the port of arrival to another port where the consumption entry will be made. If no entry of any kind is made within 15 days, the article cannot move and the carrier or other authorized party must notify U.S. Customs and a general order (i.e., bonded or secure) warehouse that the article remains unentered. Generally, at that point, the article is moved to the bonded warehouse (or such other facility as the U.S. Customs port director might require) and held pending the filing of an entry or other action.

Accordingly, under current laws and regulations, there are times when FDA does not receive complete information about the food imports it regulates until days after the food has arrived in the U.S. and been moved from the port it arrived in.

FDA receives information about imported food through its Operational and Administrative System for Import Support (OASIS). Entry information is usually provided electronically to OASIS by U.S. Customs via its Automated Broker Interface (ABI) of the Automated Commercial System (ACS). The information that is currently supplied to FDA through this system includes: the entry type, the entry number (both ACS line number and FDA line identifier); the mode of transportation; the carrier code; the name and address of the manufacturer, shipper, importer, and ultimate consignee; the country

of origin; the FDA product code; a written description of the product in common business terms; and the quantity. If neither FDA nor U.S. Customs wishes to examine or detain the entry, the product is allowed to proceed.

By adding section 801(m) to the act, Congress changed when information about FDA-regulated food imports must be provided to FDA. The major components of new section 801(m) of the act are:

- Requires prior notice of imported food shipments beginning on December 12, 2003;
- Provides that, if adequate notice is not provided, the food shall be refused admission and held until adequate notice is given;
- Amends section 301 of the act to make it a prohibited act to import or offer for import an article of food in violation of any requirements under section 801(m) of the act; and
- Mandates that prior notice be submitted no less than 8 hours and not more than 5 days before it is imported or offered for import, if final rules are not in effect on December 12, 2003, and until such rules become effective.

In addition to section 307 of the Bioterrorism Act, which establishes the requirement for prior notice for food imported or offered for import into the U.S., FDA is relying on sections 701(a) and 701(b) of the act (21 U.S.C. 371(a) and (b)) in issuing this proposed rule. Section 701(a) authorizes the agency to issue regulations for the efficient enforcement of the act, while section 701(b) of the act authorizes FDA and the Department of Treasury to jointly prescribe regulations for the efficient enforcement of section 801 of the act.

II. Preliminary Stakeholder Comments

On July 17, 2002, FDA sent an open letter to the members of the public interested in food issues outlining the four provisions in Title III of the

Bioterrorism Act that require FDA to issue regulations in an expedited time period, and FDA's plans for implementing them (see http://www.cfsan.fda.gov/~dms/sec-ltr.html). In the letter, FDA invited stakeholders to submit comments to FDA by August 30, 2002, for FDA's consideration as it developed this proposed rule. FDA also held meetings with representatives of industry, consumer groups, other Federal agencies, and foreign embassies after sending out the July 17, 2002, letter, to solicit stakeholder comments. In response to these solicitations, FDA received 37 comments regarding section 307 of the Bioterrorism Act.

FDA has considered all the comments received by August 30, 2002. FDA will consider all comments we have received so far with the comments we receive during the public comment period on this proposed rule in developing the final rule. Several broad themes emerged from the comments FDA received on or before August 30, 2002, including:

- Maintaining flexibility when setting the minimum time required for prior notice and taking into account different modes of transportation, the nature of perishable food, and the needs of businesses which operate close to the U.S. border;
- Permitting the prior notice to be amended;
- Integrating with U.S. Customs and other agencies to avoid duplication of notification requirements;
- Allowing a qualified agent to submit prior notices for authorized submitters;
- Providing immediate acknowledgement of the submission, if prior notice is submitted electronically;
- Defining "food" consistent with the act's definition;
- Extending FDA's hours of operation;

- Complying with international trade obligations; and
- Including a model of the Prior Notice screen.

III. The Proposed Regulation

This rule would enhance FDA's ability to inspect imported food when it arrives in the U.S. This in turn would result in a significant improvement in FDA's ability to deter, prepare for, and respond effectively to bioterrorism and other public health emergencies that might result from imported food. Additionally, should an outbreak or a bioterrorism event occur, prior notice would enhance FDA's ability to respond to the event by enhancing FDA's ability to prevent entry of shipments that appear related and to facilitate product tracking for containment. This proposed rule would facilitate product tracking because we would know, at the time of receipt of prior notice, the name and address of the actual importer and consignee in the United States. We could then use the U.S. importer and consignee information to follow-up and trace the location of the goods. FDA thus would be better able to ensure that consumers in the United States do not eat food that is contaminated (whether intentionally or otherwise). This information would also assist FDA and other authorities in determining the source and cause of problems and in communicating with affected firms. Finally, we believe that the information provided by prior notice would help us use our foreign inspection resources more effectively.

In establishing and implementing this proposed rule, FDA will comply fully with its international trade obligations, including the applicable World Trade Organization (WTO) agreements and the North American Free Trade Agreement ("NAFTA"). For example, we believe this proposed rule is not more trade restrictive than necessary to meet the objectives of the Bioterrorism Act.

A. Highlights of This Rule

The key features of this proposed rule are:

- The purchaser or importer of an article of food (or their agent) who resides or maintains a place of business in the United States generally is responsible for submitting the notice.
- The notice must be submitted by noon of the calendar day before the day of arrival.
  - Amendments relating to product identity information are allowed under specified circumstances.
  - Updates about arrival information are required if plans change.
- The notice must be submitted electronically through the Prior Notice System unless the FDA system is not functioning. The FDA Prior Notice System will be designed to provide an automatic electronic acknowledgment of receipt of a complete prior notice submission, with a time and date "stamp." The notice must contain information that identifies:
  - The individual and firm submitting the prior notice;
  - The entry type and U.S. Customs ACS entry number or other U.S. Customs identification number associated with the import;
  - If the article of food is under hold under proposed § 1.278, the location where it is being held;
  - The identity of the article of food being imported or offered for import:
    - The complete FDA product code;
    - The common or usual name or market name;
    - The trade or brand name, if different from the common or usual name or market name;
    - The quantity described from smallest package size to largest container; and

– The lot or code numbers or other identifier of the food if applicable;

- The manufacturer;
- All growers, if known;
- The country from which the article originates;
- The shipper;
- The country from which the article of food was shipped;
- The anticipated arrival information;
- Information related to U.S. Customs entry process;
- The importer, owner, and consignee; and
- The carrier.

- Amendments relating to product identity are allowed if complete information about product identity does not exist by the deadline for prior notice for the planned shipment:
  - Information regarding identity of the article may be amended once;
  - Amendments may not be used to change the nature of the article of food;
  - Quantity may be amended; and
  - Any amendments must be submitted no later than 2 hours prior to arrival.
- If a change occurs in the anticipated port of entry or anticipated time of arrival stated in the prior notice, the information must be updated.
- The proposed rule does not apply to:
  - Food that is carried by an individual entering the United States in that individual's personal baggage for that individual's personal use; or
  - Meat food products, poultry products, and egg products that at the time of importation are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA).

B. General Provisions

1. What Imported Food is Subject to This Subpart? (Proposed § 1.276)

Under new section 801(m)(1) of the act, prior notice is required for all food "being imported or offered for import into the United States." Accordingly, prior notice requirements apply to all food that is brought across the U.S. border (with the following four exceptions) regardless of whether the food is intended for consumption in the United States. In other words, FDA believes that food that is brought into the United States to be put into foreign trade zones, or for transshipment or reexport immediate or otherwise, is "imported or offered for import" and thus must comply with the prior notice requirements.

The proposed rule establishes four categories of imported food that are not subject to the prior notice requirements. In each of these cases, FDA believes that the statutory language requires this result.

The first category is food that individual travelers carry in their personal baggage for their own personal enjoyment. Although we believe that this food is imported into the United States, the information that section 801(m)(1) of the act requires in a prior notice, in conjunction with the purpose of the provision, demonstrates that Congress did not intend prior notice to apply to food that travelers bring into the United States in their personal baggage for personal use (i.e., consumption by themselves, family or friends, not for sale to anyone). In particular, under section 801(m)(1) of the act, a prior notice must contain the identity of the shipper of the food. When travelers bring food back from their travels in their personal baggage for their own use, we do not believe that Congress intended for us to characterize such travelers as "shippers" for purposes of section 801(m) of the act. We seek comment on this reasoning.

However, when travelers bring food into the United States in their personal baggage to sell or otherwise distribute in a broader fashion, the travelers would seem to be acting for or on behalf of other entities. Under these circumstances, these travelers would seem to be shippers and subject to the provisions of this proposed rule.

The remaining three categories of imported food not subject to the prior notice requirement are those foods within the exclusive jurisdiction of USDA. In accordance with section 801(m)(3)(B) of the act, FDA is proposing to exempt from the requirements of this regulation imported foods that, at the time of importation, are subject to USDA's exclusive jurisdiction under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

2. What Definitions Apply to This Subpart? (Proposed § 1.277)

The following definitions are used throughout the proposed rule:

a. *The act.* The proposed rule defines "the act" as the Federal Food, Drug, and Cosmetic Act. The proposed rule applies the definitions of terms in section 201 of the act to such terms as used in the proposed rule.

b. *Calendar day.* The proposed rule defines "calendar day" as "every day shown on the calendar."

c. *Country from which the article of food was shipped.* The proposed rule defines "country from which the article of food was shipped" as the country in which the article of food was loaded onto the conveyance that brings it to the United States. A conveyance is the means of transportation, e.g., ship, truck, car, van, plane, railcar, etc., not the shipping container that could be moved from a ship to a truck to a train bed.

FDA is requesting comment on whether this term should include the countries of intermediate destination.

d. *Food.* FDA is proposing to refer to the definition of "food" in section 201(f) of the act (21 U.S.C. 321(f)), which is: "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." FDA also is proposing to include examples of products that are considered food under section 201(f) of the act. Examples listed in the proposed rule include: fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or components of food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food; dietary supplements and dietary ingredients; infant formula; beverages, including alcoholic beverages and bottled water; live food animals (such as hogs and elk); bakery goods; snack foods; candy; and canned foods. FDA already receives entry information on all these articles of food as defined in section 201(f) of the Act.

With respect to articles that can be used for food and non-food uses, FDA believes that prior notice is required if the article is being imported for use as food.

e. *Originating country.* The proposed rule defines "originating country" as "the country from which the article of food originates." FDA is proposing this definition to be consistent with the language used in the Bioterrorism Act. This proposed definition is also consistent with the definition that describes one of the critical data elements that brokers and other filers currently submit to FDA's OASIS via ACS when entry is made. The proposed definition refers to the country where the product that is shipped to the United States was

grown or produced, depending on the kind of article. If the article is fresh produce, for example, the originating country is most likely to be the country where it is grown and harvested. If, on the other hand, the article is a processed food, e.g., canned vegetables, the originating country is likely to be the country in which the vegetables were canned. With respect to wild-caught fish or seafood that is harvested in the waters of the United States or by a U.S. flagged vessel or that is processed aboard a U.S. flagged vessel, FDA is proposing that the originating country be the United States. Otherwise, the originating country is the country under which the vessel is flagged. FDA aligned this aspect of the proposed definition of "originating country" with the principles proposed by USDA's Agricultural Marketing Service guidance published in the **Federal Register** on October 11, 2002, in response to the Farm Security and Rural Investment Act of 2002 (commonly known as the 2002 Farm Bill).

FDA recognizes that this proposed definition may not be identical in all respects to the meaning of the term "country of origin" traditionally used by U.S. Customs. However, FDA believes that using the U.S. Customs meaning would not serve the purpose of the Bioterrorism Act. The U.S. Customs term primarily serves tariff, quota, and other trade purposes; it does not provide information needed for the evaluations that Congress has directed FDA to make under the Bioterrorism Act and the act. We seek comment on this interpretation and our proposed definition of "originating country". FDA also seeks comment on whether its use of a different term will have any impact, and if so, what that impact will be.

f. *Port of entry.* For purposes of the proposed rule, FDA is defining "port of entry" as "the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where food first

arrives in the United States" FDA is proposing this definition because the port where the food arrives in the United States may be different than the port where the entry of the article of food is processed for U.S. Customs purposes, i.e., where the article is "entered." Under U.S. Customs statutes, products can be imported into one port and then transported to another port under a custodial bond before a consumption entry is filed. For example, food may be imported into the United States from Canada through Buffalo, NY, but not be entered for consumption with U.S. Customs until it reaches St. Louis, MO, several days later. In this example, under FDA's proposed definition, the port of entry is Buffalo, NY. If food is imported into the United States from Mexico through Otay Mesa, CA, for transport through the United States for exportation into Canada, the port of entry under FDA's proposed definition is Otay Mesa, CA.

The prior notice authority in the Bioterrorism Act is intended to give FDA better tools to deter, prepare for, and respond to bioterrorism and other food related problems. Given this purpose, "port of entry" must be defined as the port of arrival, that is, the location where the food first physically appeared in the United States. Allowing food that is presented for importation into the United States without prior notice to be shipped around the country and potentially lost to government oversight simply is not consistent with the Bioterrorism Act's stated purpose. FDA believes that its ability to protect U.S. consumers from terrorism or other food-related emergencies will be strongest if food can be examined, and if necessary, held at the point when it first arrives in the United States. FDA requests comments on the proposed definition of "port of entry."

g. *You*. The proposed definition of "you" is the description of the party responsible for submitting the prior notice in proposed § 1.285. FDA is proposing to define "you" in proposed § 1.277(f) as the "purchaser or importer of an article of food who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or importer" or, "if the article of food is imported with the intention of in-bond movement through the United States for export, i.e., Transportation for Exportation or Immediate Export entries, the arriving carrier or, if known, the in-bond carrier."

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

As set out in section 801(m)(1) of the act, proposed § 1.278(a) provides 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 under section 801(m) of the act. Examples of inadequacy are untimely, inaccurate, or incomplete prior notice.

As set out in section 801(m)(2)(B)(i) of the act, proposed § 1.278(b) provides that if the food is refused admission under section 801(m), it must be held at the port of entry unless FDA directs its removal to a secure facility.

In accordance with section 801(m)(2)(B)(i), proposed § 1.278(c) provides that FDA may require that an article of food be held in a secure facility as appropriate. FDA may determine such storage is appropriate because of the condition of the product, circumstances of importation, or other information available to the government, e.g., a concern with the safety or security of the article of food or space limitations in the port of entry.

Examples of secure facilities include U.S. Customs Bonded Warehouses, Container Freight Stations, and Centralized Examinations Stations. Perishables, however, may not be stored in U.S. Customs Bonded Warehouses; thus, FDA may direct fresh produce or seafood that requires storage to another facility. FDA and U.S. Customs plan to issue guidance for their field offices that will identify locations of secure storage facilities that may be used for food required to be held for failure to provide adequate prior notice.

In order to minimize confusion about who is responsible for making arrangements if food is refused admission under section 801(m) of the act, proposed § 1.278(d) provides that if FDA requires the article of food to be held at the port of entry or in a secure facility, the carrier or the person who submitted the prior notice must arrange for the movement of the food under appropriate custodial bond and promptly notify FDA of the location. This provision also makes clear that the purchaser, owner, importer, or consignee is responsible for transportation and storage expenses. We note that when section 801(m) of the act requires that food be held, it does not appear to mandate that the government take actual physical custody of the goods; instead it limits both the movement of the goods and the potential storage locations, thereby making government oversight straightforward. As described previously, U.S. Customs has identified a well-established network of storage facilities that are secure. When these storage facilities are used, charges are borne by the private parties. We thus believe that although Congress intended strict controls over food refused admission under § 801(m), it did not intend to require FDA or U.S. Customs to take custody of or pay for the holding of such food. We seek comment on this issue.

In accordance with section 801(m)(2)(B)(i) of the act, proposed § 1.278(e)(1) provides that the article of food must be held at the port of entry or in the secure facility until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified the U.S. Customs Service and the person who submitted the prior notice that the article of food no longer is subject to refusal of admission under section 801(m)(1) of the act.

FDA recognizes that food may be shipped in the same container or truck with non-food items. Since articles that are not food are not subject to this proposed rule, when mixed or consolidated imported freight contains articles of food that must be held at the port of entry or moved to a secure facility, those articles that have been refused must be dealt with before the rest of the shipment proceeds.

In accordance with section 801(m)(2)(B)(i) of the act, proposed § 1.278(e)(2) makes clear that food under a hold may not be delivered to the importer, owner, or consignee and that section 801(b) of the act does not apply. Therefore, delivery will not be allowed under a basic importation or entry bond. Even though delivery to them is not allowed, FDA believes that importers, owners, and consignees of food that has been refused under 801(m) of the act can make arrangements for food to be held: these arrangements can be made without taking possession of the food.

The proposed rule (proposed § 1.278(f)) differentiates between a refusal of admission under section 801(m)(1) of the act (prior notice) and refusal of admission under section 801(a) and other provisions of the act or other U.S. laws. The proposed rule makes clear that a determination that an article of food is no longer subject to refusal of admission under section 801(m)(1) of

the act does not mean that it will be admitted to the United States. The other provisions of the act and other U.S. laws that currently apply to food imported or offered for import to the United States still apply and also govern admissibility.

Although FDA believes that information in a prior notice will help facilitate admissibility decisions under section 801(a), FDA is not proposing to specify in the rule that it will make an 801(a) admissibility decision at the time it receives a prior notice. A prior notice is a pre-entry submission to comply with requirements under section 801(m). FDA will make the 801(a) decision when the complete entry information is submitted to U.S. Customs and transmitted to FDA. Normally (in about 98 percent of the cases), this is accomplished by electronically filing certified entry information with U.S. Customs ACS, which electronically transmits it to FDA's OASIS System. FDA's 801(a) admissibility decisions are transmitted from OASIS to the filer.

In accordance with section 301(ee) of the act, the proposed rule (§ 1.278(g)) provides 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 act or otherwise violate any requirement under section 801(m). The proposed rule explains that, under section 302 of the act, the United States can bring a civil action in federal court to enjoin persons who commit a prohibited act and, under section 303 of the act, can bring a criminal action in Federal court to prosecute persons who commit a prohibited act. The proposed rule also explains that, under section 305a of the act, FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States.

FDA notes that there are several differences between refusal of admission under sections 801(a) and (b) of the act and refusal of admission under new section 801(m). First, in section 801(m) of the act, Congress did not provide for any kind of application, petition, or appeal of FDA's determination that an article shall be refused admission for failing to comply with prior notice requirements. Congress provided that an article that has been refused admission under section 801(m) of the act can be admitted only if the necessary information is subsequently submitted, examined by FDA, and found to be adequate. Second, food refused admission under section 801(m) cannot be delivered under bond pursuant to section 801(b) and, as we describe elsewhere, must be held at the U.S. port of entry. Finally, the Bioterrorism Act does not provide specific procedures for the disposition of food refused admission under section 801(m) when no subsequent adequate notice is submitted. Section 801(a) and (b) provide that food refused admission under section 801(a) must be destroyed or reexported. FDA thus believes that the general requirements of Title 19 of the United States Code and the U.S. Customs implementing regulations that apply to imports for which entry has not been made apply in these circumstances.

Under 19 U.S.C. 1448 and 1484, entry of merchandise must be made within the time period prescribed by regulation, which is 15 days after the food arrives in the United States. See 19 CFR Part 1422. If entry is not made within this timeframe, the carrier or other authorized party is required to notify U.S. Customs and a general order warehouse. Generally, at that point the warehouse must arrange to take and store the food at the expense of the consignee. The disposition of this merchandise is governed by 19 U.S.C. 1491 and the implementing regulations at 19 CFR Part 127. Typically, after 6

months, unentered merchandise is deemed unclaimed and abandoned and can be disposed of by the United States. Before this 6 month period runs, however, such merchandise can be reexported. FDA and U.S. Customs plan to develop additional guidance to explain how the agencies will handle food when it must be placed in general order warehouses due to refusal under section 801(m) of the act.

C. Requirements to Submit Prior Notice of Imported Food

1. Who is Authorized to Submit Prior Notice for an Article of Food That is Imported or Offered for Import Into the United States? (Proposed § 1.285)

FDA is proposing that a purchaser or importer of an article of food who resides or maintains a place of business in the United States is authorized to submit prior notice. FDA is also proposing that an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or U.S. importer is authorized to submit prior notice. FDA believes that the customs broker/filer should be authorized to be a submitter if it is the U.S. agent of the U.S. importer or U.S. purchaser.

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

FDA believes that the proposed rule should specify which parties are responsible for submitting prior notice and that this specificity will minimize confusion about who should or will submit prior notice among the several parties who can be involved in importing food. Less confusion will lead to

greater compliance. Less confusion will also mean that fewer imports will be delayed for lack of prior notice.

FDA chose the U.S. entities in proposed § 1.285(a) for several reasons. First, we do not believe that there is importation of food to the United States that does not involve one of the U.S. entities identified, except in those instances where the food is imported with the intention of in-bond movement through the United States for export (where the proposed rule authorizes submission by the arriving carrier or, if known, the in-bond carrier). We also believe that it is the U.S. importer or U.S. purchaser who orders or buys the article of food, thereby initiating its importation into the United States. These persons thus should possess, or have the ability to obtain, the information required to be submitted in the prior notice within the time period in proposed § 1.286. As U.S. businesses, these persons are also more likely to already have web access than some foreign businesses, which reduces potential costs and impacts on trade. Finally, placing responsibility on these U.S. entities will facilitate FDA's ability to conduct audits, investigations, and inspections, which will facilitate efficient enforcement of section 801(m).

FDA notes that the submitter is the entity responsible for ensuring the adequacy and accuracy of the prior notice. For the reasons described above, FDA believes that these entities are in the best position to do so.

FDA seeks comment on whether others should be authorized to provide prior notice and, if so, why.

2. When Must the Prior Notice be Submitted to FDA? (Proposed § 1.286)

Based on consideration of the factors set out in the statute, FDA is proposing that the prior notice must be submitted to FDA no later than noon

of the calendar day before the day the article of food will arrive at the border crossing in the port of entry.

Section 801(m)(1) of the act makes clear that a primary purpose of prior notice is to enable inspections or other FDA action upon arrival of food in the United States to protect consumers in the United States from food imports that may be at risk of intentional adulteration or that may pose other risks. Section 801(m)(2)(A) of the act states that the deadline for prior notice "shall be no less than the minimum amount of time necessary for [FDA] to receive, review, and appropriately respond to such notification." In addition, section 801(m)(2)(A) provides that FDA may take other factors into consideration when deciding on the deadline for prior notice, specifically: its effect on commerce; the locations of various ports; various modes of transportation; types of food; and any other consideration. However, although the statute gives FDA some latitude in setting the deadline for prior notice, it nonetheless makes clear that we must establish a timeframe for prior notice that allows FDA to receive, review, and appropriately respond to all prior notices. Finally, section 801(m)(1) states, "Nothing in this section may be construed as a limitation on the port of entry for an article of food."

Reading section 801(m) as a whole and in conjunction with other provisions in the Bioterrorism Act, FDA believes that Congress intended that FDA assess the information in the prior notice to determine if inspection upon arrival or other action is appropriate. For FDA to inspect, upon arrival, food imports that may be at risk of intentional adulteration or that may pose other risks to U.S. consumers, FDA must be able to effectively deploy its staff. Although FDA inspectors are located throughout the United States, FDA does not have staff located at or near all of the 250 ports where over 4.7 million

entry lines of food were entered in fiscal year (FY) 2001. Port locations are established by U.S. Customs and, under the statute, FDA cannot limit ports at which food may be imported or offered for import. Thus, FDA must have enough time, on a daily basis, to process the information in the approximately 20,000 prior notices we expect to receive and to send inspectors to any port in the United States if necessary. FDA believes that the minimum amount of time necessary to ensure it can plan and that its staff can travel to the arrival point is noon of the calendar day before the day the article arrives at the border crossing. FDA believes that this timeframe will give it the minimum time it needs to conduct its assessments and provide the information to its field offices so they can allocate their inspectional resources on a daily basis and plan any necessary travel.

Before proposing this deadline FDA also considered its potential effects on imported food. FDA believes that in most circumstances information regarding imports is generated when the article to be imported is ordered or purchased, not when it is shipped to the United States. FDA has examined a selection of imported food documents and compared dates of these documents with the dates of arrival in the United States and U.S. Customs entry. FDA asked several field offices to send entry documents with invoices covering imported foods. Sixty-four packages of entry documents were received in response to this request. The dates the invoices were compared to the dates of arrival and receipt in OASIS. In 48 cases (75 percent), the invoice date or date of sale preceded the arrival date by least 1 day. In 31 cases (48 percent), the invoice or sale date preceded the arrival date by 2 or more days. In 16 cases (25 percent), the invoice date was the same as the arrival date. FDA invites comment on the representativeness of this sampling. Based

on this examination, we believe that orders are normally placed a day or more prior to shipment. See the compilation of imported food documents that FDA has placed in the administrative record and the docket (Ref. 1). FDA believes that the information required for prior notice therefore generally does exist by noon of the calendar day before the day of arrival. FDA recognizes, however, that currently one person may not possess all of the information and that some practices regarding the flow of information about food imports will have to change to ensure that the submitter has all of the information needed to submit a prior notice for the food shipment by the deadline.

FDA believes that this proposed deadline will have the most impact on those who import food by truck and rail over the land borders, with less effect at airports, and almost no effect at water ports. However, even on the land borders, FDA believes that the information required by prior notice will be, in most cases, sufficiently fixed by noon of the calendar day before arrival to allow the U.S. importer or U.S. purchaser, or their U.S. agents, to submit prior notice to FDA that meets the proposed requirements without slowing down the shipment.

FDA is proposing to allow submitters to amend prior notices for that portion of the product identity information that cannot be completed, because it does not yet exist by noon of the calendar day prior to arrival. We believe this may be the case with product identity for fresh products imported from countries close to the United States (e.g., Canada or Mexico). For example, fresh seafood may be ordered as "catch-of-the-day" from Canada or Mexico; the importer intends to import the fish the day after the order is placed, but cannot find out what exact species and quantity will arrive by the deadline for prior notice because the boat is not due back until late afternoon on the

day prior notice is due. Another example is an importer who orders fresh lettuce for import the day after the order but cannot find out the exact variety and quantity of lettuce that will be shipped by the deadline for prior notice because the field has not been harvested or the supplier has not yet received the day's harvest by the time prior notice of the planned shipment is due. In these instances, the importer knows generally what kind of product has been ordered, but not the exact type (species for fish and variety for lettuce). The proposed amendment process would allow submitters who cannot report complete product identity information to FDA by the prior notice deadline because it does not yet exist to maintain current business practices. However, it would provide FDA some of the information that it needs to begin the assessment of whether a particular shipment of food should be investigated and if so, to ensure that FDA personnel can be available when the food arrives at the port. FDA does not intend this amendment process to apply when a shipper "tops off a container" by filling unused space in the container or truck bed with additional different food products.

FDA also recognizes that information concerning the anticipated arrival may change after the article is ordered due to unforeseen traffic or weather issues and has accommodated those potential changes by requiring updates of that information.

"Noon" means 12:00 p.m. in the time zone in which the FDA office with responsibility over the anticipated port of entry resides. For example, if the anticipated port of entry is the Peace Bridge in the Buffalo, NY, and the anticipated date of entry is January 9, 2004, the prior notice must be submitted to the FDA Prior Notice System before noon Eastern Standard Time (EST) on January 8, 2004.

FDA is proposing that prior notice may not be submitted until all of the information required by § 1.288 exists except as provided in § 1.288(e)(2) and § 1.290, both of which relate to product identity amendments. FDA is also proposing that the prior notice may not be submitted more than 5 days before the anticipated date of arrival of the food at the anticipated port of entry. For example, if the anticipated date of arrival is January 12, 2004, the prior notice may not be submitted before January 7, 2004. This 5 day limitation is consistent with the limitation set by Congress in section 307(a)(2)(A) of the Bioterrorism Act. Such limitations are necessary to ensure that FDA's Prior Notice System is not overburdened with premature information or submissions that may need to be cancelled and resubmitted.

3. How Must You Submit the Prior Notice? (Proposed § 1.287)

FDA is proposing that the prior notice, amendments, and updates must be submitted electronically to FDA through FDA's Prior Notice System. The web-based FDA Prior Notice System is under development with an anticipated completion date of no later than October 12, 2003. A "mock-up" of the Prior Notice Screen a submitter would see once he or she accessed this system is part of this proposed rule.

FDA has consulted with the U.S. Customs Service of the Department of the Treasury about this proposed rule. FDA and U.S. Customs considered modifying ACS to accommodate the new prior notice requirement. However, during these consultations, U.S. Customs determined that ACS could not be modified to accommodate the data requirements of the prior notice regulation by the December 12, 2003, statutory deadline. Currently, U.S. Customs is focusing its resources on developing the Automated Commercial Environment (ACE) as a replacement for ACS, and integrating its other electronic systems,

such as the Automated Manifest System (AMS). FDA is participating in the development of ACE through the International Trade Data System (ITDS) Board and directly through integration of FDA and U.S. Customs business practices, policies, and border cooperation. FDA intends to allow prior notice to be submitted through ACE when it is fully operational. However, implementation of ACE is not expected before 2005. Given these circumstances, FDA and U.S. Customs agreed that to meet the statutory deadline, an FDA stand-alone, web-based electronic system to execute receipt of prior notice would be necessary until ACE is fully operational.

FDA seeks to minimize the submission of duplicative information. The Bioterrorism Act requires certain prior notice information to be submitted to FDA. FDA seeks comments on the extent to which these proposed prior notice requirements would result in persons submitting duplicative prior notice information to more than one federal agency. FDA also seeks comments on whether there is any way, consistent with the requirements and purpose of the Bioterrorism Act, to minimize the duplication of information required to be submitted to the federal government under these prior notice requirements. As discussed previously, FDA and U.S. Customs are working together on their systems to allow prior notice to be submitted to FDA through U.S. Customs System when ACE is fully operational.

FDA is proposing to require electronic submission of prior notice because we believe an electronic system will be the least burdensome and most efficient way to implement and enforce the requirement of section 801(m) of the act. Nationwide, in FY 2001 FDA received over 4.7 million food entry lines; therefore, we believe a paper system would be unmanageable for FDA, require a longer deadline, and could slow down imports for some food products.

Moreover, we currently receive the majority of information we base admissibility decisions on electronically from U.S. Customs. Thus, we already have the electronic capability to process and screen the information. We also believe that an electronic system will mean fewer errors than a paper system. Another important benefit of electronic submission will be immediate and accurate communication between FDA offices and between FDA offices and U.S. Customs about arrivals and adequacy of the prior notice.

An electronic prior notice system will have several key features that will benefit firms that export to the United States, U.S. importers, and FDA. First, the volume of submissions on a daily basis is expected to be such that electronic submission and processing are the only practical way for FDA to manage prior notice—FDA expects, upon average, 20,000 submissions per day. Second, an electronic system will be able to provide instantaneous confirmation of receipt of the prior notice. Third, an electronic system will be able to ensure that the form is filled out completely (though not accurately) by being set to reject submissions until all of the mandatory fields are completed. Finally, an electronic system will make it more likely that information in the submissions is "legible" to FDA.

In contrast, prior notice by mail, fax, or e-mail would have several significant downsides for firms that export to the United States, U.S. importers, and FDA. All three of these methods would require FDA to input the data manually to process it, which means that FDA would need to set a longer deadline for submission or devote resources on data entry that are better spent on tasks like inspections. Those whose paper submissions were not legible or complete would not know until their shipments arrived at the port and were refused admission.

Moreover, FDA believes that almost all proposed submitters have access to the Internet, either within their companies or through public libraries, copy centers, schools, or Internet cafes, as well as through agents or brokers. FDA requests comments on this assumption. Because most of the persons responsible for submitting the prior notice must reside or maintain a place of business in the United States, the FDA Prior Notice System will be in English. This will also allow for the information to be placed in standard data elements that can then be maintained in a database, screened against standard criteria, and used for communication among field offices.

In proposed § 1.287(b), FDA is proposing that if its Prior Notice System is unable to receive prior notice electronically, the prior notice, amendments, and updates must be submitted using a printed version of the Prior Notice Screen delivered in person, by fax, or by e-mail to the FDA field office with responsibility over the geographical area in which the anticipated port of entry is located. If the submitter does not receive electronic acknowledgement from the FDA Prior Notice System then it should check to see if its system is working. If it is, then the submitter should assume that the FDA system might be down and attempt to contact the appropriate FDA field office to confirm.

The Prior Notice System will not provide a response to the submitter of the agency's decision regarding the adequacy or timeliness of the prior notice as this assessment will turn on information that will not be available until the food arrives in the United States. FDA anticipates the system will date and time stamp an electronic confirmation of the system's receipt of each prior notice, amendment, and update, which the system will send to the submitter automatically.

FDA believes that the prior notice process under section 801(m) precedes the review process under section 801(a). Thus, FDA's response to the prior notice will not constitute entry review. The section 801(a) review process will be separate from, and subsequent to, the prior notice process. Therefore, the FDA Prior Notice System's electronic confirmation of a prior notice submission is not an 801(a) admissibility decision and should never be construed as an FDA "release" or "may proceed."

If a person wishing to submit prior notice to the FDA is unable to do so because his or her own system is not operating, FDA expects the submitter to use an alternative Internet system for submission (e.g., a local library or copy-center with Internet access). FDA is developing a web-based system to reduce the likelihood that intermittent system outages will impact prior notice submissions.

Although the system may be developed in a way that will allow for establishment of a personal account, users will not have to be licensed or otherwise pre-approved or have specialized software. FDA also plans to develop and provide guidance and training to potential submitters and their agents that will further describe the data elements and the submission process before December 12, 2003, which is when the requirement to provide prior notice begins. The Prior Notice Screen of FDA's Prior Notice System also identifies the information that must be submitted.

4. What Information Must be Submitted in a Prior Notice? (Proposed § 1.288)

Proposed § 1.288 lists the information or data elements that must be included in each prior notice. Much of this list is taken directly from section 801(m)(1) of the act. The remainder of the list, although not explicitly listed in section 801(m), is information that FDA believes is necessary for the

efficient enforcement of section 801(m) of the act and is thus authorized under section 701(b) of the act. We explain below why each of these items is necessary for the efficient enforcement of section 801(m). Accordingly, as set out in proposed § 1.278(a), FDA is proposing that a prior notice that does not contain all of the information listed in proposed § 1.288 will be considered inadequate. FDA solicits comments on this approach.

Most of this information is already supplied by the filer to FDA through ACS as part of the U.S. Customs entry process, including the entry type; the entry number (both ACS line number and FDA line identifier); the FDA product code; a written description of the product in common business terms; brand name; the quantity; lot numbers; the manufacturer; country of origin; shipper; importer; ultimate consignee; and the carrier (the mode of transportation and the carrier code).

Before discussing each data element in the context of prior notice, we want to emphasize that the prior notice requirement does not apply to a whole shipment; for the purpose of section 801(m) of the act, it applies to "each article of food." FDA believes that in section 801(m) "each article of food" means each article of food produced by each manufacturer. Thus, any food product identified by a specific FDA product code and quantity description produced by a single manufacturer (or grower, if fresh) associated with a single entry line number (U.S. Customs entry number plus ACS line number plus OASIS/FDA line number) must be covered by a prior notice. Therefore, each article of food that is represented by an FDA line must be covered by a prior notice.

Thus, if a shipment consists of four different kinds of food products, e.g., 1,000 cases of 48/6 oz. cans each of Brand X tuna, 240 cases of 24/15.25 oz.

cans each of yellow corn, 300 cases of 24/12 oz cans each of Brand X tuna, and 1,500 cases of 48/6 oz. cans each of Brand P tuna, four prior notices are required. These four prior notices may be contained in one submission. If the shipment consists of only one product, e.g., 2,400 cases of 24/15.25 oz. cans each of yellow corn, one prior notice is required. If this corn came from two different manufacturers, however, two prior notices would be needed. In its Prior Notice System FDA will give the submitter the option of completing additional prior notices for other articles after each notice is completed. We are working with the developers of the Prior Notice System to accept "header" information that will permit repeated information to be automatically entered. This "header" would contain information consistent across several articles of food within the same submission, i.e., U.S. Customs entry. This will reduce the amount of data entry and potentially reduce typing and transcription errors. FDA plans to develop its Prior Notice System to allow submitters to automatically repeat information already entered in the submission where appropriate (e.g., all information is the same except for the identity of the article or the manufacturer).

FDA is proposing to require the following information in the prior notice identifying the following details for each article of food:

a. ~~1.~~ *The submitter.* FDA is proposing to require the identity of the submitter and the associated submitting firm. This information is needed so that FDA may communicate the adequacy or non-adequacy of the prior notice to the responsible party and to follow up when audits, inspections, or enforcement are necessary.

Generally, for all firms that the proposed rule requires to be identified in a prior notice (submitter, importer, owner, consignee, manufacturer, growers

(if known), shipper), FDA is proposing that the prior notice include the firm's name, address, phone number, fax number, and e-mail address, and if the firm is required to register a facility associated with the article of food, the facility's registration number. The registration requirement is contained in a separate provision of the Bioterrorism Act (section 305). FDA believes that it needs identifying information in addition to the registration number (if one exists) to minimize the chance that typographical errors in registration numbers will lead to prior notices being considered incorrect and thus inadequate. We are considering designing the Prior Notice System to require at least one "confirmatory" data element (firm name or city or country) in addition to the registration number to allow for validation edits before automatically filling in the remaining data fields.

The phone and fax numbers and e-mail address are required (if they exist) so that FDA can communicate with the firm, if necessary. If the firm does not have a fax number or e-mail address, the prior notice submission should declare this. FDA plans to develop its Prior Notice System to allow submitters to repeat information already entered in the submission where appropriate (e.g., where the submitter is also the importer and consignee of the article).

b. ~~2.~~ *The U.S. Customs ~~E~~ntry ~~T~~ype.* FDA is proposing to require the submission of the U.S. Customs entry type associated with the article of food being imported or offered for import (proposed § 1.288(b)). Some examples of types of entries are Consumption entries, Warehouse entries, Temporary Importation Bond entries, Transportation for Exportation Bond entries, Trade Fair entries, mail entries, and baggage entries. Each of these types has a pre-designated U.S. Customs entry type code. That code must be submitted in the prior notice. This information will tell us if the article of food is intended for

consumption in the U.S. or is intended for export or other uses. We need this information for proper screening of the information and identification of the appropriate articles for inspection. FDA also believes that submission of this information is critical for matching the prior notice to the corresponding U.S. Customs entry in order to assess the adequacy of the prior notice when shipments arrive and are presented for review.

C. 3. The U.S. Customs ACS Entry Line Number or Other U.S. Customs Identification Number. FDA is proposing to require the submission of the U.S. Customs ACS entry line number, consisting of the entry number, the U.S. Customs ACS line number, and the FDA entry line number, which will be associated with the entry of the food for U.S. Customs purposes (proposed § 1.288(c)). For each entry number, there may be one or more U.S. Customs ACS lines and for each U.S. Customs ACS line there may be one or more FDA lines. For example, U.S. Customs entry number 0123456789–0 may identify an entry of peppers; the U.S. Customs ACS line 123456789–0–001 may identify fresh peppers; and the FDA entry line 0123456789–0–001–001 may identify fresh sweet peppers and FDA entry line 0123456789–0–001–002 may identify fresh hot peppers.

If the article of food is not intended for consumption entry, FDA is proposing to require submission of the U.S. Customs identification number associated with that type of entry. Some examples of other types of entries are Warehouse entries, Temporary Importation Bond entries, Transportation for Exportation Bond entries, and Trade Fair entries.

FDA believes that this information is necessary for proper screening of the information and identification of the appropriate articles for inspection. FDA also believes that submission of this information is critical for matching

the prior notice to the corresponding U.S. Customs entry in order to assess the adequacy of the prior notice when shipments arrive and are presented for review. FDA believes that these numbers can be obtained by the proposed deadline for prior notice. We seek comment on this issue.

d. 4. The Location Where The Food Is Being Held Under Proposed § 1.278, If Applicable. FDA is proposing to require that, if the article of food has been refused admission due to inadequate prior notice and thus is required to be held at the port of entry or in a secure facility, the submitter of the prior notice must inform FDA both that the article is under hold, and the location where the shipment is being held (proposed § 1.288(d)). Additionally, FDA is proposing to require the date that the article will arrive at that location as well as the identification of a contact at that location. This information is necessary to ensure FDA can locate the food for inspection and to ensure that the hold requirement is being compiled with.

e. 5. The Product Identity. Section 801(m)(1) states that a prior notice must contain the identity of the article of food being imported or offered for import. FDA is proposing the following data elements to ensure that each prior notice adequately and completely identifies the food being imported or offered for import.

i. (i) The Complete FDA Product Code.

FDA is proposing to require the submission of the complete FDA product code as an element of the identity of the product (proposed § 1.288(e)(1)(i)). The FDA product code is a unique code currently used for classification and analysis of merchandise. The FDA product code is currently available via the Internet at www.accessdata.fda.gov/scripts/ora/pcb/pcb.htm as a "buildable" code which is used to describe the food by industry, industry class, subclass,

container/packaging, process, and specific product. We will work with the developers of the FDA prior notice system to ensure that there is a link from that system to the Product Code Builder. We are working with the developers to design the link to the product code builder which will allow the product code selected to be automatically pasted back to the Prior Notice Screen. We will also design the system so that if the submitter already knows the product code, it can be entered directly into the Prior Notice Screen.

The FDA product code for canned tuna fish is 16AEE45, which translates as 16= fishery/seafood products, A= fish, E= subclass metal (cans), E= commercially sterile, 45= tuna. The filer currently submits the FDA product code to U.S. Custom's ACS when entry is made; it subsequently is transmitted to FDA's OASIS for each entry line.

FDA is proposing that if all of the information concerning the product identity exists by noon of the calendar day before the article will arrive at the port of entry, it must be included in the prior notice and the prior notice may not be subsequently amended. (Proposed § 1.288(e)(2)). If any of the product identity information does not exist by the deadline, the information that does exist must be provided to FDA, and the submitter must indicate that it will amend the prior notice. FDA identifies the conditions appropriate for amendments related to product identity in proposed § 1.290. FDA notes that, in determining whether the information exists, the standard set out in the proposed rule is not whether the submitter knows the information when filing the prior notice, but whether the information could be known by the submitter by the noon deadline. In the discussion of proposed § 1.289, we describe under what circumstances we think complete product identity will not exist. FDA

solicits comment on this standard and whether it is sufficiently flexible to achieve our goals.

ii. ~~(ii)~~ The ~~C~~ommon or ~~U~~sual or ~~M~~arket ~~N~~ame.

FDA is proposing 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 (proposed § 1.288(e)(1)(ii)). This is a description, in common terms, detailed enough to allow the kind of product to be identified. (See 21 CFR § 102.5 for additional information about common or usual names.) The filer currently submits the common or usual or market name to U.S. Custom's ACS when entry is made, and it subsequently is transmitted to FDA's OASIS for each entry line. This information is necessary to confirm the accuracy of the product code.

iii. ~~(iii)~~ The ~~T~~rade or ~~B~~rand ~~N~~ame.

FDA is proposing 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 (proposed § 1.288(e)(1)(iii)). For example, the brand name of canned tuna would be XYZ brand tuna. This information is necessary to ensure that FDA knows the brand identity of the product, which is often a critical piece of information when making inspection decisions. The filer currently submits the trade or brand name to U.S. Custom's ACS when entry is made, and it subsequently is transmitted to FDA's OASIS for each entry line.

iv. ~~(iv)~~ The ~~Q~~uantity.

FDA is proposing to require the submission of the quantity of food described from smallest package size to largest container as an element of the identity of the product (proposed § 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). Some examples of quantity descriptions are: 100 cartons of 48/6 oz. cans each of tuna; 100 pallets of 2/100 lb. totes each of frozen tuna loins for a total of 20,000 pounds; 100 pallets of 2/100 lbs. cartons each of dehydrated pig ears for a total of 20,000 lbs.; and 100 cartons of 20 lbs. of fresh watermelons each for a total of 2000 lbs. The filer currently submits the quantity of each line entry to U.S. Custom's ACS when entry is made, and it subsequently is transmitted to FDA's OASIS. FDA requests comment on whether changes in quantity will occur after the deadline for prior notice and, if so, how commonly changes occur and how significant the changes usually are.

V. ~~(v)~~ The ~~L~~ot or ~~C~~ode ~~N~~umbers or ~~O~~ther ~~I~~dentifier.

FDA is proposing 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(f)(1)(v)). These numbers are the identification number or code of a production lot and are needed to more specifically identify a product. Currently, there may be more than one identifier represented in an entry line. The prior notice system will be developed to accept more than one lot identifier per article.

f. ~~6~~. *The ~~M~~anufacturer.* As provided for in section 801(m)(1), FDA is proposing to require the submission of the identity of the manufacturer of each article of food (proposed § 1.288(f)). The filer currently submits the identity of the manufacturer to U.S. Custom's ACS when entry is made, and it subsequently is transmitted to FDA's OASIS.

g. ~~7~~. *The ~~G~~rowers, ~~I~~f ~~K~~nown.* As required by section 801(m)(1), FDA is proposing to require the submission of the identity of all growers of each article

and the growing location if different from the grower's business address, if known at the time of submission of the prior notice (proposed § 1.288(g)). If the submission is amended, the proposed rule provides that the identity of all growers must be provided if known at the time of the amendment (proposed § 1.290(d)). FDA wants to emphasize that section 801(m)(1) of the act states that grower information must be submitted if it is known. Thus, this information is not optional: if it is known, it must be submitted. If a product is sourced from more than one grower, the prior notice must provide the identification of all growers, if known. The FDA Prior Notice System will be developed to accommodate submission of up to three different growers.

FDA solicits comments on two particular aspects of the statutory requirement that the grower be identified. First, does the act give FDA any flexibility to exempt or otherwise treat differently so-called processed foods produced with products from more than one grower? Second, does the term "grower" include a harvester or collector of wild products, e.g., some fish and botanicals?

h. ~~8~~. *The ~~O~~riginating ~~C~~ountry.* As provided for in section 801(m)(1), FDA is proposing to require the submission of the identity of the originating country of the article of food (proposed § 1.288(h)). This term is defined in proposed § 1.277(c)(2).

i. ~~9~~. *The ~~S~~hipper.* As provided for in section 801(m)(1), FDA is proposing to require the submission of the identity of the shipper of the article of food (proposed § 1.288(i)). FDA considers the shipper to be the person who arranges for a shipment to get to its first destination in the United States. The shipper typically is responsible for initiating the bill of lading or airbill covering the transportation of the article by the carrier. The shipper is usually a foreign

firm that is located or maintains an address in the country from which the article was shipped. The shipper is typically not the carrier.

j. ~~10~~. *The Country of Shipping.* As provided for in section 801(m)(1), FDA is proposing 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).

k. ~~11~~. *Anticipated Arrival Information.*

i. ~~(i)~~ The Anticipated Port of Entry.

As provided for in section 801(m)(1), FDA is proposing to require the submission of the anticipated port of entry at which the article of food will arrive in the United States (proposed § 1.288(k)(1)(i)). "Port of entry" is defined in proposed § 1.277(c)(5).

ii. ~~(ii)~~ The Anticipated Date of Arrival.

FDA is proposing to require the submission of the anticipated date when the article of food will arrive at the port of entry in the United States (proposed § 1.288(k)(1)(ii)). FDA believes that this information is necessary to plan inspections.

iii. ~~(iii)~~ The Anticipated Time of Arrival.

FDA is proposing to require the submission of the anticipated time when the article of food will arrive at the port of entry in the United States (proposed § 1.288(k)(1)(iii)). FDA believes that this information is necessary to plan inspections.

FDA is proposing 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 are necessary so FDA can change its plan when anticipated arrival information changes. The conditions appropriate for updates are provided in proposed § 1.294.

l. ~~12~~. *The Port Where Entry Will Be Made For U.S. Customs Purposes.* FDA is proposing to require the submission of the identification of the port where entry will be made for U.S. Customs purposes (proposed § 1.288(l)). Often, this port will be different than the port where the article of food arrived in the United States. FDA believes that this information is necessary to facilitate communication with U.S. Customs and FDA field offices concerning the adequacy of the prior notice. It is also necessary to enable FDA to coordinate resources for inspections, examinations, or sampling.

m. ~~13~~. *The Anticipated Date Of U.S. Customs Entry.* FDA is proposing to require the submission of the anticipated date of entry for U.S. Customs purposes (subpart 1.288(m)). FDA believes that this information is critical to enable it to allocate resources for inspecting imported food shipments and efficient communication with and between U.S. Customs and FDA field offices.

n. ~~14~~. *The Importer, Owner, and Consignee.* Under section 801(m)(2)(B)(i) and proposed § 1.278(e)(2), food that is offered for import with no or inadequate notice may not be delivered to the importer, owner, or consignee. Thus, FDA is proposing to require their identities so that FDA knows who they are and can take steps to ensure that food refused admission under section 801(m) is not delivered to them illegally. FDA is proposing that only one importer, owner, and consignee can be identified for each prior notice. Under most circumstances, FDA believes the importer will be the importer of record for U.S. Customs Entry Summary purposes.

o. ~~15~~. *The Carrier.* FDA is proposing 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. This identification includes the submission of the Standard Carrier Abbreviation Code.

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 filer currently submits carrier information to U.S. Custom's ACS when entry is made, and it subsequently is transmitted to FDA's OASIS.

5. What Changes are Allowed to a Prior Notice After it Has Been Submitted to FDA? (Proposed § 1.289)

FDA is allowing additional information to be supplied once a prior notice is submitted in two situations. FDA believes that under the standards in section 801(m)(2)(A) for establishing the timeframes for submission of prior notice, amendments are appropriate when complete product identity will not exist by the deadline for the submission of a prior notice. As described in more detail elsewhere, FDA believes that these situations largely involve fresh produce and fish harvested in countries close to the United States, e.g., Mexico and Canada. Second, FDA believes that it must have accurate arrival information in order to ensure it can inspect an article or take other appropriate action. In the event that other information in the prior notice must be changed, no amendment or update is permitted. The submitter must cancel the initial prior notice and submit a new one.

6. 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 is proposing that the prior notice must be amended if all information about the identity of the food required by proposed § 1.288(e)(1) does not exist by noon of the calendar day before the day of arrival. The submitter must

indicate his or her intention to amend the information at the time the initial prior notice is submitted. FDA is proposing that the prior notice may be amended only once. FDA is limiting the number of times a prior notice may be amended because FDA believes that it would be an inefficient use of its review and planning resources to address intermediate, still incomplete submissions. FDA wants to encourage submissions that are as complete as possible to allow FDA to deploy its resources effectively. FDA requests comment on our proposal to restrict the number of amendments to one.

FDA is proposing that only the information required by proposed § 1.288(e)(1) and indicated in the initial prior notice as being subject to amendment may thereafter be amended. FDA is proposing to limit the information that may be amended in a prior notice to the product identification information required in proposed § 1.288(e)(1). As we explain elsewhere in this preamble, we believe that in most situations, complete product identity will exist by noon of the calendar day before the day of arrival. However, we recognize that in certain limited circumstances, such as wild-caught fresh fish and fresh produce with many varieties that are caught or harvested close to the time of shipment in locations close to the U.S. border, this specificity may not be known by noon of the calendar day before the day of arrival. FDA is proposing that the last two digits of the FDA product code and other product identity information that provides the specific identity of the article may be amended when this information does not exist by the prior notice deadline.

For example, there may be occasions when an entry of lettuce is ordered and prior notice is submitted by noon the calendar day prior to arrival, but the specific variety of lettuce that will be shipped does not exist because the growers that supply the shippers have not yet harvested their crops. At or

before the time when the article is placed in the carrier for shipment, however, the complete identity of the article exists and the prior notice must be amended to identify the specific type of lettuce (e.g., romaine or leaf).

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.

If an article of food is not covered by a specific FDA product code, e.g., a root vegetable not more specifically described by numerical code in the FDA product code builder, then the last two numbers of the product code may be provided as "99" which means root vegetables, not elsewhere classified. However, this prior notice cannot be amended later to identify the product as carrots because, even though carrots are root vegetables, there is an FDA product code that is specific to carrots and thus it should have been used in the initial notice. We plan to design the prior notice system so that it will not acknowledge that a prior notice submission is completely filled out if it does not contain a seven-digit product code. The system will be designed to provide, where appropriate, a reminder about the need for amendment with the electronic message acknowledging receipt of the initial submission.

The information that may be amended also includes the common or usual or trade name, brand name, lot or code or identification numbers, and quantity.

FDA is proposing that, if the identity of the grower was not provided at the time the prior notice was submitted because it was not known at that time but the identity is known at the time of the amendment, the amendment must include information that identifies all known growers.

7. What is the Deadline for Product Identity Amendments Under § 1.290? (Proposed § 1.291)

FDA is proposing a 2 hour minimum deadline for amendments submitted under proposed § 1.291, or updates submitted under proposed § 1.294.

FDA believes that the deadline will allow submitters to provide FDA the information it needs in order to effectively assess whether a particular shipment of food needs to be investigated and if so, to ensure FDA personnel are present to do so when the food arrives at the port of entry, while allowing submitters to amend and/or update information that may not be known with exact certainty by noon of the prior calendar day. FDA considered the type of food in proposing the deadline for amendment to the product identity and updates to the anticipated arrival information.

FDA believes that product identity amendments are most likely to be needed to accommodate articles imported by land or air rather than water arrivals. FDA also recognizes that this limitation on amendments may also affect the practice of "topping off a container" by filling unused space in the container or truck bed with last-minute shipments of other food products not covered by prior notice.

FDA notes that under its amendment proposal "topping off" with the article of food that is already the subject of a prior notice would be allowed. To the extent "topping off" with non-food items occurs, this practice would not be affected. FDA believes, however, that this limitation is dictated by the Bioterrorism Act's requirements and moreover is necessary to ensure that FDA has adequate notice of all FDA-regulated food imports such that FDA can deploy its resources effectively. In this case, a separate prior notice would be

required for these foods not already covered by a prior notice. FDA solicits comment how common "topping off" is and the quantities of food involved.

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

FDA is proposing to limit the way in which a prior notice may be amended or updated. FDA is proposing 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 FDA's Prior Notice System. Only the information concerning product identity and grower identity can be electronically amended under proposed § 1.290. Only the information concerning the anticipated location, date, and time of arrival and grower identity can be electronically updated under proposed § 1.294.

FDA proposes to design its Prior Notice System to require identification of the type of submission (Initial, Amended, Updated) and to be capable of differentiating amongst them. If FDA's Prior Notice System is unable to receive submissions electronically, amendments or updates may be communicated directly to FDA using a printed version of the Prior Notice Screen, and delivered either in person, by fax, or by e-mail to the FDA field office with responsibility over the geographical area in which the port of entry is located, as provided by proposed § 1.287(b). If the identification of the anticipated port of entry is being updated, and the FDA system is down, the updated printed version of the Prior Notice Screen should be delivered to the FDA field office with responsibility over the port covered by the initial submission. FDA intends to issue guidance for communication between the field office receiving the initial prior notice and the field office covering the updated port of entry.

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

FDA is proposing 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 does not amend it appropriately and within the applicable timeframe, then the prior notice is inadequate for the purposes of proposed § 1.278(a). By telling FDA that the prior notice will be amended they are telling us that it is incomplete. We therefore will be waiting for complete information upon which to make our inspection decision. Without complete product identity, FDA cannot complete the assessment of whether to inspect or take other action when the food arrives in the United States. The consequences of inadequate prior notice are the same as the consequences for failing to provide prior notice; the food shall be refused admission and held at the port of entry unless FDA directs its removal to a secure facility. The consequences are more fully described previously in the discussion of proposed § 1.278.

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

FDA is proposing to require the submitter to update anticipated arrival information submitted in a prior notice, if the anticipated information changes after the submission. The types of information FDA expects may change between submission of prior notice and actual importation are the date, time, and location of arrival. Although the statute requires only anticipated port of entry, accurate, up-to-date arrival information (if different) is necessary for FDA field offices to reschedule inspections. FDA thus believes that it has the authority to require this information.

If anticipated arrival information submitted in a prior notice changes, FDA is proposing that the submitter be required to provide the new port of entry (proposed § 1.294(a)(1)), and the new time of arrival in an update electronically filed in the Prior Notice System (proposed § 1.294(c)). FDA is proposing that if the time of arrival is expected to be more than 1 hour earlier (proposed § 1.294(a)(2)) or more than 3 hours later (proposed § 1.294(a)(3)) than the anticipated time of arrival, the time of arrival must be updated. FDA is proposing that, if the identity of the grower was not provided at the time the prior notice was submitted and that identity is known at the time of the update, the amendment must include information that identifies growers (proposed § 1.294(b)).

The FDA Prior Notice System will be designed to accommodate updates. As stated above, FDA is proposing to design its Prior Notice System to require identification of the type of submission (Initial, Amended, Updated) and to be capable of differentiating amongst them.

FDA is proposing to limit the time within which a prior notice may be updated. The proposed regulation would require updated information to be submitted in accordance with the deadline for amendments under proposed § 1.291, that is, an update to a prior notice must be submitted 2 hours prior to arrival.

IV. Analysis of Economic Impacts

A. Preliminary Regulatory Impact Analysis

FDA has examined the economic implications of this proposed 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 proposed rule is a significant regulatory action as defined by Executive Order 12866.

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of $100 million; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, OMB has determined that this proposed rule, when final, will be a major rule for the purpose of congressional review.

1. Need for Regulation

Section 307 of the Bioterrorism Act (Public Law 107–188), requires advance 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. The Reason for the Regulation

Getting food from the farm or sea to the plate involves a complex system of production and distribution. The system works using local knowledge and information; each participant needs to know only as much about the overall system as is necessary for his or her business. Market prices convey most of the information necessary for the ordinary production and distribution of food. In the event of an actual or suspected contamination of the food supply, however, more complete information is needed where it can be centrally used. The suspect food must be traced backward and forward through the distribution chain, both to protect consumers and to find the source and cause of the event.

No individual firm or organization has sufficient financial incentive to establish a central information system relating to food safety for the entire economy. The nation's food producers and importers as a whole would benefit from such a system because it would be easier to uncover and solve problems, but the private costs to create the system would probably be prohibitive for any single firm or third party organization.

The events of September 11, 2001, led Congress to conclude that public creation and provision of an information system is necessary. The Bioterrorism Act and its implementing regulations would establish an information system that would allow FDA to have a more integrated picture of the food distribution system. This particular regulation addresses one important aspect of this information system: the need to know what imported foods are entering the United States, where they came from, and when they will arrive. FDA is

proposing three regulations to address these needs so the costs and benefits of any one regulation will be closely associated with related provisions in other proposed rules. With the regulations in place, the agency would have the additional tools necessary to help deter and respond to deliberate threats to the nation's food supply as well as to other food safety problems.

3. Proposed Rule Coverage

This proposed rule would apply to all FDA-regulated food for human and animal consumption imported or offered for import into the United States with the exception of food carried in a traveler's personal baggage for personal use. As required by the Bioterrorism Act, the notification must provide the identity of the article, the identity of importer, manufacturer, shipper, and grower (if known), the originating country, the country from which the article was shipped, and the anticipated port of entry. In addition, the notification must provide the identity of the person who submits the prior notice, the owner, the consignee, the carrier, the U.S. Customs entry number, anticipated time and date of arrival, and, if the food has already been refused admission and required to be held, the location where it is held.

A growing percentage of food consumed in the United States is imported; the value of food imports is now close to $50 billion per year. (Ref. 2) In the aftermath of the terrorist attacks on the United States on September 11, 2001, Congress determined that the existing requirements for the importation of FDA-regulated food products were insufficient to protect the safety of the U.S. food supply.

Before September 11, 2001, FDA had approximately 150 personnel in the field processing imported food entries based on FDA's programs and assignments, all using guidance documents, such as Import Alerts, Compliance

Policy guides, and other manuals. After September 11, 2001, FDA hired three hundred additional counterterrorism Consumer Safety Officers primarily for food imports. This step alone is insufficient to ensure the safety of food imported or offered for import into the United States.

When deciding which imported food shipments to physically inspect and sample, FDA inspectors consider, among other things, compliance programs, assignments, import alerts, and whether the product is a low-risk or high-risk food. New requirements imposed by Section 307 of the Bioterrorism Act will require importers to give notice to FDA of incoming articles of food before the shipment reaches a U.S. border, rather than when the shipment arrives at the U.S. border or as part of the official U.S. Customs entry. Requiring prior notice of imported food shipments will allow FDA inspectors to have earlier information on foods that are coming into the United States, which will enable FDA to better deploy its inspection resources and to use this increased amount of information in cases where FDA action against the food is warranted, e.g., a credible threat to the food supply is suspected.

Number of Establishments Affected

Using 2001 FY information from FDA's OASIS system (industry codes 02 through 52, 54, and 70 through 72), FDA has determined that there are approximately 77,427 importers and consignees who receive imported food shipments. Under the proposed rule, the U.S. importers or U.S. purchasers (or their agents) of the products will be responsible for submitting a timely and accurate prior notice to FDA. Using information from the OASIS system, FDA was also able to determine that there are approximately 100,000 foreign manufacturers (of a finished product). Foreign manufacturers are not responsible for submitting prior notice, and therefore, while not unaffected by

prior notice, foreign manufacturer costs associated with this proposed rule will be assumed to be spread across the supply chain and therefore are not directly addressed in this analysis.

FDA requests information on the size of establishments likely to be affected by this rule, including the foreign manufacturers of food products and the importers and consignees receiving the imported food shipments.

New and closing importer establishments

In addition to the U.S. importers currently in existence, in future years some new import businesses will open and some existing import businesses will close. According to the Small Business Administration Office of Advocacy, in 2001 about 10 percent of all businesses were new and 10 percent of all businesses closed. These new importers would 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.

Baseline

FDA considers the baseline for this analysis the current state of the world, pre-statute, and we assume this baseline has zero costs and benefits.

Current State of The World

The majority of the information that will be required by section 307 of the Bioterrorism Act now is currently supplied at the time of entry by a U.S. Customs broker or self-filer, and usually is submitted electronically. Although importers already must notify U.S. Customs of entries, the Bioterrorism Act requires notification to FDA prior to the food shipment reaching the U.S. border or point of crossing. This requirement will change the current practice

of notifying U.S. Customs 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 U.S. Customs) at a U.S. port of entry.

FDA's OASIS reporting system shows that approximately 2.5 million food entry lines were imported via sea and air transportation in FY 2001. Information on food-importing practices indicates that U.S. Customs and FDA are notified of imported food products traveling to the United States by vessel before the products' arrival. Vessels can notify U.S. Customs months before the actual shipping date, but U.S. Customs will not certify the entry until 5 days before the ship is expected to dock at a U.S. port. FDA is notified of the shipment then, through U.S. Customs, as early as 5 days before the vessel's arrival at a U.S. port.

Importers bringing food products in by airplane can notify U.S. Customs 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 U.S. Customs until the plane has taken off from the airport of the exporting country ("wheels-up"). FDA is then notified through U.S. Customs of the plane's scheduled arrival. U.S. Customs has informed FDA that they receive flight information for 87.6 percent of the flights at time of "wheels up."

FDA's OASIS reporting system shows that around 2.2 million entry lines of food were imported into the United States via ground transportation in FY 2001. The usual practice today for food brought in by truck or train (mainly products coming directly from Canada or Mexico) is not to notify U.S. Customs and FDA until their actual arrival at a U.S. border or point of entry. (Filers can certify their entry data up to 24 hours before arrival at the border, but

U.S. Customs does not give a "screening response" to the entry until actual arrival.) Even though these importers most likely have the invoices and orders for these products in advance, they do not currently notify U.S. Customs and FDA until their arrival at the border.

4. Regulatory Options Considered

We analyzed five options for a prior notice regulation:

1. Current state of the world, pre-statute (baseline).

2. Prior notice time of 4 hours or less; 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 a United States based-importer or purchaser (or their U.S.-based agent). This option applies to all imported foods, except for food exclusively regulated by USDA and food imported with personal baggage for personal use, regardless of entry type or mode of transportation used for import. Submission of prior notice information (including addresses of all importers, owners, manufacturers, consignees, identity and quantity of food, originating country, country of shipping, date, expected time of arrival, expected port of entry, and grower if known) must be electronic.

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

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

5. Require all components of option 4, but allow some prior notice information to be revised prior to arrival at a U.S. port (proposed option).

Option one: Current state of the world, pre-statute.

Having no prior notice requirements is option 1 in our analysis. The statute requires that FDA issue prior notice regulations, so this is not a legally viable option. However, 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.

Option two: Minimum prior notice timeframe of 4 hours or less; electronic submission of information; any change in information requires resubmission.

Costs: The party responsible for transmitting prior notice to FDA will incur administrative and notification costs to comply with this proposed 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 conversation with other business operators who also must comply with prior notice. Once the U.S. importer or U.S. purchaser of the food 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.

To become familiar with the requirements for this rule, FDA estimates that it initially will take responsible parties with Internet access about 1 hour to research the prior notice requirements, and responsible parties without readily available Internet access about 2 hours to research the requirements. Comments from both the Produce Marketing Association (PMA) and the National Food

Processors Association (NFPA) indicate that about 96 percent of the industry has readily available Internet access.

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 research the prior notice requirement. For an administrative worker, the cost per hour is $25.10: for a manager, $56.74. FDA assumes that only the administrative worker's time will be used to research the prior notice requirements. As shown in table 1, total costs of this research activity for firms with Internet access are $1,865,683; for firms without Internet access, the total research costs are $155,469.

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 and the present value of this cost, using a 7 percent discount rate, are also shown in table 1.

TABLE 1.—COST TO RESEARCH PRIOR NOTICE

Cost to Research Prior Notice	With Internet Access	No Internet Access
Number of Firms	74,330	3,097
Administrative wage rate per hour (including overhead)	$25.10	$25.10
Total time to research regulation	1 hour	2 hours
First year one-time research costs	$1,865,683	$155,469
Annual one time research costs for new firms entering industry in subsequent years	$186,568	$15,547
Present value of cost of firms entering the industry	$2,665,257	$222,100
Total research cost burden	$4,530,940	$377,569

All prior notices must be submitted electronically, so we will assume that the 3,097 responsible parties without Internet access will have to purchase a computer and gain Internet access to actually transmit the information via a prior notice screen. This one-time computer cost and a recurring Internet access cost for these facilities of $7,559,777 are shown in table 2.

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. However, it becomes more unlikely with the passage of time that persons will be purchasing this computer equipment solely to comply with prior notice. Therefore, a present value of this cost is not calculated.

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 x 12)	$240
Search costs for equipment and access ($25.10 x 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
Total electronic transmitting costs	$8,315,755

FDA used OASIS information to find out that 4.7 million entry lines for food were imported into the United States in FY 2001. An "entry line" is an FDA term used by the OASIS reporting system, which refers to a line on an invoice that reflects a certain article specific to manufacturer or packaging: e.g., 100 cases containing 48 six-ounce cans of tuna. This 4.7 million entry line total includes the 2.2 million entry lines for food that came into the United States in 2001 via ground transportation (trucks and trains) and the 2.5 million entry lines for food that came into the United States in 2001 via airplane and vessel.

The entry line totals for FY 2001 do not include food brought into the United States as personal baggage with the food intended for sale or other distribution, not for personal use. Under the proposed rule, persons bringing

food into the United States in this manner, however, are required to submit prior notice to the FDA. FDA does not know how common the practice is of importing food for non-personal use as part of personal baggage. For FY 2002, there were only 18 entry lines associated with food imported as U.S. mail and 486 food entry lines imported by courier. FDA believes that entries of food imported as part of personal baggage but not for personal use will fall somewhere between mail and courier entries. Since any number of entries in this range is minimal as compared with the 4.7 million total OASIS entries, FDA likewise believes the costs associated with prior notice for food in personal baggage entries will be minimal and thus these costs are not included in this analysis. FDA requests comment on this assumption.

According to OASIS data, the average imported 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 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.

U.S. Customs Form 3461, Entry and Immediate Delivery Application, OMB No. 1515–0069, is the entry document upon which information is provided to U.S. Customs by which it makes its decision to release the merchandise. The burden estimate on U.S. Customs Form 3461 for purposes of the Paperwork Reduction Act is 15.5 minutes. The FDA calculation of average time for completion of the prior notice includes verification of accuracy of the data and supervision time.

FDA estimates that it will take, on average, 1 hour to prepare a prior notice each time an import entry of 2.6 lines is submitted, including the time it takes to update or amend information for each entry line as necessary. This time

is an average; some prior notices will take longer than 1 hour to complete and other prior notices will take less than 1 hour to complete. FDA requests comment on the time it will take to complete a prior notice form, including the time it will take for amendments and updates to the information.

This hour includes 45 minutes of an administrative worker's time to gather information to initially complete the screen and then update the information as necessary, and then 15 minutes of the 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 is estimated to take about 23 minutes to complete.

Using the OASIS information that the average imported entry contains 2.6 lines; we can then divide the 4.7 million OASIS lines by 2.6, which results in 1,807,692 expected import entries. Table 3 shows that the annual cost of prior notice submissions based on 1,807,692 entries would be $59,689,990.

TABLE 3.—COST TO FILL OUT PRIOR NOTICE SCREENS BY IMPORT ENTRY (MUST BE ELECTRONIC)

Administrative worker time at $25.10 wage rate	45 minutes
Manager time at $56.74 wage rate	15 minutes
Administrative worker costs per entry	$18.83
Manager costs per entry	$14.19
Total Cost per import entry	$33.02
FY 2001 OASIS entry total based on 4.7 million lines	1,807,692
Total Annual Costs of all prior notice screens based in lines, and including updates and amendments to the information	$59,689,990

FDA Costs: We assume that FDA's information technology (IT) costs for this option and each option hereafter are the costs of developing a stand-alone, web-based, electronic system to receive prior notice information and then to respond electronically with an acknowledgement of the transmission to the

submitting party. The stand-alone prior notice system will be used until U.S. Customs new automated system, ACE, becomes operational. FDA will coordinate with U.S. Customs to develop ACE to accommodate the information required by prior notice. Once ACE is operational, it will simplify prior notice transmissions. For now, building a stand-alone IT system to handle prior notice submissions will require design, development, implementation, maintenance, modernization, and upgrades. These costs include the labor hours, hardware, and software costs needed to make the prior notice system operational. Table 4 shows that FDA estimates the costs to the agency for setting up the prior notice system to be about $4.4 million. This total cost includes FDA personnel, contractor development of the hardware and software needed, industry outreach and training, and a computer firewall.

TABLE 4.—FDA PRIOR NOTICE SYSTEMS COSTS

Hardware	$500,000
Analysis, Design, Implementation	$3,000,000
Software licenses and Security	$500,000
Network Interface	$200,000
FTEs	2
Cost per FTE	$110,588
Total FTE costs	$221,176
Total Systems Cost	$4,421,176

Current operating practices affected: A 4-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. Some comments received indicated that it would be preferable if the minimum prior notice time were set at 4 hours or less. Comments requested the shorter minimum prior notice time because the source of some food products often is close to the U.S. border, and some products are perishable. However, it is the U.S. importer or U.S. purchaser or their U.S. agent who is responsible for

submitting the prior notice, and the information required in prior notice should be sufficiently fixed after the order is placed and will not depend on the location of the source of the food product.

How many business practices will be affected by prior notice requirements largely depends on how early the orders for the food products are placed compared to the time by which prior notice must be submitted. Most orders for products, even for those of a perishable nature, are often placed days or weeks if not months before the actual delivery date. Therefore, if the order for the product was sent a week, or even 1 day, before the delivery date, a minimum prior notice time of 4 hours should not cause any delay in the order. FDA requests comments on this assumption.

Also important in determining how business practices will be affected by the prior notice requirements is when the prior notice was submitted compared with when the shipment corresponding to that prior notice was loaded onto a vehicle. For example, if the prior notice was submitted as soon as the order was received, or even a few hours before loading the vehicle, there is a possibility that unforeseen factors, including composition of the actual shipment, may cause the prior notice information submitted to not match the actual shipment on the vehicle. However, if the prior notice is not submitted until the vehicle is actually loaded, the probability of submitting an incomplete prior notice is greatly reduced. Thus, when the order for the shipment is received, when the prior notice is submitted, and when the vehicle is loaded play large roles in how much the requirement for prior notice will affect operating practices for those importing some perishable products from Mexico and Canada. FDA requests specific information about how business practices for all operations could change as a result of the prior notice requirement.

If importers have orders for perishable products from Canada and Mexico filled more than 4 hours before scheduled arrival at a U.S. border point, then the only change in business practice that should occur is when they will submit their prior notice to FDA.

There will be those shipments by vehicle, however, for which the order was not received in advance of the shipping time, those shipments for which the quantity and composition of the product has changed since the time when the prior notice was submitted, and those 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 ground 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; until better information is available, we will assume that 20 percent of the fresh produce and seafood being imported to the United States from Canada and Mexico would have a reason for which their original prior notice submission must be changed and resubmitted less than 4 hours before entry.

FDA chooses 20 percent as the percent of prior notices that need to be submitted based on information that most orders for products are placed well in advance of the actual shipping date, most orders are filled with the exact product and quantity the customer requests, and the 4 hour prior notice entry time is minimal when compared to when the order was actually received. Depending on the entry point, 40 to 100 percent of shipments are loaded onto

vehicles less than 4 hours before entry. We chose one-half of the lower percent as the percent of prior notices that would need to be resubmitted under this option.

The following paragraphs and tables outline how FDA calculated a loss in product value to account for the time that fresh produce and seafood being brought by ground transportation into the United States might have to wait to cross the border due to prior notice resubmission. This wait at the border occurs if prior notice is resubmitted with revised information regarding the shipment when the shipment is closer to the border than the 4 hours required; the transporter of the shipment must wait for the minimum prior notice time to elapse before crossing the border or risk being refused entry.

Table 5 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). Importers of products currently regulated by the Agricultural Marketing Agreement Act, e.g., tomatoes, avocados, oranges, are required to notify USDA at least 1 day prior to U.S. entry 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 period. FDA requests comments on the perishability of the produce that is used in this count.

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, which can range from 100 percent to 600 percent (Ref. 7). 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. We will reexamine our choice of the 100 percent mark-up rate in a sensitivity analysis presented later in the costs section.

Assuming that perishable produce has an average life span of 7 days, we can then estimate the value of the time lost (4 hours) for 20 percent of the imports waiting to cross the border as a 2.4 percent loss (4 hours out of 168 hours) in the product's value. Applying this percent loss in value to one-quarter of the total retail revenue of imported Mexican fresh produce results in a $16,600,920 loss in produce value.

TABLE 5.—FRESH 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	6491	0.29	188,239,000
Peppers (all varieties)	6088	0.53	322,664,000
Squash	4158	0.71	295,218,000
Mangoes	3461	0.57	197,277,000
Papaya	1587	0.45	71,415,000
Broccoli	1138	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-misc.	78	1.67	13,026,000

TABLE 5.—FRESH PRODUCE IMPORTED FROM MEXICO—Continued

Perishable produce from Mexico	Total Volume for 2001 (100,000 lb units)	Current Wholesale Price per lb. (Sept. 2002)	Total Revenues Wholesale
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
2.4% reduction in value for 20% of the products			$16,600,920

We repeat the exercise outlined above in table 5 for Canada, as shown in table 6. Again, until FDA acquires updated information, we will assume that Canadian produce growers use business practices that are similar to those used by Mexican growers. FDA solicits comments on this assumption. While FDA acknowledges that their business practices may be different in some ways, it is possible that Canadian produce growers will also have to adjust business practices so that submitters can comply with the prior notice requirement. We seek comment on this issue.

As with the Mexican produce, only Canadian produce that is highly or very highly perishable and did not fall under the purview of the Agricultural Marketing Agreement Act is included in table 6.

We again calculate the 2.4 percent loss in product value due to the importer having to resubmit prior notice for 20 percent of the Canadian imported fresh produce. This loss in product value due to the 4-hour wait time totals $1,928,765.

TABLE 6.—FRESH 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

TABLE 6.—FRESH PRODUCE IMPORTED FROM CANADA—Continued

Perishable Produce from Canada	Total Volume for 2001 (100,000 lb units)	Current Wholesale Price per lb. (Sept. 2002)	Total Revenues Wholesale
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
2.4% reduction in value for 20% of the products			$1,928,765

We used the same logic for seafood as we did for produce to account for the possibility of having to resubmit prior notice, i.e., a change in the quantity of seafood in the shipment made after the original notice was submitted, less than 4 hours before scheduled entry. We will 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.

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 fresh, perishable seafood products imported from Mexico and Canada. As we did for fresh produce, we mark-up the wholesale price of the fresh seafood by 100 percent (Ref. 9) to represent the retail value of the products. Then, assuming that perishable seafood will keep for 2 days in a consumer's refrigerator, (Ref. 10) we find that an 4-hour

delay in delivery time caused by the prior notice requirement for 20 percent of the products results in a 8.3 percent loss in that seafood's value (4 hours out of 48 hours). Table 7 shows that the lost time results in a $1,863,805 loss on the value of Mexican fresh seafood imports. FDA requests comment on the perishability of the seafood used in tables 7 and 8.

TABLE 7.—FRESH SEAFOOD IMPORTED FROM MEXICO

2001 Fresh 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
Groundfish 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

TABLE 7.—FRESH SEAFOOD IMPORTED FROM MEXICO—Continued

2001 Fresh Mexican Seafood Products	Pounds	Dollars
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
8.3% reduction in value for 20% of products		$1,863,805

Table 8 shows the 4 hours of lost time due to prior notice resubmission for 20 percent of all imported Canadian fresh seafood causes a value loss of $30,929,417.

TABLE 8.—FRESH SEAFOOD IMPORTED FROM CANADA

2001 Fresh 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

TABLE 8.—FRESH SEAFOOD IMPORTED FROM CANADA—Continued

2001 Fresh Canadian Seafood Products	Pounds	Dollars
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
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

TABLE 8.—FRESH SEAFOOD IMPORTED FROM CANADA—Continued

2001 Fresh Canadian Seafood Products	Pounds	Dollars
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
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
16.7% reduction in value for 20% of products		$30,929,417

Table 9 presents a summary of the costs associated with option 2. Also presented in table 9 is the present value of the costs associated with this option, calculated using the OMB-recommended discount rate of 7 percent.

TABLE 9.—SUMMARY OF COSTS FOR OPTION 2

Research costs	$4,908,509
Computer acquisition costs	$8,315,755
Annual costs to fill out prior notice screens (including updates and amendments)	$59,689,990
FDA prior notice system cost	$4,421,176
Lost value for Mexican produce	$16,600,920
Lost value for Canadian produce	$1,928,765
Lost value for Mexican seafood	$1,863,805

TABLE 9.—SUMMARY OF COSTS FOR OPTION 2—Continued

Lost value for Canadian seafood	$30,929,417
Total Costs for Option 2	$128,658,337
Present value of costs	$1,603,543,969

Option three: Minimum prior notice timeframe of 8 hours; electronic submission of information; any change in information requires resubmission.

Option three is to allow the minimum timeframe for prior notices, as dictated by the statute, to take effect. Comments indicated that Canadian and Mexican produce growers and seafood processors are concerned that the longer the minimum time required for the prior notice, the less fresh their products will be when they reach customers. Less-than-optimal fresh (i.e., lower quality) products would result in a lower price paid for the imported produce or seafood shipments, or possibly even the loss of a customer's business to a domestic producer. For importers of perishable products such as seafood and produce, the 8-hour minimum time for prior notice might change business practices in the industry. These changes in business practices would be in addition to the costs of learning about the proposed regulation, submitting forms, and the FDA IT costs outlined in option two.

How much importer, produce grower, and seafood processor business practices will be affected by prior notice requirements again will depend on how early the orders were received compared with how early prior notice must be submitted. If the order for the product was placed more than 8 hours before the truckload 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 was submitted.

For example, if the prior notice is submitted just a few hours before loading the truck, unforeseen factors, including composition of the actual shipment, may cause the prior notice information submitted to not match the actual shipment on the truck. This is just one example of how 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 articles start heading for the border. Therefore it is likely that some shipments may have to wait several hours and possibly the full 8-hour minimum for the resubmitted prior notice to be accepted by FDA.

If the prior notice time for submission is 8 hours instead of 4 hours, the probability of having to adjust and resubmit prior notice information will be higher. Now, instead of 20 percent of the importers of perishable products from Canada and Mexico having to resubmit their notices, we will assume that the 8-hour submission timetable means that 25 percent will have to resubmit their notices. We do not expect the number of resubmissions to increase greatly as the minimum timeframe for prior notice is still minimal and FDA expects most orders to be placed well in advance of the 8-hour timeframe. We assume that as the minimum notice time increases, the likelihood of a resubmission also increases, but less than proportionally to the change in minimum notice time.

Carriers of these products may not be able to cross the border for 8 hours instead of 4 hours, which affects 4.8 percent of the produce life span (8 hours

out of 168 hours) and 16.7 percent of the seafood life span (8 hours out of 48 hours).

Table 10 shows the loss in value caused by the resubmitted prior notice information for the 25 percent of imported Mexican and Canadian fresh seafood and produce affected.

TABLE 10.—LOSS IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION 3

Perishable Produce	
2001 Imported Mexican Produce Total Retail Value	$3,458,525,000
4.8% reduction in value for 25% of Mexican produce	$41,502,300
2001 Imported Canadian Produce Total Retail Value	$401,826,000
4.8% reduction in value for 25% of Canadian produce	$4,821,912
Perishable Seafood	
2001 Imported Mexican Seafood Total Retail Value	$112,277,406
16.7% reduction in value for 25% of Mexican seafood	$4,687,582
2001 Imported Canadian Seafood Total Retail Value	$1,863,217,894
16.7% reduction in value for 25% of Canadian seafood	$77,789,347

Table 11 presents a summary of the costs associated with option 3. Also presented in table 11 is the present value of the costs associated with this option using the OMB-recommended discount rate of 7 percent.

TABLE 11.—SUMMARY OF COSTS FOR OPTION 3

Research costs	$4,908,509
Computer acquisition costs	$8,315,755
Annual costs to fill out prior notice screens (including updates and amendments)	$59,689,990
FDA prior notice system cost	$4,421,176
Lost value for Mexican produce	$41,502,300
Lost value for Canadian produce	$4,821,912
Lost value for Mexican seafood	$4,687,582
Lost value for Canadian seafood	$77,789,347
Total Costs for Option 3	$206,136,571
Present value of costs	$2,710,375,883

Option four: prior notice received by noon of the calendar day prior to the day of crossing; electronic submission of information; any change in information requires resubmission.

This option requires that prior notification be submitted no later than noon of the calendar day prior to the expected day of crossing. Under this option, prior notice submitters will have to let FDA know of the incoming food shipment at least 12 hours before the shipment reaches a U.S. point of crossing. This fourth option would likely cause a change in importer business practices and the business practices of their clients in much the same way as option three, but the potential loss of product value is higher because the minimum prior notice time has increased.

Again, how business practices will be affected by prior notice requirements depends on how early the invoice orders are received, the timeframe in which the truck was loaded, and when prior notice is submitted. FDA requests comments on any additional costs that might result from changes in business practices as a result of this proposed rule.

As before, we assume that as the minimum notice time increases, the likelihood of a resubmission also increases, but less than proportionally to the change in minimum notice time. Thus, since the prior notice timeframe for submission is at least 12 hours instead of 8 hours, the probability of having to adjust and resubmit prior notice information is higher. Instead of 25 percent of the importers of perishable products from Canada and Mexico having to resubmit their notices, we will assume that the 12-hour submission timetable means that 40 percent will have to resubmit their notices.

We increase the percentage of resubmission this time by 15 percent because as the prior notice timeframe increases relative to the time of entry,

it becomes more likely that the prior notice information will change after the notice is submitted to FDA, thus requiring resubmission. The transporters of products with resubmitted prior notices may then have to wait as long as 12 hours, which affects 7.1 percent of the produce life span (12 hours out of 168 hours) and 25 percent of the seafood life span (12 hours out of 48 hours).

Table 12 shows the loss in value caused by the resubmitted prior notice information for the 40 percent of imported Mexican and Canadian fresh seafood and produce that might be affected. As a result of having to give prior notice by noon the calendar day prior to entry, the Mexican fresh produce industry would lose $98,222,110 and the Canadian fresh produce industry would lose $11,411,858. The Mexican fresh seafood industry would lose $11,227,741 and the Canadian fresh seafood industry would lose $186,321,789 in value.

TABLE 12.—LOSS IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION FOUR

Perishable Produce	
2001 Imported Mexican Produce Total Retail Value	$3,458,525,000
7.1% reduction in value for 40% of Mexican produce	$98,222,110
2001 Imported Canadian Produce Total Retail Value	$401,826,000
7.1% reduction in value for 40% of Canadian produce	$11,411,858
Perishable Seafood	
2001 Imported Mexican Seafood Total Retail Value	$112,277,406
25% reduction in value for 40% of Mexican seafood	$11,227,741
2001 Imported Canadian Seafood Total Retail Value	$1,863,217,894
25% reduction in value for 40% of Canadian seafood	$186,321,789

Table 13 presents a summary of the costs associated with option 4. Also presented in table 13 is the present value of the costs associated with this option using the OMB-recommended discount rate of 7 percent.

TABLE 13.—SUMMARY OF COSTS FOR OPTION 4

Research costs	$4,908,509
Computer acquisition costs	$8,315,755

TABLE 13.—SUMMARY OF COSTS FOR OPTION 4—Continued

Annual costs to fill out prior notice screens (including updates and amendments)	$59,689,990
FDA prior notice system cost	$4,421,176
Lost value for Mexican produce	$98,222,110
Lost value for Canadian produce	$11,411,858
Lost value for Mexican seafood	$11,227,741
Lost value for Canadian seafood	$186,321,789
Total Costs for Option 4	$384,518,928
Present value of costs	$5,258,695,269

Option five: prior notice received by noon of the calendar day prior to the day of crossing; electronic submission of information; allow changes to the prior notice submission up to two hours prior to entry (proposed option).

We now take the estimates in option 4 and adjust them to account for the effects of allowing changes to the prior notice submission. Since prior notice must be submitted by noon on the calendar day prior to U.S. entry, it is reasonable to expect that not all the information required on a prior notice will be final. Allowing changes to the original submission, in the form of electronic product identity amendments and arrival updates, should improve the flow of import traffic by reducing the number of prior notice resubmissions and thereby reducing the loss of value for perishable foods, since they will not have to wait much extra time, if any at all, before crossing the U.S. border.

The prior notice screen will have required fields for the addresses of the submitter, importer, owner, and consignee, as well as transporter, manufacturer, and grower if known. Required information would also include the identity of the article of food, its originating country, the country from

which the food was shipped, its U.S. Customs entry number, and the date, time, and expected port of entry.

Increasing the number of required fields that can be changed on the prior notice screen prior to entry reduces the likelihood that the information would have to be completely resubmitted by importers. This change would lessen the time burden, and therefore the cost, of having to submit prior notice. Allowing a 2 hour amendment and updates to prior notice would provide some flexibility for importers in industries where pieces of information, such as the quantity of the product being imported, time to port of arrival, and the anticipated port may change or is not known until just before shipping.

Assuming that prior notice can be amended and updated would reduce the number of resubmissions that would normally occur. For this option then, with amendment and updates, we will assume that the number of prior notice resubmissions necessitated by changes in information on the notice will be reduced from 40 percent (as in option 4) to 5 percent.

This option lowers the prior notice costs to importers (as compared to option 4) and therefore to Mexican and Canadian fresh produce growers and seafood processors, because they will not have to resubmit their prior notices when importing food to the United States as frequently. Instead they can amend or update the notices. Option 5 would save a minimum of 10 hours wait time per entry that can be amended or updated for the prior notice over the time used in option 4; the maximum time products would have to wait at the border would be 2 hours, or 1.2 percent of the fresh produce life span (2 hours out of 168 hours) and 4.2 percent of the fresh seafood life span (2 hours out of 48 hours). Table 14 shows the costs of submitting prior notice

for a 12-hour minimum time, with a 2-hour amendment and updates, for Canadian and Mexican fresh produce and seafood.

TABLE 14.—LOSS IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION FIVE

Perishable Produce	
2001 Imported Mexican Produce Total Retail Value	$3,458,525,000
1.2% reduction in value for 25% of Mexican produce	$2,075,115
2001 Imported Canadian Produce Total Retail Value	$401,826,000
1.2% reduction in value for 25% of Canadian produce	$241,096
Perishable Seafood	
2001 Imported Mexican Seafood Total Retail Value	$112,277,406
4.2% reduction in value for 25% of Mexican seafood	$235,783
2001 Imported Canadian Seafood Total Retail Value	$1,863,217,894
4.2% reduction in value for 25% of Canadian seafood	$3,912,771

Table 15 compares the reduction in the costs of this rule if an amendment and update to prior notice is allowed (option 5) as opposed to the no-amendment option 4.

TABLE 15.—COMPARISON OF OPTION FOUR WITH OPTION FIVE

Perishable Mexican Produce Value loss	
Option 4–12 hour minimum notice	$98,222,110
Option 5–12 hour notice with changes	$2,075,115
Savings with amendment and update	$96,146,995
Perishable Canadian Produce Value loss	
Option 4–12 hour minimum notice	$11,411,858
Option 5–12 hour notice with changes	$241,096
Savings with amendment and update	$11,170,762
Perishable Mexican Seafood Value loss	
Option 4–12 hour minimum notice	$11,227,741
Option 5–12 hour notice with changes	$235,783
Savings with amendment and update	$10,991,985
Perishable Canadian Seafood Value Loss	
Option 4–12 hour minimum notice	$186,321,789
Option 5–12 hour notice with changes	$3,912,758
Savings with amendment and update	$182,409,031

Table 16 presents a summary of the costs associated with option 5. Also presented in table 16 is the present value of the costs associated with this option using the OMB-recommended discount rate of 7 percent.

TABLE 16.—SUMMARY OF COSTS FOR OPTION 5

Research costs	$4,908,509
Computer acquisition costs	$8,315,755
Annual costs to fill out prior notice screens (including updates and amendments)	$59,689,990
FDA prior notice system cost	$4,421,176
Lost value for Mexican produce	$2,075,115
Lost value for Canadian produce	$241,096
Lost value for Mexican seafood	$235,783
Lost value for Canadian seafood	$3,912,758
Total Costs for Option 5	$83,800,182
Present value of costs	$962,713,183

Summary of Options

Table 17 gives a summary of the costs associated with the prior notice rule for each option presented.

TABLE 17.—SUMMARY OF COSTS ASSOCIATED WITH EACH OPTION

Costs	Option 1	Option 2	Option 3	Option 4	Option 5
Research Costs	$0	$4,908,509	$4,908,509	$4,908,509	$4,908,509
Costs of acquiring electronic capacity	$0	$8,315,755	$8,315,755	$8,315,755	$8,315,755
FDA prior notice system cost	$0	$4,421,176	$4,421,176	$4,421,176	$4,421,176
Total annual cost to submit prior notice forms	$0	$59,689,990	$59,689,990	$59,689,990	$59,689,990
Lost value for perishable foods	$0	$51,322,907	$128,801,141	$307,183,498	$6,464,752
First year cost of each option	$0	$128,658,000	$206,137,000	$384,519,000	$83,800,000
Annual cost of each option	$0	$114,656,000	$192,134,000	$370,517,000	$69,798,000
Present value total cost of each option	$0	$1,603,544,000	$2,710,376,000	$5,258,695,000	$962,713,000

Sensitivity Analysis

We estimate that the social costs of the proposed rule (option 5) would be about $84 million in the first year and $70 million in later years. At a 7 percent discount rate, the present value of the costs of the proposed rule, discounted indefinitely into the future, would be about $963 million. These estimates rely on several important assumptions:

• In option 4, forty percent of prior notices will need to be changed if the notice must be submitted by noon on the calendar day prior to entry. (Option 4 is the base for option 5 before amendment.)

• Five percent of prior notices will still need to be changed even when the amendment option is available.

• The amendment option will eliminate all but 1.2 percent of the lost value of imported fresh produce and all but 4.2 percent of the lost value of imported fresh seafood.

• The amendment or update time is two hours before entry.

• The retail value of imported fresh seafood and produce is 100 percent higher than its wholesale value.

• The number of import entries requiring prior notice will not increase over time.

• The discount rate for calculating present value is 7 percent.

We now show how our estimates of costs for the proposed option change under different assumptions. We substitute the following assumptions for those used above:

• In option 4, fifty percent of prior notices will need to be changed if the notice must be submitted by noon on the calendar day prior to entry. (Option 4 is the base for option 5 before amendment.)

• 15 percent of prior notices will still need to be changed even when the amendment option is available.

• The amendment option will eliminate all but 5 percent of the lost value of imported fresh produce and all but 12 percent of lost value of imported fresh seafood.

• The amendment or update time is 4 hours before entry.

• The retail value of imported fresh seafood and produce is 200 percent higher than its wholesale value.

• The number of import entries requiring prior notice will increase 3 percent per year over time.

• The discount rate for calculating present value is 3 percent.

Tables 18 and 19 show the results of the sensitivity analysis. The tables show that the estimated cost of the proposed rule is most sensitive to the assumed fraction of prior notices that will need to be changed. The present value of the proposed rule is most sensitive to the rate of discount.

TABLE 18.—SENSITIVITY ANALYSIS FOR ASSUMPTIONS MADE FOR OPTION 5 (PROPOSED OPTION)

Test	Annual Cost Under Base Assumption	Annual Cost Under Test Assumption	Change in Annual Cost (or Value)	Percent Change in Present Value
50% prior notices changed	$370,516,823	$447,312,699	$76,795,876	21
15% prior notices changed with amendment	$69,798,077	$71,727,578	$1,929,501	3
5% lost value for produce, 12% lost value for seafood	$69,798,077	$84,837,174	$15,039,097	22
Amendment time is 4 hours	$69,789,077	$123,843,623	$54,045,546	77
Retail value is 200% of wholesale value	$69,798,077	$73,030,451	$3,232,374	5
Prior notice entries increase 3% in second year	$69,798,077	$71,588,777	$1,790,700	3

TABLE 19.—PRESENT VALUES FOR SENSITIVITY ANALYSIS FOR ASSUMPTIONS MADE FOR OPTION 5 (PROPOSED OPTION)

Test	Present Value of Base Total Cost	Present Value of New Total Cost Under Test Assumption	Change in Present Value	Percent Change in Present Value
50% prior notices changed	$5,258,695,269	$6,355,779,211	$1,097,083,942	21
15% prior notices changed with amendment	$962,713,183	$1,042,325,126	$79,611,943	8
5% lost value for produce, 12% lost value for seafood	$962,713,183	$1,177,557,426	$214,844,243	22
Amendment time is 4 hours	$962,713,183	$1,786,840,054	$824,126,871	86
Retail value is 200% of wholesale value	$962,713,183	$1,008,889,954	$46,176,771	5
Prior notice entries increase 3% in second year	$962,713,183	$988,294,611	$25,581,428	3
3% Discount rate	$962,713,183	$2,222,803,507	$1,260,090,324	131

Benefits: Requiring prior notice of imported food shipments and defining the required data elements should improve FDA's ability to detect accidental and deliberate contamination of food and deter deliberate contamination. Having notice of an imported food shipment before it reaches a U.S. border would allow FDA personnel to be ready to respond to shipments that appear to be adulterated, whether through intentional or accidental means, as well as when FDA receives credible evidence that an entry represents a serious threat to human or animal health.

Historical evidence suggests that a terrorist or other intentional strike on the food supply is a low-probability, but potentially high-cost event. FDA lacks data to estimate the likelihood and resulting costs of a strike occurring. Without knowing the likelihood or cost of an event, we cannot quantitatively measure the reduction in probability of an event occurring, or the possible reduction in cost of an event associated with each regulatory option. Further hindering any quantification of benefits are the complementary effects of the other regulations that are being developed to implement Title III of the Bioterrorism Act.

To understand possible costs of an intentional strike on the food supply, FDA examined five outbreaks resulting from accidental and deliberate contamination, and from both domestic and imported foods. An intentional attack on the food supply that sought to disrupt the food supply and sicken many U.S. citizens could be much larger than the examples given.

TABLE 20.—SUMMARY OF FIVE FOODBORNE OUTBREAKS

Pathogen	Location and year	Vehicle	Confirmed or reported cases	Estimated number of cases	Total illness cost
Salmonella enteritidis	Minnesota, 1994	Ice cream	150 cases; 30 hospitalizations	29,100 in MN 224,00 Nationwide	$3,187,744,000 to $5,629,792,000
Shigella sonnei	Michigan, 1988	Tofu salad	3,175 cases	Not available	$45,183,000 to $79,795,000
Outbreaks resulting from deliberate contamination					
Salmonella Typhimurium	Dalles, Oregon 1984	Salad bars	751 cases; 45 hospitalizations	Not available	$10,687,000 to $18,875,000
Shigella dysentreriae type 2	Texas, 1996	Muffins and doughnuts	12 cases; 4 hospitalizations	All cases identified	$83,000
Outbreaks resulting from imported foods					
Cyclospora cayaetanensis	United States and Canada, 1996	Raspberries (probably imported from Guatemala)	1465 cases identified, less than 20 hospitalization	Not available	$3,941,000

Salmonella enteritidis in ice cream

In 1994, approximately 224,000 people were sickened by ice cream contaminated with Salmonella enteritidis. The source of the contamination appeared to be pasteurized pre-mix that had been contaminated during

transport in tanker trailers that previously had carried non-pasteurized eggs. There were 150 confirmed cases of salmonellosis associated with the outbreak in Minnesota. However, ice cream produced during the contamination period was distributed to 48 states. To calculate the total number of illnesses associated with the outbreak, researchers calculated an attack rate of 6.6 percent. This attack rate was extrapolated to the population that consumed the ice cream, giving a total number sickened of 224,000 (Ref 11).

Salmonellosis most commonly causes gastrointestinal symptoms. Almost 91 percent of cases are mild and cause one to three days of illness with symptoms including diarrhea, abdominal cramps, and fever. Moderate cases, defined as requiring a trip to a physician, account for 8 percent of the cases. These cases typically have duration of two to 12 days. Severe cases require hospitalization and last 11 to 21 days. In addition to causing gastroenteritis, salmonellosis also can cause reactive arthritis in a small percentage of cases. Reactive arthritis may be short or long term and is characterized by joint pain. Just over one percent of cases develop short-term reactive arthritis and two percent of cases develop chronic, reactive arthritis.

In table 21, FDA estimated the costs associated with salmonellosis, including medical treatment costs and pain and suffering. Pain and suffering is measured by lost quality adjusted life days (QALDs). QALDs measure the loss of utility associated with an illness. A QALD is measured between zero and one, with one being a day in perfect health. The total loss of a Quality Adjusted Life Year (QALY), or the loss of a year of life is valued at $100,000, based on economic studies of how consumers value risks to life (Ref 12). Thus, an entire lost QALD would be valued at $274 and fractions of QALDs are a fraction of the day's value. FDA presents two estimates of values of pain and

suffering associated with arthritis, one based on physician estimates (Ref 13) and another based on a regression analysis approach (Ref 14). This gives a range of costs for the average case of salmonellosis between $14,231 and $25,133.

TABLE 21.—THE COST OF AN AVERAGE CASE OF SALMONELLOSIS

Severity	Case Breakdown	Total QALDs Lost per Illness	Health Loss per Case (Discounted)	Medical Costs per Case (Discounted)	Weighted Dollar Loss per Case
Illness					
Mild	90.7%	1.05	$660	$0	$599
Moderate	8.1%	3.68	$2,310	$283	$209
Severe	1.2%	9.99	$6,266	$9,250	$188
Arthritis *Regression Approach*					
Short-Term	1.26%	5.41	$3,391	$100	$44
Long-Term	2.40%	2,613.12	$452,554	$7,322	$11,048
Direct Survey Approach					
Short-Term	1.26%	10.81	$6,778	$100 $87	
Long-Term	2.40%	5,223.15	$904,573	$7,322	$21,906
Death	0.04%		$5,000,000		$2,143
Total Expected Loss per Case				Regression Approach Direct Survey Approach	$14,231 $25,133

To estimate the economic cost due to illness associated with this outbreak, FDA used the range for the average cost per case. For 224,000 people, this is a total cost of between $3,187,744,000 and $5,629,792,000 from this accidental food disaster.

Shigella sonnei in tofu salad

In 1988, a tofu salad at an outdoor music festival was contaminated with Shigella sonnei and sickened an estimated 3,175 people. Over 2,000 volunteer food handlers served communal meals at the festival. (Ref 15) Shigellosis causes similar symptoms and is of similar duration to salmonellosis. It also is associated with short term and chronic reactive arthritis; thus, FDA assumed the average case of shigellosis has the same cost as salmonellosis. This gives a total cost of $45,183,000 to $79,797,000.

Salmonella typhimirium in salad bars

During September and October of 1984, two outbreaks of Salmonella typhimirium occurred in association with salad bars in restaurants in The Dalles, Oregon. At least 751 people were affected. Members of the local Rajneeshpuram commune intentionally caused the outbreak by spraying Salmonella typhimirium on the salad bars in local restaurants. Their apparent motivation was to influence a local election by decreasing voter turnout. Intentional contamination was not suspected immediately and no charges were brought until a year after the attacks (Ref. 16).

The 751 people affected primarily were identified through passive surveillance: thus the true number of people actually sickened is undoubtedly much higher. The Dalles is located on Interstate 84 in Oregon and is a frequent stop for travelers who were unlikely to be identified by passive or active surveillance for salmonellosis. However, since we do not have any estimates of the true size of the outbreak, we estimated the costs associated with known cases, recognizing this is an underestimate of the true cost of the outbreak. We use the cost estimates for salmonellosis as ranging from $14,231 to $25,133. This gives an estimated cost of known cases for the outbreak of $10,687,000 to $18,875,000.

Shigella dysenteriae type 2 among laboratory workers

Twelve people working in a laboratory who consumed muffins left in the laboratory break room contracted shigellosis in Texas in 1996. Affected workers had diarrhea, nausea, and abdominal discomfort. Investigators concluded that the outbreak likely was the result of deliberate contamination. All twelve affected workers were treated by, or consulted with, a physician.

Nine affected workers went to the emergency room, four of whom were hospitalized (Ref. 17).

To estimate the cost of this outbreak, FDA assumed that the eight cases that required consultation with a doctor, but did not require hospitalization, had the same cost as a moderate case of salmonellosis. The four cases requiring hospitalization were estimated to have the same cost as a severe case of gastroenteritis resulting from salmonellosis. This gives a cost of $82,808 for illnesses associated with the event.

TABLE 22.—SUMMARY OF COSTS FOR AN OUTBREAK OF SHIGELLOSIS

Severity	Number of cases	Cost per case	Total cost
Mild	0	$0	$0
Moderate	8	$2,593	$20,744
Severe	4	$15,516	$62,064
Total	12		$82,808

Cyclospora cayatanensis in imported raspberries

In 1996, 1,465 cases of cyclosporiasis were linked to consumption of raspberries imported from Guatemala. Nine hundred and seventy eight of these cases were laboratory confirmed. No deaths were confirmed and less than 20 hospitalizations were reported (Ref. 18). Case control studies indicated that raspberries imported from Guatemala were the source of the illnesses. Fifty-five clusters of cases were reported in 20 states, two Canadian provinces, and the District of Columbia (Ref. 19).

Cyclosporiasis typically causes watery diarrhea, loss of appetite, weight loss, and fatigue. Less common symptoms include fever, chills, nausea, and headache. The median duration of illness associated with the outbreak was more than 14 days and the median duration of diarrheal illness was 10 days (Ref 20). We estimated the cost of a mild case of cyclosporiasis as two and one half times higher than the cost of a mild case of gastroenteritis from

salmonellosis due to the longer duration. The reports of cyclosporiasis outbreaks did not include information on the number of physician visits. We assumed that the percentage of total cases that result in physician visits would be larger than the corresponding percentage for salmonellosis illnesses, due to the longer duration of illnesses. We assumed, therefore, that 40 percent of those infected with cyclosporiasis visited a physician. Less than 20 hospitalizations were reported from the cyclosporiasis outbreak. No deaths were confirmed.

TABLE 23.—SUMMARY OF COSTS OF AN OUTBREAK OF CYCLOSPORIASIS

Severity	Number of cases	Cost per case	Total cost
Mild	879	$1,650	$1,450,000
Moderate	586	$3,748	$2,196,000
Severe	19	$15,516	$294,000
Total	1,465		$3,941,000

B. Small Entity Analysis (or Initial Regulatory Flexibility Analysis)

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities consistent with statutory objectives. The analysis below, together with other relevant sections of this document, serves as the agency's initial regulatory flexibility analysis under the Regulatory Flexibility Act.

1. Number of establishments affected

FDA finds that this proposed rule would affect the 77,427 U.S. importers. Most of these importers have fewer than 500 employees, thus making them small businesses according to the definitions of the Small Business Administration. Because most of the importers affected are small, all options

considered in the Benefit-Cost Analysis in section IV.A above are regulatory relief options.

Costs per entity

Small businesses will be affected by this proposed rule in a couple of ways. First, this proposed rule requires importers to notify FDA of incoming products electronically before the food arrives at the U.S. border. The annual cost of doing so is about $770 per importer (see tables 1, 2, and 17 of this document). As discussed above and shown in tables 1 and 2, about 3,100 U.S. importers do not have electronic transmitting capacity and will have to obtain computer equipment (at a cost of about $2,000 per importer) and Internet access (at a cost of about $240 annually) in order to comply with this proposed rule. FDA could not provide flexibility for those importers who do not have electronic transmitting capacity, as paper notices could not be submitted and processed in the proposed prior notice timeframe and would therefore actually be more burdensome to importers because paper notices would need to be submitted earlier.

Second, this proposed rule will potentially cause some loss of product value if the prior notice requirement causes perishable products to have to wait any length of time before crossing the U.S. border. The costs of lost product value vary with the required notice timeframe. We discuss the various costs associated with this possibility in the options previously outlined. FDA requests comments on the effect of this proposed rule on small entities.

Additional flexibility considered

Because of the requirements of the Bioterrorism Act, FDA is precluded from selecting some of the options that typically would be considered to lessen the economic effect of the rule on small entities, including granting an

exemption to small entities. FDA tentatively concludes that it would be inconsistent with section 307 of the Bioterrorism Act to allow small entities a later effective date, since the Bioterrorism Act established a deadline for beginning prior notice that applies to all FDA-regulated imported food. Although the recordkeeping provision of the Bioterrorism Act directs FDA to take into account the size of a business when issuing implementing regulations, the prior notice provision contains no such language. Thus, it appears that Congress intended for all entities to be subject to the effective date established in the Bioterrorism Act. Nonetheless, the agency recognizes that the prior notice requirement will cause an economic burden on small businesses; therefore, we are seeking comment on whether it would be consistent with section 307 for the agency to set staggered effective dates that would give small businesses more time to comply. FDA also seeks comment on how FDA could effectively distinguish between large and small businesses if it considered staggered effective dates.

C. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses before any rule making if the rule would include a "Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year." The current inflation-adjusted statutory threshold is $112 million. FDA has determined that this proposed rule does not constitute a significant rule under the Unfunded Mandates Reform Act. See table 17 for the total costs.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Prior Notice of Imported Food

Description: Section 801(m) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 381(m)) requires prior notification to the Secretary of Health and Human Services of an article of food that is being imported or offered for import into the United States. The purpose of this notification is to enable the food to be inspected at ports of entry into the United States.

Section 801(m) of the Act states that the Secretary shall by regulation identify the parties responsible for providing the notice and explain the

information that the prior notice is required to contain, the method of submission of the notice, and the minimum and maximum period of advance notice required. Section 801(m)(1) of the Act states that the Secretary shall require submission of notice providing the identity of each of the following: the article of food; the manufacturer; the shipper; the grower, if known at the time of notification; the originating country; the shipping country; and the anticipated port of entry. Section 801(m)(2)(A) of the Act states that the Secretary shall by regulation prescribe the time of submission of the notification in advance of importation or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed five days. FDA's prior notification of imported food shipments proposed regulation would implement these statutory provisions.

FDA estimates the burden for this information collection as follows:

TABLE 24.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Part 1, Subpart I	No. Of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Capital Costs	Operating and Maintenance Costs	Total Hours
1.285–1.290, 1.294[1]	77,427	23.3	1,807,692	1–2	$6,194,000	$743,280	1,888,216
1.278(d)[1]	90,385	1	90,385	0.5	$0	$0	45,193
1.278(d), 1.285–1.290, 1.294[2]	77,427	23.8	1,844,116	0.5–1	$620,000	$817,680	1,833,822
Total hours for first year							1,888,216
Total recurring hours							1,833,822

[1] First year burden.
[2] Recurring burden.

Burden Estimate

Number of establishments affected

Using 2001 FY information from FDA's OASIS system (industry codes 02 through 52, 54, and 70 through 72), FDA has determined that there are approximately 77,427 importers and consignees who receive shipments of food

for human and animal consumption into the United States. It is these 77,427 U.S. importers or U.S. purchasers (or their agents) that will be primarily responsible for submitting the prior notice information.

New and closing importers

In addition to the U.S. importers currently in existence, in future years, new import businesses will open and some existing import businesses will close. These new importers would have to become familiar with the FDA prior notice system and possibly obtain computer equipment and Internet access to comply with prior notice requirements.

According to the Small Business Administration Office of Advocacy, in 2001, about 10 percent of all businesses were new and 10 percent of businesses closed. Using the 10 percent opening and closing business statistic, and given that there are currently 77,427 U.S. importers, FDA will assume, then, that on a yearly basis 7,743 importers will leave the market and 7,743 importers will enter the market.

Hour Burden Estimate Researching the Prior Notice Requirement

To become familiar with the requirements for this rule, FDA estimates it will initially take responsible parties with Internet access (74,330 importers) about one hour to research the prior notice requirements and responsible parties without readily available Internet access (3,097 importers) about 2 hours to research the requirements. This one-time search burden for the existing importers is 80,524 hours.

In the years that follow the start-up year for prior notice, it is reasonable to expect a certain percentage of importing firms to enter and leave the market. Thus, in addition to the first year burden to research prior notice, it is expected that 8,053 hours will be spent annually researching the prior notice

requirement by the anticipated 7,743 new importers entering the market annually that must learn about prior notice, 7,433 of whom are estimated to have Internet access and 310 of whom do not.

Submitting prior notice

To estimate the repetitive effort of submitting a prior notice, and updating and amending the information, as needed, FDA will assume the activity takes one hour each time an entry (based on an average of 2.6 lines, and therefore notices, per entry) must be submitted. This includes 45 minutes of an administrative worker's time to fill out the screen, including updating, and then 15 minutes of the manager's time to verify the information. FDA does not have information on how many prior notices will come from each of the 77,427 importers. However, we assume that 1,807,692 prior notices will be submitted annually (based on FY 2001 OASIS information); we can take this number and divide by the 77,427 importers to get an average response frequency per importer of 23.3 notices.

Secure storage and notifying FDA

If an article of food is imported or offered for import with no prior notice or inadequate (e.g. untimely, inaccurate, or incomplete) prior notice, the food must be held at the port of entry or in a secure facility. In these cases, the submitter or carrier must promptly notify FDA of the location where the goods are held.

It is quite likely that more imported products will be held during the first year that the prior notice is required than in subsequent years as importers will learn from experience. Therefore, FDA estimates that imported products with insufficient prior notice will be held or sent to secure storage about 5 percent of the time during the first year and 2 percent of the time thereafter.

This means that of the 1,807,692 prior notice entries received annually, in the first year prior notice is in effect we would expect 90,385 of the entries to be held or sent to secure storage; 36,154 entries would be held or sent to secure storage in subsequent years.

Most port storage facilities and secure storage facilities located at or near ports are probably familiar to submitters or carriers; therefore it should only take one-half hour per entry to notify FDA of the shipment's location. Thus, in the first year of the regulation, submitters or carriers will spend 45,193 hours notifying FDA of secure storage locations; 18,077 hours in subsequent years.

Capital Cost and Operating and Maintenance Cost Burden

Since all prior notices must be submitted electronically, we will assume that the 3,097 responsible parties without Internet access will have to purchase the appropriate IT equipment and gain Internet access to actually transmit the information. Assuming computer equipment costs each firm $2,000 and yearly Internet access costs each firm $240 ($20 per month for 12 months), this results in a one-time computer cost for these facilities of $6,194,000 and a recurring Internet access cost of $743,280. For the 7,743 new firms that enter the import market each year, we can expect 310 of them to need to purchase computer equipment and obtain Internet access. Thus, on an annual basis we can expect new importers to spend $620,000 on computers and $74,400 on Internet access to be able to submit prior notice information.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection to the Office of Information and

Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, FDA Desk Officer.

VI. Analysis of Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement has not been prepared.

VIII. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to http://www.fda.gov/dockets/ecomments or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with

the docket number found in brackets in the heading of this document. FDA cannot be responsible for addressing comments submitted to the wrong docket or that do not contain a docket number. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FDA notes that the comment period for this document is shorter than the 75-day period that the agency customarily provides for proposed rules that are technical or sanitary or phytosanitary (SPS) measures. FDA believes that a 60-day comment period is appropriate in this instance. Executive Order 12889, "Implementation of the North American Free Trade Agreement" (58 FR 69681, December 30, 1993), states that any agency subject to the Administrative Procedure Act must provide a 75-day comment period for any proposed Federal technical regulation or any Federal SPS measure of general application. Executive Order 12889 provides an exception to the 75-day comment period where the United States considers a technical regulation or SPS measure of general application necessary to address an urgent problem related to the protection of human, plant, or animal health or sanitary or phytosanitary protection. FDA has concluded that this proposed rule is subject to the exception in Executive Order 12889.

The Bioterrorism Act states that it is intended "[t]o improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies." In order to meet these objectives, section 307 of the Act requires the FDA to propose and issue final regulations requiring prior notice of food imported or offered for import into the United States within 18 months of the Bioterrorism Act's enactment, which is by December 12, 2003. Section 307 also provides that if FDA does not issue final regulations

by this date, FDA still must receive prior notice of food imported or offered for import into the United States by December 12, 2002, of no less than 8 hours and no more than 5 days, subject to compliance with the final regulations when the final regulations are made effective. This expedited timeframe reflects the urgency of the United States government's need to prepare to respond to bioterrorism and other food-related emergencies and FDA's need to have the final rule in place, tested, and fully operational by December 12, 2003. This means that the final rule must publish in early October 2003.

FDA will not consider any comments submitted after the 60-day comment period closes and does not intend to grant any requests for extension of the comment period due to the Bioterrorism Act's requirement to have a final regulation in effect by December 12, 2003, which requires publication on or before October 12, 2003.

IX. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the nonFDA Web sites after this document publishes in the **Federal Register**.)

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4. USDA Agricultural Marketing Service (March 2002) Fresh Fruits and Vegetable Shipments. www.ams.usda.gov

5. Kasmire, Dr. Robert F. Vegetable Marketing Specialist, www.thepacker.com/rbcs/handbookarticles/properis.htm Accessed on 9.16.02.

6. USDA Agricultural Marketing Service produce point price reports for various border crossings for the dates September 12, 2002 and September 16, 2002. www.ams.usda.gov

7. Florida Department of Agriculture and Consumer Services (FDACS) www.ffva.com/rps.htm.

8. National Marine Fisheries Service, Fisheries Statistics and Economics Division, www.st.nmfs.gov accessed September 2002.

9. Florida Department of Agriculture and Consumer Services, http://doacs.state.fl.us/press/1999/090999.html and www.ffva.com/rps.htm

10. Center for Food Safety and Applied Nutrition, http://www.cfsan.fda.gov/~dms/qa-sto8.html

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12. Cutler, D., Richardson, E., 1999. Your Money and Your Life: The Value of Health and What Affects It. Working Paper 6895. National Bureau of Economic Research.

13. Zorn, D., Klontz, K., 1998. Appendix: The Value of Consumer Loss to Foodborne Reactive Arthritis", **Federal Register**, 63, May 1, 1998.

14. Scharff R and A Jessup. Valuing Chronic Disease for Heterogenous Populations: the Case of Arthritis. 2002. Mimeo.