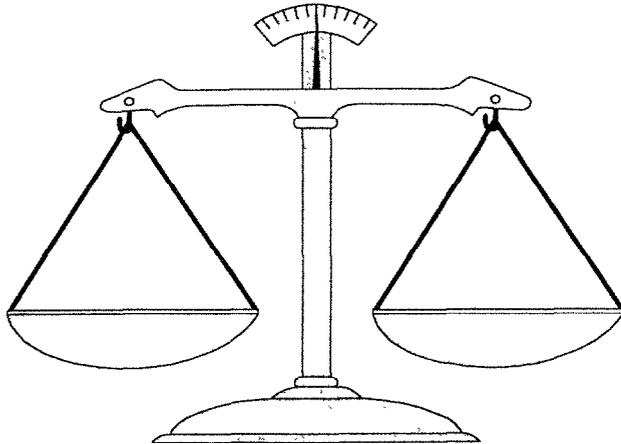


Revisions made in Response to Comments
or Suggestions from OMB/OIRA, or Any Other
Agency or Governmental Component to Which
OMB/OIRA Sent the Document for Review

Revisions made in Response to Comments
or Suggestions from DHHS, including FDA,
In Consultation with OMB/OIRA, while the
Document was Under Review at OMB/OIRA

January 24, 2003

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION



OFFICE OF POLICY

REGULATIONS POLICY
AND
MANAGEMENT STAFF (HF-26)

FOOD AND DRUG ADMINISTRATION

5600 FISHERS LANE, ROOM 12A-17
ROCKVILLE, MD 20857
Ph. 301-827-3480, FAX 301-827-1696

DATE: 1-24-03

TO: STUART SHAPIRO

FROM: KEN SMITH

(202) 395-6974

Number of Pages
COVER + 15

MESSAGE: BT - PRIOR NOTICE

MARK-UPS (SET 1/3: INSERTS & MARK-UPS

FOR PAGES 8, 13, 24, 31, 32, 35, 37, 42, 43, 52, 54, 59, 73)

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Insert #1 on page 8, first paragraph (as revised by OCC):

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 U.S. We could then use the U.S. importer and consignee information to follow-up and trace the location of the goods.

Insert #2 on page 13: (as revised by OCC):

FDA also seeks comment on whether its use of a different term will have any impact, and if so, what that impact will be.

Insert #3 on *the insert to* page 24 (as revised by OCC):

FDA invites comment on the representativeness of this sampling.

Insert #4 on page 32:

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 customs entry. This will reduce the amount of data entry and potentially reduce typing and transcription errors.

Insert #5 also on pages 31-32:

Add the word automatically to the following sentence:

“FDA plans to develop its Prior Notice System to allow submitters to *automatically* repeat information already entered . . .”

Insert #6 on page 32:

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.

Insert # 7 on page 35:

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.

NEW Insert # 7.5 on page 37 added by OCC:

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.

Insert # 8 on page 42(as revised by OCC):

FDA requests comment on our proposal to restrict the number of amendments to one.

Insert # 9 page 43(as revised by OCC):

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.

Insert # 10 - Revise the first paragraph on page 52 to read as follows:

After September 11, 2001, FDA hired three hundred additional counterterrorism Consumer Safety Officers primarily for food imports. This step . . .

Insert # 11 on page 54, second paragraph, the following sentence at the end of the paragraph:

Customs has informed FDA that they receive flight information for 87.6 percent of the flights at time of "wheels up."

Insert # 12 on as a new paragraph two on page 59:

Customs Form 3461, Entry and Immediate Delivery Application, OMB No. 1515-0069, is the entry document upon which information is provided to Customs by which it makes its decision to release the merchandise. The burden estimate on 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.

Insert # 13 on page 73:

FDA requests comments on any additional costs that might result from changes in business practices as a result of this proposed rule.

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. FDA thus would be better able to ensure that consumers in the U.S. 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

INSERT #1
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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 ~~the proposed rule~~ is not more trade restrictive than necessary to meet the objectives of the Bioterrorism Act.

OCC 12/20
make 2 new PP
OCC 12/20/03
OCC/USF
OIP
12/16/03

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 U.S. ^{generally} is responsible for submitting the notice.

OCC 12/20/03

- The notice must be submitted by noon c day of arrival.

3 1/3/03

- (fi) Amendments relating to product identity under specified circumstances.

- (fi) Updates about arrival information are required.

03

- The notice must be submitted electronically through the System unless the FDA system is not functioning. The F System will be designed to provide an automatic electronic acknowledgment.

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 of origin be the United States. Otherwise, the ^{originating country} country of origin is the country under which the vessel is flagged. FDA aligned this aspect of the proposed definition of "^{originating country} country of origin" 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} definition for "country of origin" traditionally used by U.S. Customs. However, FDA believes that using the U.S. Customs ^{meaning} definition would not serve the purpose of the Bioterrorism Act. The U.S. Customs ^{term} definition 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 ^{originating} interpretation and our proposed definition of "country of origin".

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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 U.S. 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.

Insert on p. 24

FDA asked several field offices to send entry documents with invoices covering imported foods. Sixty-four packages of entry documents were received in response. The dates of the invoices were compared to the dates of arrival and receipt in OASIS. In 48 cases (75%), the invoice date or date of sale, preceded the arrival date by at least one day. In 31 cases (48%), the invoice or sale date preceded the arrival date by two or more days. In 16 cases (25%), the invoice date was the same as the arrival date.

to this request

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GDA recognizes that this sampling may not be statistically valid and we invite comment on the representativeness of this sampling

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not when it is shipped to the U.S. FDA has examined a selection of imported ^{documents} food invoices and compared ^{these documents} dates of the invoices with the dates of arrival in the U.S. and U.S. Customs entry. ^{Insert the attached} 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} invoices 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} business 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.

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 OCC 12/20/02
 OMB 1/10/03

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} business 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.

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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} business day prior to arrival. We believe this may be the case with product identity for fresh products imported from countries close to the U.S. (e.g., Canada or Mexico). For example, fresh seafood may be ordered as "catch-of-the-day" from Canada or Mexico; the importer

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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) requires its own prior notice. Any time any of this information changes, a new prior notice is required even if the items are part of the same shipment. Therefore, each article of food ^{that is} represented by an FDA line must be covered by its own prior notice.

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Thus, if a shipment consists of four different kinds of food products, e.g., 1000 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 1500 cases of 48/6 oz. cans each of Brand P tuna, four prior notices are required. If the shipment consists of only one product, e.g., 2400 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. FDA plans to develop its Prior Notice System to allow submitters

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automatically
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 to 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).

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

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, 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.

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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).

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. For example, 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.

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FDA is proposing that if all of the information concerning the product identity exists by noon of the ^{calendar} business 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 section 1.289, we describe under what circumstances we think complete product identity will not exist.

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submissions. FDA wants to encourage submissions that are as complete as possible to allow FDA to deploy its resources effectively.

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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} business 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} business 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 provide ^S the specific identity of the article may be amended when this information does not exist by the prior notice deadline.

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For example, there may be occasions when an entry of lettuce is ordered and prior notice is submitted by noon the ^{calendar} business 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).

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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.

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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. OMB 1/1

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} and that identity is known at the time of the amendment, the amendment must include information that identifies all ^{known} growers ^{if known.}

~~If the information to be amended relates to quantity, FDA is proposing that the change in quantity should be limited to 10 percent or less of the quantity initially submitted in the prior notice. FDA believes that up to 10 percent difference in quantity might include the difference expected from inspection or sampling in the country of origin or shipment or less due to over or under shipping or expected loss due to theft and damage in shipment. FDA is proposing that if the quantity change is greater than 10 percent the prior notice must be cancelled and a new prior notice submitted.~~

7. What is the deadline for product identity amendments under section 1.290? (Proposed § 1.291)

a 2 hour

FDA is proposing ~~different~~ minimum deadlines for ~~different modes~~ of ~~transportation~~ for amendments submitted under proposed § 1.291, or updates

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assignments, all using guidance documents, such as Import Alerts, Compliance Policy guides, and other manuals. ~~After September 11, 2001, FDA hired additional inspectors, but~~ This step alone is insufficient to ensure the safety of food imported or offered for import into the United States.

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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 Customs entry. Requiring prior notice of imported food shipments will allow FDA inspectors to have earlier information on foods that are coming into the U.S., 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 fiscal year 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. ~~FDA requests information on the size of establishments likely to be affected by this proposed rule, including the foreign manufacturers of food products and the importers and consignees receiving the imported food shipments.~~

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FDA's OASIS reporting system shows that approximately 2.5 million food entry lines were imported via sea and air transportation in fiscal year 2001. Information on food-importing practices indicates that Customs and FDA are notified of imported food products traveling to the United States by vessel before the products' arrival. Vessels can notify Customs months before the actual shipping date, but 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 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 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 Customs until the plane has taken off from the airport of the exporting country ("wheels-up"). FDA is then notified through Customs of the plane's scheduled arrival.

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FDA's OASIS reporting system shows that around 2.2 million entry lines of food were imported into the U.S. via ground transportation in fiscal year 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 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 Customs does not give a "screening response" to the entry until actual arrival.) Thus, ~~Even though these importers most likely have the invoices and orders for these products in advance, the fact that they do not currently notify Customs and FDA until their arrival at the border, will require them to change business practices, including when they notify the U.S. of the impending shipment.~~

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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.

FDA estimates that it will take, on average, one 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 one hour to complete and other prior notices will take less than one hour to complete.

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 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 \$58.74 wage rate	15 minutes
Administrative worker costs per entry	\$18.83
Manager costs per entry	\$14.19
Total Cost per import entry	\$33.02
FY2001 OASIS entry total based on 4.7 million lines	1,807,692

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TABLE 9.—LOSS IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION THREE—Continued

Perishable Seafood	
16.7% reduction in value for 25% of Canadian seafood	577,789,347

Insert J here

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

6.11 E
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This option requires that prior notification be submitted no later than noon of the ^{calendar} ~~business~~ 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.

13

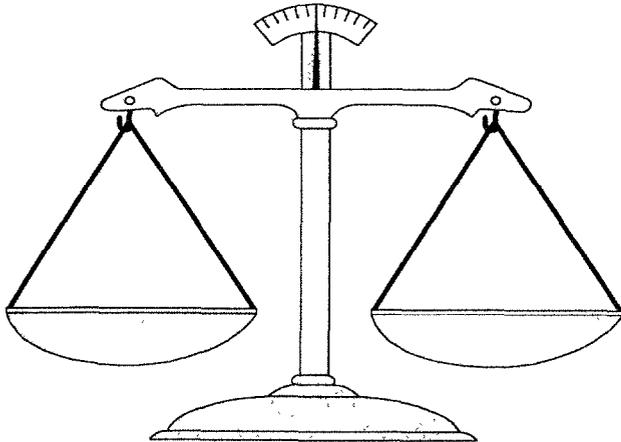
Again, how business practices will be affected by prior notice requirements depends on how early the invoice orders are received, the timeframe in which the truck was loaded, and when prior notice is submitted.

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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 time frame 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 time frame increases relative to the time of entry,

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION



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FOOD AND DRUG ADMINISTRATION

5600 FISHERS LANE, ROOM 12A-17
ROCKVILLE, MD 20857
Ph. 301-827-3480, FAX 301-827-1696

DATE: 1-24-03

TO: STUART SHAPIRO

FROM: KEN SMITH

(202) 395-6974

Number of Pages
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* NOTE:
SECOND PASSBACK
REVISIONS HAVE
BEEN CIRCLED

* NOTE: THIS SET WILL
HAVE SOME FURTHER
REVISED PAGES/INSERTS
FROM SET 1/3 - TRACKED
EVOLUTION

MESSAGE: BT - PRIOR NOTICE (SET 2/3)

MARK-UPS pp. 9-13, revised insert B for p. 33, REVISED

INSERT FOR p. 24, 31, 40, 41, 43, 44, 46, 47, 101, 108. *NOTE: MODE OF TRANSPORT HAS BEEN DELETED

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of receipt of a complete prior notice submission, with a time and date "stamp."

The notice must contain information that identifies:

(fi) the individual and firm submitting the prior notice;

(fi) the entry type and U.S. Customs Service's Automated Commercial System (ACS) entry number or other U.S. Customs Service identification number associated with the import;

(fi) if the article of food is under hold under proposed § 1.278, the location where it is being held;

(fi) 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;

(fi) the manufacturer;

(fi) all growers; ^{if known}
(fi) the country of origin; ^{from which the article originates}

(fi) the shipper;

(fi) the country from which the article of food was shipped;

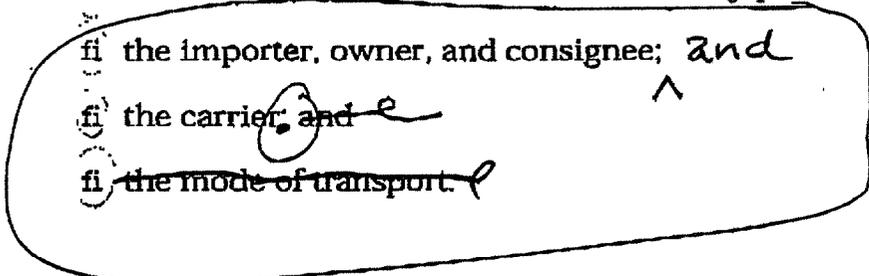
(fi) the anticipated arrival information;

(fi) information related to U.S. Customs entry process;

(fi) the importer, owner, and consignee; and

(fi) the carrier; and

(fi) the mode of transport.



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• 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:

- (fi) Information regarding identity of the article may be amended once;
- (fi) Amendments may not be used to change the nature of the article of food;

(fi) Quantity may be amended ~~only if minor~~; and

(fi) Any amendments must be submitted no later than ~~4 hours prior to arrival for shipments by water, 3 hours prior to arrival for shipments by air, and 2 hours prior to arrival for shipments by land.~~

• 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:

(fi) Food that is carried by an individual entering the U.S. in that individual's personal baggage for that individual's personal ^{use} consumption; or

(fi) 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 four exceptions described below) regardless of whether the food is intended for consumption in the U.S. In other words, FDA believes that food that is brought into the U.S. to be put into foreign trade zones, or

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manufacturing/processing (including packaging) by another foreign facility outside the United States." In other words, foreign facilities involved in the initial stages of manufacturing/processing food are not required to register if another facility further manufactures/processes or packs the food produced at that facility ~~before that food is exported to~~ ^{outside} the United States.

— LN

~~This exemption would not apply to facilities if the~~

— FDA

~~Such further manufacturing/processing, which would exempt the previous~~
~~at the subsequent facility from registration, does not include activities~~ ^{is} ~~of a de minimis nature,~~

such as adding labeling to a package or adding plastic rings to the outside of beverage bottles to hold them together. **The facility conducting the de minimis activity would also be required to register.**

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The following are examples of which foreign facilities would be subject to, or exempt from, the registration requirement, based on the activities they perform:

(1) A foreign facility would be required to register if it prepares a finished food and places it into packages suitable for sale and distribution in the United States.

(2) A foreign facility distributing food to food processors outside the United States for further manufacturing/processing before the food is exported for consumption in the United States would not be required to register, unless the further manufacturing/processing entails adding labeling or other de

minimis activity. **If the further manufacturing / processing is of a de minimis nature, both the facility conducting the de minimis activity and the facility**

(3) The last foreign facility that manufactures/processes an article of food before it is exported to the United States would be required to register, even if the food subsequently is held or stored at a different facility outside of the United States. FDA is proposing to require these manufacturers/processors to register because the Bioterrorism Act exempts a foreign facility from registering only if another facility subsequently processes or packages the food.

immediately prior to it would be required to register.

1. Add to the end of the second paragraph on p. 11 (immediately after ". . . would also be required to register."): This proposal is based on FDA's tentative conclusion that the statute's exclusion of labeling and "similar activity of a de minimis nature" from the definition of "further processing and packaging" applies only for purposes of the definition of "foreign facility." FDA tentatively concludes that this limitation does not apply to the term "processing" as used elsewhere in the registration provision of the Bioterrorism Act. Accordingly, facilities that label food or engage in similar activities would be required to register as processors. FDA requests comment on this interpretation of the Bioterrorism Act.

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 to applies the definitions of terms in section 201 of the act to such terms as used in the proposed rule.

b. ^{Calendar} ~~Business~~ day. The proposed rule defines "business day" as ^{calendar} "the hours ^{every day shown on the calendar} of operation of the ~~FDA field office (e.g., district office or resident post)~~ with responsibility for the geographical area in which the port of entry is located. ~~FDA is proposing this definition because different FDA offices are located in different time zones and maintain different hours of operation due to different administrative practices. If hours of operations at specific locations change, the term "business day" is defined in a way that will accommodate such changes.~~

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^{Originating} ~~country of origin~~. The proposed rule defines "country of origin" as "the ^{originating} country from which the article of food originates." FDA is proposing this definition to be largely 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 U.S. was grown or produced,

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depending on the kind of article. If the article is fresh produce, for example, ^{ORIGINATING COUNTRY} the country of origin 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 ^{ORIGINATING COUNTRY} vegetables, the country of origin is likely to be the country in which the



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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~~ ^{country} of ~~origin~~ ^{originating} be the United States. Otherwise, the ~~country of origin~~ ^{country} is the country under which the vessel is flagged. FDA aligned this aspect of the proposed definition of "~~country of origin~~" ^{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 ~~definition~~ ^{meaning of the term} for "country of origin" traditionally used by U.S. Customs. However, FDA believes that using the U.S. Customs ~~definition~~ ^{meaning} would not serve the purpose of the Bioterrorism Act. The U.S. Customs ~~definition~~ ^{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 "~~country of origin~~" ^{originating}.

c. d. 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 U.S. 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.

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2. Add a new phrase to the language of Insert B on p. 33. The whole insert is below with the new language underlined.

“FDA seeks to minimize the burden of this rule on covered facilities and the submission of duplicative information. FDA is aware that existing registrations required by FDA and other federal agencies ask for information that may be duplicative of some of the information FDA is proposing be submitted under this rule. The Bioterrorism Act requires that certain facilities register with FDA. The Bioterrorism Act also specifies that certain information must be contained in the facilities' registration submissions. FDA seeks comments on whether there are registration requirements under which facilities must submit duplicative information to more than one federal agency. If so, 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 under these registration requirements. In particular, FDA is interested in comments on whether it has authority, under the Bioterrorism Act or another regulatory mandate, to grant a partial or full exemption from the FDA registration requirement to facilities that have already registered with another federal agency. If such authority exists, FDA is also interested in whether the goals of the Bioterrorism Act could be met if FDA does not have complete registration information.

Insert on p. 24

FDA asked several field offices to send entry documents with invoices covering imported foods. Sixty-four packages of entry documents were received in response. The dates of the invoices were compared to the dates of arrival and receipt in OASIS. In 48 cases (75%), the invoice date or date of sale, preceded the arrival date by at least one day. In 31 cases (48%), the invoice or sale date preceded the arrival date by two or more days. In 16 cases (25%), the invoice date was the same as the arrival date.

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~~that such sampling may not be statistically valid and we invite comment on the representativeness of this sampling~~

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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"

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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 requires its own prior notice. Any time any of this information changes, a new prior notice is required even if the items are part of the same shipment. Therefore, each article of food ^{Text 15} represented by an FDA

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line must be covered by its own prior notice. Thus, if a shipment consists of four different kinds of food products, e.g.,

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1000 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 1500 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., 2400 cases of 24/15.25 oz. cans each of yellow corn, one prior notice is required. If this corn

OCC 1/22/03

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.

FDA plans to develop its Prior Notice System to allow submitters

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enable it to allocate resources for inspecting imported food shipments and efficient communication with and between U.S. Customs and FDA field offices.

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 purposes.

Entry Summary
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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 U.S. 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 U.S. 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

~~16. *The Mode of Transport.* FDA is proposing to require the identification of the mode of transport. FDA is proposing to set a deadline for amendments and updates to correspond to the mode of transport (proposed section 1.291). Therefore, FDA believes that the mode of transport, i.e., by land, air, or water, must be identified so that the agency can determine whether the prior notice~~

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1/22/03

~~meets the time limitations for amendments and updates set forth in proposed~~

~~§ 1.291~~

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 U.S., 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 it has been submitted 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} business 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 ~~allow~~ intermediate, still incomplete

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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.

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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. *OMB*

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

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~~If the information to be amended relates to quantity, FDA is proposing that the change in quantity should be limited to 10 percent or less of the quantity initially submitted in the prior notice. FDA believes that up to 10 percent difference in quantity might include the difference expected from inspection or sampling in the country of origin or shipment or loss due to over or under shipping or expected loss due to theft and damage in shipment. FDA is proposing that if the quantity change is greater than 10 percent the prior notice must be cancelled and a new prior notice submitted.~~

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7. What is the deadline for product identity amendments under section 1.290?

(Proposed § 1.291)

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FDA is proposing ~~different~~ minimum deadlines ~~for different modes of transportation~~ for amendments submitted under proposed § 1.291, or updates

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submitted under proposed § 1.294. ~~The proposed regulation would require an amendment or an update to a prior notice to be submitted 4 hours prior to arrival for shipments by water, 3 hours prior to arrival for shipments by air and 2 hours prior to arrival for shipments by land.~~

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FDA believes that the deadlines 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} ~~business~~ day. FDA considered the ~~mode of transportation and~~ type of food in proposing the deadlines for amendments to the product identity and updates to the anticipated arrival information. ~~FDA~~

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~~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 require the changing of the business 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.~~

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FDA notes that under its amendment proposal ^{with the article of food that is already the subject of a prior notice} "topping off" would be allowed ~~with up to 10 percent more of the food that is already the subject of a prior notice.~~ 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 ^{moreover} and 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

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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 timeframes, 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 U.S. 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 or U.S. Customs directs its removal to a secure facility. The consequences are more fully described above in the discussion of proposed § 1.278.

10. What must you do if the anticipated arrival information (required under section 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.

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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 ²/₄ hours prior to arrival ~~for shipments by water, 3 hours prior to arrival for shipments by air, and 2 hours prior to arrival for shipments by land~~



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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

Calendar

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every day shown on the calendar.

(1) ~~Business day~~ means the hours of operation of the FDA field office (e.g. ~~district office or resident post~~) with responsibility for the geographical area

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~~in which the port of entry is located.~~

Originating

(4)(2) ~~Country of origin~~ means the country from which the article of food originates. If the article of food is fresh produce or fresh aquacultured fish or seafood, the originating country is the country in which it is grown and

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harvested. If the article of food is wild-caught fish or seafood and it is harvested in the waters of the United States or by a U.S. flagged vessel or processed aboard a U.S. flagged vessel, the ORIGINATING COUNTRY is the United States.

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Otherwise, the originating country is the country in which the article of food is produced.

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(2)(3) ~~Country from which the article of food was shipped~~ means the country in which the article of food was loaded onto the conveyance that brings it to the United States.

(3)(4) ~~Food~~ has the meaning given in section 201(f) of the act. Examples of food include, but are not limited to, 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, bakery goods, snack foods, candy, and canned foods.

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(5) ~~Port of entry~~ means the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where food first arrives in the United States. This port may be different than the port where the article of food is entered for U.S. Customs Service purposes.

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(p) The name, address, phone number, fax number, and e-mail address of the consignee, and if the consignee is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility; *and*

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(q) The names, addresses, phone numbers, fax numbers and e-mail addresses of all the carriers which are or will be carrying the article of the food from the country from which the article of food was shipped to the United States, and the carriers' Standard Carrier Abbreviation Codes (SCAC) if appropriate; *and*

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~~(r) The identification of the final mode of transport to the United States, i.e. water, air or land.~~

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~~(s) The Prior Notice Screen of FDA's Prior Notice System also identifies the information that you must submit to FDA.~~

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§ 1.289 What changes are allowed to a prior notice after it has been submitted to FDA?

After a prior notice has been submitted to FDA, it may only be changed as set out in § 1.290 which relates to product identity amendments or § 1.294 which relates to arrival updates. If other information provided in the prior notice changes, you must cancel the prior notice in the FDA Prior Notice System and submit a new prior notice to FDA.

§ 1.290 Under what circumstances must you submit a product identity amendment to your prior notice after you have submitted it to FDA?

(a) If any of the information required by § 1.288(e)(1) did not exist at the time you submitted your prior notice and the prior notice you submitted was therefore incomplete, you must amend your prior notice with complete product identity information by the deadline specified in § 1.291.

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§ 1.291 *What is the deadline for product identity amendments under § 1.290?*

Your product identity amendment must be submitted no later than:

~~(a) 4 hours prior to the time of arrival if the final mode of transport to the United States is by water; or~~

~~(b) 3 hours prior to the time of arrival if the final mode of transport to the United States is by air; or~~

~~(c) 2 hours prior to the time of arrival if the final mode of transport to the United States is by land.~~

§ 1.292 *How do you submit a product identity amendment to a prior notice?*

You must submit product identity amendments in accordance with

§ 1.287.

§ 1.293 *What are the consequences if you do not submit a product identity amendment to your prior notice?*

(a) If you informed FDA in your prior notice that you would be submitting a product identity amendment but you do not amend your prior notice completely, the prior notice is inadequate for the purposes of § 1.278(a).

(b) If you informed FDA in your prior notice that you would be submitting a product identity amendment and you submit your amendment after the deadline provided in section 1.291, the prior notice is inadequate for the purpose of § 1.278(a).

§ 1.294 *What must you do if the anticipated arrival information (required under § 1.288(k)(1)) submitted in your prior notice changes?*

(a) If any of the anticipated arrival information required under § 1.288(k)(1) changes after you submit a prior notice to FDA, you must submit an arrival

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
 Food and Drug Administration
PRIOR NOTICE SUBMISSION

Form Approved OMB No. 0910-0001
 Expiration Date: 03/31/03

Paperwork Reduction Act Statement
 An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 0.5-1.0 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Office, Paperwork Reduction Project (0910-0001), Washington, DC 20543-4142.

Initial Amendment Cancel

Product Identity

Mandatory Information

Submitter

First Name _____
 Last Name _____

Submitting Firm

U.S. Purchaser U.S. Importer
 U.S. Agent of Purchaser U.S. Agent of Importer
 Carrier In-bond Carrier

Name of Firm _____
 FDA Registration Number _____
 Street Address _____
 City _____
 State _____
 Zip _____
 Phone _____
 FAX _____
 E-mail address _____

Entry Mode

Consumption T & E IE Mail Trade Fair
 Warehouse TIB Baggage Other

Customs Entry Number _____

Customs Line Number _____

Customs Line Number _____

Product Name _____

Product Code _____

Product Description _____

Product Address _____

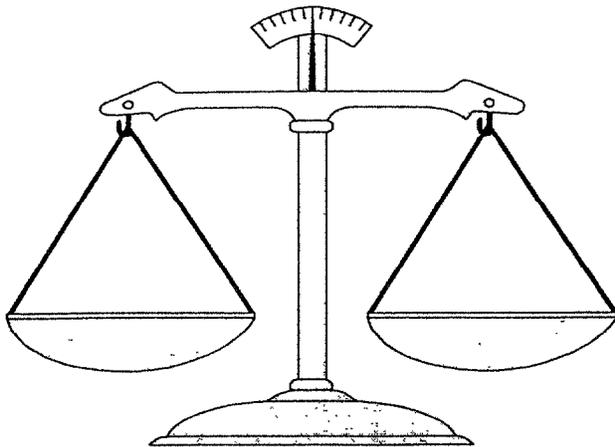
Product Phone _____

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 (Form 3540)
 with FAX'd
 Version
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City	
State/Province	
Zip/mail code	
Country	
Phone	
FAX	
E-mail address	
<input type="checkbox"/> No <input type="checkbox"/> Yes How Many?	
Carrier 2	
Standard Carrier Abbreviation Code	
Name of Firm	
Street Address	
City	
State/Province	
Country	
Zip/Mail code	
Phone	
FAX	
E-mail address	
Carrier 3	
Standard Carrier Abbreviation Code	
Name of Firm	
Street Address	
City	
State/Province	
Country	
Zip/Mail code	
Phone	
FAX	
E-mail address	
Mode of Transport	
LAND <input checked="" type="checkbox"/>	<input type="checkbox"/> Truck <input type="checkbox"/> Auto <input type="checkbox"/> Other
AIR <input checked="" type="checkbox"/>	<input type="checkbox"/> Plane <input type="checkbox"/> Other
WATER <input checked="" type="checkbox"/>	<input type="checkbox"/> Boat <input type="checkbox"/> Ocean vessel <input type="checkbox"/> Other
Amendment to follow <input type="checkbox"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No
Cancel this submission <input type="checkbox"/>	<input type="checkbox"/> Yes <input type="checkbox"/> No
<i>This form must be submitted by the U.S. Importer or U.S. Purchaser, or U.S. Agent of the importer or purchaser, of the article of food being imported or offered for import. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.</i>	

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION



OFFICE OF POLICY

REGULATIONS POLICY
AND
MANAGEMENT STAFF (HF-26)

FOOD AND DRUG ADMINISTRATION

5600 FISHERS LANE, ROOM 12A-17
ROCKVILLE, MD 20857
Ph. 301-827-3480, FAX 301-827-1696

DATE: 1-24-03

TO: STUART SHAPIRO

FROM: KEN SMITH

(202) 395-6974

Number of Pages
COVER + 43

MESSAGE: BT - PRIOR NOTICE (SET 3/3)

ECONOMIC SECTION MARK-UPS

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→ 80 AGAIN

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TO
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U.S., where they came from, and when they will arrive. ~~However, as stated above,~~ 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. ~~Regulatory Options Considered~~ 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.

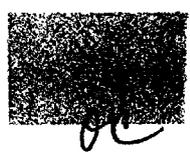
~~consumption.~~ As required by the Act, the notification must provide the identity of the article, the identity of importer, manufacturer, shipper, and grower (if known), the originating country, the country of origin, the country from which the article was shipped, and the anticipated port of entry. In addition, the notification must provide the identity of the person who submits the prior notice, the owner, the consignee, the carrier, the 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 U.S. 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 U.S. 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

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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 not addressed in this analysis.

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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.

4. Regulatory Options ^{considered} 55

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We analyzed six options for a prior notice regulation:

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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 U.S. to notify FDA of their intent to import articles of food through a U.S. 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} consumption, regardless of entry type or mode of transportation used for import.

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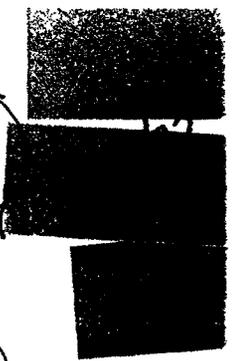
Submission of prior notice information (including addresses of all importers, owners, manufacturers, consignees, identity and quantity of food, ^{originating} country of origin, country of shipping, date, expected time of arrival, expected port of entry, and grower if known) must be electronic.

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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} business 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).



~~6. Require all the components of option 4, allow some prior notice information to be revised but allow minimum time prior to arrival for information changes to vary by mode of transportation (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, the Office of Management and Budget (OMB) cost-benefit analysis guidelines recommend discussing statutory requirements that

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.

FDA estimates that it will take, on average, one 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 one hour to complete and other prior notices will take less than one hour to complete.

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 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
FY2001 OASIS entry total based on 4.7 million lines	1,807,692

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aware of the registration requirement at the U.S. port of entry. For these facilities, the cost of complying would be the possible one-time loss of value of their shipment and other costs of delay, in addition to the cost of registering and finding and hiring a U.S. agent. FDA estimates the cost to foreign facilities of becoming informed about the regulatory requirement is the number of foreign facilities multiplied by either the cost of information, re-exporting the shipment, or a delayed shipment at the U.S. port, whichever is lower.

FDA must hold shipments at the United States port for as long as it takes the foreign facility to register with FDA. To register, a foreign facility first must be informed of the delay at the port by the importer, consignee, owner, or transporter. This may happen very quickly via a phone call or e-mail message, or take hours if there is a large difference in time zones. Next, the foreign facility must find and hire a U.S. agent, if it does not already have one. If the foreign facility is open during United States business hours and has access to the Internet and a fax machine to find an agent and sign a contract, it may find an agent quickly. If the foreign facility is not in a time zone compatible with customary business hours in the United States or does not have easy access to the Internet or fax machine, finding and hiring an agent may take longer. The cost of the delay to the foreign facility is the cost of storing the shipment and loss of value of the shipment due to the delay. For perishable products, a delay may reduce the value of the shipment significantly, perhaps even to zero. For non-perishable products, there may be transaction costs due

to cancellation of a contract and finding a new buyer. FDA requests comments on the length of delay for shipments held while waiting for the foreign facility to register and on the costs of the delay, such as loss of product value, storage costs, and transaction costs.

ix. FDA costs

FDA's costs include creating and maintaining a database, processing paper submissions, and sending annual mailings to registrants. Developing and

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FDA expects that to the extent there are significant port delays, they typically will occur with food manufactured/processed, packed or held at facilities that ship infrequently to the United States. Delays will also be longer and more likely for shipments from facilities that are more distant from the United States or have difficulty communicating with the United States. Perishables, due to their short shelf life, are more likely to be shipped from countries that are geographically close to the United States. For these reasons, FDA expects that costs arising from delays for non-perishable products may be as high or higher than costs arising from perishable products.

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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 Two

Research costs	\$4,908,509
Computer acquisition costs	\$8,315,755
Annual costs to fill out prior notice screens (includes 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
Lost value for Canadian seafood	\$30,929,417
Total Costs for Option 2	\$128,658,337
Present Value of Costs	\$1,603,543,969

Perishable Seafood

16.7% reduction in value for 25% of Canadian seafood

\$77,789,347

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Option four: prior notice received by noon of the ^{calendar}~~business~~ 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}~~business~~ 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. ←

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 time frame for submission is at least 12 hours instead of 8 hours; ^{please use comma} 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 time frame increases relative to the time of entry,

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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 ~~10~~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 ~~business~~^{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 ~~10~~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

Option five: prior notice received by noon of the ~~business~~^{calendar} day prior to the day of crossing; electronic submission of information; allow changes to the prior notice submission up to ~~four~~^{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 ~~business~~^{calendar} day prior to U.S. entry,

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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, the originating country, the country from which the food was shipped, its Customs entry number, and the date, time, and expected port of entry.

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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 two 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) back to 20 percent (as in option 2).

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This more flexible option 5 lowers the cost to importers and therefore Mexican and Canadian fresh produce growers and seafood processors, because they will not have to resubmit their prior notice when importing food to the U.S. as frequently, but instead can amend or update the notice. This option would save a minimum of 8 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 (4 hours out of 168 hours) and 2.4 percent of the fresh seafood life span (4 hours out of 48 hours). Table 11 shows the costs of submitting prior notice for a 12-hour minimum time, with a 4-hour amendment and updates, for Canadian and Mexican fresh produce and seafood.

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TABLE 11.—LOSS IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION FIVE

Perishable Produce	
2001 Imported Mexican Produce Total Retail Value	\$3,458,525,000
2.4% reduction in value for 20% of Mexican produce	\$46,600,920 8,300,460
2001 Imported Canadian Produce Total Retail Value	\$401,826,000
2.4% reduction in value for 20% of Canadian produce	\$1,928,765 964,383
Perishable Seafood	
2001 Imported Mexican Seafood Total Retail Value	\$112,277,406
8.3% reduction in value for 20% of Mexican seafood	\$1,663,805 931,903
2001 Imported Canadian Seafood Total Retail Value	\$1,863,217,894
8.3% reduction in value for 20% of Canadian seafood	\$30,829,417 15,464,909

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Table 12 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 12.—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	\$16,000,920 8,300,460
Savings with amendment and update	\$81,624,190 89,921,650
Perishable Canadian Produce Value loss	
Option 4—12 hour minimum notice	\$11,411,858

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This more flexible option 5 lowers the prior notice costs to importers (as compared to option 4) and therefore Mexican and Canadian fresh produce growers and seafood processors, because they will not have to resubmit their prior notice when importing food to the U.S. as frequently, but instead can amend or update the notice. However, option 5 will be more burdensome to the fresh produce growers and seafood processors than option 2, even though the final time for submission of the prior notice information is four hours before entry in both cases. This is because the initial timeframe for prior notice submission in option 5 is longer (noon the calendar day prior to entry) than option 2 and therefore requires more effort and planning than the four hour prior to entry notice with no amendment.

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This ~~more flexible~~ option ^X lowers the prior notice costs to importers (as compared ^{with} 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 U.S. as frequently. ~~but I~~ ^{they} Instead 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.

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Table 14-Loss in Value Caused by Resubmitted Prior Notice under Option Five

<u>Perishable Produce</u>	
2001 Imported Mexican Produce Total Retail Value	\$3,458,525,000
1.2% reduction in value for 5% of Mexican produce	\$2,075,115
2001 Imported Canadian Produce Total Retail Value	\$401,826,000
1.2% reduction in value for 5% of Canadian produce	\$241,096
<u>Perishable Seafood</u>	
2001 Imported Mexican Seafood Total Retail Value	\$112,277,406

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4.2% reduction in value for 5% of Mexican seafood	\$235,783
2001 Imported Canadian Seafood Total Retail Value	\$1,863,217,894
4.2% reduction in value for 5% of Canadian seafood	\$3,912,758

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.

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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	\$10,991,958
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 Five

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Research costs	\$4,908,509
Computer acquisition costs	\$8,315,755
Annual costs to fill out prior notice screens (includes 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

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Table 14-Loss in Value Caused by Resubmitted Prior Notice under Option Five

<u>Perishable Produce</u>	
2001 Imported Mexican Produce Total Retail Value	\$3,458,525,000
2.4% reduction in value for 25% of Mexican produce	\$20,751,150
2001 Imported Canadian Produce Total Retail Value	\$401,826,000
2.4% reduction in value for 25% of Canadian produce	\$2,410,956
<u>Perishable Seafood</u>	
2001 Imported Mexican Seafood Total Retail Value	\$112,277,406
8.3% reduction in value for 25% of Mexican seafood	\$2,329,756
2001 Imported Canadian Seafood Total Retail Value	\$1,863,217,894
8.3% reduction in value for 25% of Canadian seafood	\$38,661,771

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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	\$20,751,150
<i>Savings with amendment and update</i>	<i>\$77,470,960</i>
Perishable Canadian Produce Value loss	
Option 4- 12 hour minimum notice	\$11,411,858
Option 5- 12 hour notice with changes	\$2,410,956
<i>Savings with amendment and update</i>	<i>\$9,000,902</i>
Perishable Mexican Seafood Value loss	
Option 4- 12 hour minimum notice	\$11,227,741
Option 5- 12 hour notice with changes	\$2,329,756
<i>Savings with amendment and update</i>	<i>\$8,897,985</i>
Perishable Canadian seafood Value loss	
Option 4- 12 hour minimum notice	\$186,321,789
Option 5- 12 hour notice with changes	\$38,661,771
<i>Savings with amendment and update</i>	<i>\$147,660,018</i>

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 Five

Research costs	\$4,908,509
Computer acquisition costs	\$8,315,755
Annual costs to fill out prior notice screens (includes updates and amendments)	\$59,689,990
FDA prior notice system cost	\$4,421,176
Lost value for Mexican produce	\$20,751,150
Lost value for Canadian produce	\$2,410,956
Lost value for Mexican seafood	\$2,329,756
Lost value for Canadian seafood	\$38,661,771
Total Costs for Option 5	\$141,489,063
Present Value of Costs	\$1,786,840,054

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TABLE 12.—COMPARISON OF OPTION FOUR WITH OPTION FIVE—Continued

Perishable Canadian Produce Value loss	
Option 5—12 hour notice with changes	\$1,920,766 964,383
Savings with amendment and update	\$9,469,093 10,447,477
Perishable Mexican Seafood Value loss	
Option 4—12 hour minimum notice	\$11,227,741
Option 5—12 hour notice with changes	\$1,863,886 931,903
Savings with amendment and update	\$9,383,936 10,295,833
Perishable Canadian seafood Value loss	
Option 4—12 hour minimum notice	\$186,321,789
Option 5—12 hour notice with changes	\$30,929,417 15,464,709
Savings with amendment and update	\$166,392,372 1

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 Option six: prior notice received by noon of the ~~business~~ day prior to the day of crossing; electronic submission of information; changes to prior notice vary in time allowed for submission by mode of transportation.

As we outlined in our description of option 2, current information on food-importing practices shows that the party responsible for imported food products traveling to the United States by vessel notifies Customs and FDA before their arrival, especially in cases of trans-oceanic voyages. Allowing changes, through amendments or updates to their prior notices could be useful, but it is likely that few parties responsible for food being imported by vessel will need to use this option. Importers transporting food products by airplane currently certify their cargo manifests with Customs as soon as the plane has taken off from the airport of the exporting country. Allowing changes to prior notice of import for airplane shipments may or may not be useful to the importer, depending on the originating foreign location and the mandated original prior notice submission time.

Given the above assumptions regarding vessel and airplane shipments of imported food, we will assume that prior notice amendment or updates will not have substantial effects on costs for these two conveyance types. Instead,

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we again turn our attention to imported food that arrives in the U.S. via ground transportation, especially by truck, because these shipments do not currently give notice prior to their arrival at a U.S. border and thus would most likely benefit from being given the option to change the information on their original prior notice submission before arrival at the U.S. border.

As in option 5, we assume that the original prior notice form must be submitted by noon of the ^{calendar} ~~business~~ day prior to crossing a U.S. border. We also assume that the initial prior notice can be amended or updated in a number of ways: to change shipment quantity, to add the name of the grower, to change the anticipated port of entry, or to change the expected time of arrival at a U.S port.

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Allowing updating and amendments to prior notice just a few hours before arrival at a U.S. border would be useful, for example, for those Mexican and Canadian fresh produce and seafood producers whose shipments originate from farms or waters within a short distance of the U.S. border. A flexible time limit on amendments and updates for trucks would allow the truck to pass through the border much sooner than with no amendment or update, or with an amendment or update time not varied by conveyance type.

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We assume that having an amendment and update option with a time frame specifically for trucks reduces the number of prior notice resubmissions from ^{under option 5} ~~20~~ ₂₅ percent to 5 percent ^{under option 6} for fresh produce and seafood imported from Mexico and Canada. We reduce the number of resubmissions by ²⁰ ~~15~~ percent to account for the decreasing number of resubmissions necessary as the minimum time for prior notice amendment submission decreases. We assume that as the minimum notice time decreases, the likelihood of a resubmission

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also decreases, but more than proportionally to the change in minimum notice time. FDA requests comments on this assumption.

Table 13 shows the costs in terms of lost value for fresh produce and seafood from Mexico and Canada if importers are allowed to amend and update their original prior notice submission up to two hours prior to crossing the border. In the worst case, the truck might have to wait 2 hours (2 hours of the 168 hour life span for produce, 2 hours of the 48 hour life span for seafood) at the border before being able to cross. Annual costs associated with loss in value for these fresh products would be \$1,729,263 for Mexican produce and \$200,913 for Canadian produce, and \$235,783 for Mexican seafood and \$3,912,758 for Canadian seafood.

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TABLE 13.—LOSS IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION SIX (PROPOSED RULE)

Perishable Produce	
2001 Imported Mexican Produce Total Retail Value	\$3,458,525,000
1% reduction in value for 5% of Mexican produce	\$1,729,263
2001 Imported Canadian Produce Total Retail Value	\$401,826,000
1% reduction in value for 5% of Canadian produce	\$200,913
Perishable Seafood	
2001 Imported Mexican Seafood Total Retail Value	\$112,277,406
4.2% reduction in value for 5% of Mexican seafood	\$235,783
2001 Imported Canadian Seafood Total Retail Value	\$1,863,217,894
4.2% reduction in value for 5% of Canadian seafood	\$3,912,758

Table 14 shows the fresh seafood and produce value saved by the addition of an amendment or update to the prior notice submission by conveyance type is \$281,522,043, compared with not having an amendment or update option and \$19,582,788 saved when compared to having a generic amendment and update option.

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TABLE 14.—COMPARISON OF OPTIONS FOUR, FIVE, AND SIX (PROPOSED RULE)

Perishable Mexican Produce Value loss	
Option 4—12 hour minimum notice	\$98,222,110
Option 5—12 hour notice with amendment/update	\$46,600,020 8,300,460
Option 6—12 hour notice with amendment/update by conveyance type	\$1,729,263

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Table 18-Comparison of Options Four, Five, and Six
(Proposed Rule)

Perishable Mexican Produce Value loss	
Option 4- 12 hour minimum notice	\$98,222,110
Option 5- 12 hour notice with amendment/update	\$20,751,150
Option 6- 12 hour notice with amendment/update by conveyance type	\$1,729,263
Savings as compared to non-amendment/update option	\$77,470,960
Savings as compared to generic amendment/update	\$19,021,887
Perishable Canadian Produce Value loss	
Option 4- 12 hour minimum notice	\$11,411,858
Option 5- 12 hour notice with amendment/update	\$2,410,956
Option 6- 12 hour notice with amendment/update by conveyance type	\$200,913
Savings as compared to non-amendment/update option	\$9,000,902
Savings as compared to generic amendment/update	\$2,210,043
Perishable Mexican Seafood Value loss	
Option 4- 12 hour minimum notice	\$11,227,741
Option 5- 12 hour notice with amendment/update	\$2,329,756
Option 6- 12 hour notice with amendment/update by conveyance type	\$235,783
Savings as compared to non-amendment/update option	\$8,897,985
Savings as compared to generic amendment/update	\$2,093,973
Perishable Canadian seafood Value loss	
Option 4- 12 hour minimum notice	\$186,321,789
Option 5- 12 hour notice with amendment/update	\$38,661,771
Option 6- 12 hour notice with amendment/update by conveyance type	\$3,912,758
Savings as compared to non-amendment/update option	\$147,660,018
Savings as compared to generic amendment/update	\$34,749,013

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Table 19 presents a summary of the costs associated with option 6. Also presented in Table 19 is the present value of the costs associated with this option using the OMB-recommended discount rate of 7 percent.

Table 19-Summary of Costs for Option Six

Research costs	\$4,908,509
Computer acquisition costs	\$8,315,755
Annual costs to fill out prior notice screens (includes updates and amendments)	\$59,689,990
FDA prior notice system cost	\$4,421,176
Lost value for Mexican produce	\$1,729,763
Lost value for Canadian produce	\$200,913
Lost value for Mexican seafood	\$235,783
Lost value for Canadian seafood	\$3,912,758
Total Costs for Option 6	\$83,414,147
Present Value of Costs	\$957,198,397

This ~~more flexible~~ option 5 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 notice ^s when importing food to the United States as frequently, but Instead ^{they} can amend or update the notice ^s. However, option 5 will be more burdensome to the fresh produce growers and seafood processors than option 2, even though the final time for submission of the prior notice information is 4 hours before entry in both cases. This is because the initial timeframe for prior notice submission in option 5 is longer (noon the calendar day prior to entry) than option 2 and therefore requires more effort and planning than the 4 hour prior to entry notice with no amendment.

← This ² 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 4 hours, or ^{1.2} 2.4 percent of the fresh produce life span (4 hours out of 168 hours) and ^{4.2} 8.3 percent of the fresh seafood life span (4 hours out of 48 hours). Table 14 shows the costs of submitting prior notice for a 12-hour minimum time, with a ² 4-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% ^{2.4} reduction in value for 25% of Mexican produce	\$ 2,075,115	\$20,751,150
2001 Imported Canadian Produce Total Retail Value		\$401,826,000
1.2% ^{2.4} reduction in value for 25% of Canadian produce	\$ 241,096	\$2,410,956
Perishable Seafood		
2001 Imported Mexican Seafood Total Retail Value		\$112,277,406
4.2% ^{8.3} reduction in value for 25% of Mexican seafood	\$ 235,783	\$2,320,756
2001 Imported Canadian Seafood Total Retail Value		\$1,863,217,894
4.2% ^{8.3} reduction in value for 25% of Canadian seafood	\$ 3,912,758	\$38,881,771

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	\$20,751,150 \$ 2,075,115
Savings with amendment and update	\$77,470,960 \$ 96,146,995
Perishable Canadian Produce Value loss	
Option 4—12 hour minimum notice	\$11,411,858
Option 5—12 hour notice with changes	\$2,410,956 \$ 241,096
Savings with amendment and update	\$9,000,902 \$ 11,170,762
Perishable Mexican Seafood Value loss	
Option 4—12 hour minimum notice	\$11,227,741
Option 5—12 hour notice with changes	\$2,329,756 \$ 235,783
Savings with amendment and update	\$9,897,985 \$ 10,991,958
Perishable Canadian Seafood Value Loss	
Option 4—12 hour minimum notice	\$186,321,789
Option 5—12 hour notice with changes	\$98,661,771 \$ 3,912,758
Savings with amendment and update	\$147,660,018 \$ 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	\$20,751,150 \$ 2,075,115
Lost value for Canadian produce	\$2,410,956 \$ 241,096
Lost value for Mexican seafood	\$2,329,756 \$ 235,783
Lost value for Canadian seafood	\$98,661,771 \$ 3,912,758
Total Costs for Option 5	\$141,489,063 \$ 83,800,182
Present value of costs	\$1,786,840,054 \$ 962,713,183

Option six: prior notice received by noon of the calendar day prior to the day of crossing; electronic submission of information; changes to prior notice vary in time allowed for submission by mode of transportation.

As we outlined in our description of option 2, current information on food-importing practices shows that the party responsible for imported food products traveling to the United States by vessel notifies Customs and FDA before their arrival, especially in cases of trans-oceanic voyages. Allowing changes, through amendments or updates to their prior notices could be useful, but it is likely that few parties responsible for food being imported by vessel will need to use this option. Importers transporting food products by airplane currently certify their cargo manifests with Customs as soon as the plane has taken off from the airport of the exporting country. Allowing changes to prior notice of import for airplane shipments may or may not be useful to the importer, depending on the originating foreign location and the mandated original prior notice submission time.

Given the above assumptions regarding vessel and airplane shipments of imported food, we will assume that prior notice amendment or updates will not have substantial effects on costs for these two conveyance types. Instead, we again turn our attention to imported food that arrives in the United States via ground transportation, especially by truck, because these shipments do not currently give notice prior to their arrival at a U.S. border and thus would most likely benefit from being given the option to change the information on their original prior notice submission before arrival at the U.S. border.

As in option 5, we assume that the original prior notice form must be submitted by noon of the calendar day prior to crossing a U.S. border. We also assume that the initial prior notice can be amended or updated in a

number of ways: to change shipment quantity, to add the name of the grower, to change the anticipated port of entry, or to change the expected time of arrival at a U.S. port.

Allowing updating and amendments to prior notice just a few hours before arrival at a U.S. border would be useful, for example, for those Mexican and Canadian fresh produce and seafood producers whose shipments originate from farms or waters within a short distance of the U.S. border. A flexible time limit on amendments and updates for trucks would allow the truck to pass through the border much sooner than with no amendment or update, or with an amendment or update time not varied by conveyance type.

We assume that having an amendment and update option with a timeframe specifically for trucks reduces the number of prior notice resubmissions from 25 percent under option 5 to 5 percent under option 6 for fresh produce and seafood imported from Mexico and Canada. We reduce the number of resubmissions by 20 percent to account for the decreasing number of resubmissions necessary as the minimum time for prior notice amendment submission decreases. We assume that as the minimum notice time decreases, the likelihood of a resubmission also decreases, but more than proportionally to the change in minimum notice time. FDA requests comments on this assumption.

Table 17 shows the costs in terms of lost value for fresh produce and seafood from Mexico and Canada if importers are allowed to amend and update their original prior notice submission up to two hours prior to crossing the border. In the worst case, the truck might have to wait 2 hours (2 hours of the 168 hour life span for produce, 2 hours of the 48 hour life span for seafood) at the border before being able to cross. Annual costs associated with loss in

value for these fresh products would be \$1,729,263 for Mexican produce and \$200,913 for Canadian produce, and \$235,783 for Mexican seafood and \$3,912,758 for Canadian seafood.

TABLE 17.—LOSS IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION SIX (PROPOSED RULE)

Perishable Produce	
2001 Imported Mexican Produce Total Retail Value	\$3,458,525,000
1% reduction in value for 5% of Mexican produce	\$1,729,263
2001 Imported Canadian Produce Total Retail Value	\$401,826,000
1% reduction in value for 5% of Canadian produce	\$200,913
Perishable Seafood	
2001 Imported Mexican Seafood Total Retail Value	\$112,277,406
4.2% reduction in value for 5% of Mexican seafood	\$235,783
2001 Imported Canadian Seafood Total Retail Value	\$1,863,217,894
4.2% reduction in value for 5% of Canadian seafood	\$3,912,758

Table 18 shows the fresh seafood and produce value saved by the addition of an amendment or update to the prior notice submission by conveyance type is \$281,522,043, compared with not having an amendment or update option and \$19,582,738 saved when compared to having a generic amendment and update option.

TABLE 18.—COMPARISON OF OPTIONS FOUR, FIVE, AND SIX (PROPOSED RULE)

Perishable Mexican Produce Value loss	
Option 4—12 hour minimum notice	\$98,222,110
Option 5—12 hour notice with amendment/update	\$20,751,150
Option 6—12 hour notice with amendment/update by conveyance type	\$1,729,263
Savings as compared to non-amendment/update option	\$77,470,960
Savings as compared to generic amendment/update	\$19,021,887
Perishable Canadian Produce Value loss	
Option 4—12 hour minimum notice	\$11,411,858
Option 5—12 hour notice with amendment/update	\$2,410,956
Option 6—12 hour notice with amendment/update by conveyance type	\$200,913
Savings as compared to non-amendment/update option	\$9,000,902
Savings as compared to generic amendment/update	\$2,210,043
Perishable Mexican Seafood Value loss	
Option 4—12 hour minimum notice	\$11,227,741
Option 5—12 hour notice with amendment/update	\$2,329,756
Option 6—12 hour notice with amendment/update by conveyance type	\$235,783
Savings as compared to non-amendment/update option	\$8,897,985

TABLE 18.—COMPARISON OF OPTIONS FOUR, FIVE, AND SIX (PROPOSED RULE)—Continued

Perishable Mexican Seafood Value loss	
Savings as compared to generic amendment/update	\$2,093,973
Perishable Canadian seafood Value loss	
Option 4—12 hour minimum notice	\$186,321,789
Option 5—12 hour notice with amendment/update	\$38,661,771
Option 6—12 hour notice with amendment/update by conveyance type	\$3,912,758
Savings as compared to non-amendment/update option	\$147,660,018
Savings as compared to generic amendment/update	\$34,749,013

Table 19 presents a summary of the costs associated with option 6. Also presented in table 19 is the present value of the costs associated with this option using the OMB-recommended discount rate of 7 percent.

TABLE 19.—SUMMARY OF COSTS FOR OPTION 6

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	\$1,729,763
Lost value for Canadian produce	\$200,913
Lost value for Mexican seafood	\$235,783
Lost value for Canadian seafood	\$3,912,758
Total Costs for Option 6	\$83,414,147
Present value of costs	\$957,198,397

Summary of Options

Table 20 gives a summary of the costs associated with the prior notice rule for each option presented.

TABLE 20.—SUMMARY OF COSTS ASSOCIATED WITH EACH OPTION

Costs	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6
Research Costs	\$0	\$4,908,509	\$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	\$8,315,755
FDA prior notice system cost	\$0	\$4,421,176	\$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	\$59,689,990

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TABLE 20.—SUMMARY OF COSTS ASSOCIATED WITH EACH OPTION—Continued

\$6,464,752

Costs	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6
Lost value for perishable foods	\$0	\$51,322,907	\$128,801,141	\$307,183,498	\$64,159,639	\$8,978,717
First year cost of each option	\$0	\$128,658,000	\$206,137,000	\$384,519,000	\$141,489,000	\$83,414,000
Annual cost of each option	\$0	\$114,656,000	\$192,134,000	\$370,517,000	\$127,487,000	\$69,412,000
Present value total cost of each option	\$0	\$1,603,544,000	\$2,710,376,000	\$5,258,695,000	\$1,786,840,000	\$957,198,000

Sensitivity Analysis

We estimate that the social costs of the proposed rule (option ^{5e} ~~6~~) would be about ^{84e} \$83 million in the first year and ^{70e} \$69 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 ³ \$960 million. These estimates rely on several important assumptions:

→ \$83,800,000
→ \$69,798,000
→ \$962,713,000

- In option 4, forty percent of prior notices will need to be changed if the notice must be submitted by noon on the ^{calendar} ~~business~~ day prior to entry. (Option 4 is the base for option ^{5e} ~~6~~ 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 ^{1.2e} ~~one~~ 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:

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• In option 4, fifty percent of prior notices will need to be changed if the notice must be submitted by noon on the ^{calendar} business day prior to entry. (Option 4 is the base for option ^{5e} 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 four 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 ^{18e} 21 and ^{19e} 22 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 21.—SENSITIVITY ANALYSIS FOR ASSUMPTIONS MADE FOR OPTION ^{5e} (PROPOSED OPTION)

Test	Annual Cost Under Base Assumption	Annual Cost Under Test Assumption	Change in Annual Cost (or value)
50% prior notices changed	\$370,516,823	\$447,312,699	\$76,795,876
15% prior notices changed with amendment	\$69,412,042	\$84,569,473	\$12,157,431
5% lost value for produce, 12% lost value for seafood	\$69,412,042	\$84,837,174	\$15,425,132
Retail value is 200% of wholesale value	\$69,412,042	\$72,454,399	\$3,039,357
Prior notice entries increase 3% in second year	\$69,412,042	\$71,494,483	\$2,082,361

see attached new table 18, next pages

TABLE 22.—PRESENT VALUES FOR SENSITIVITY ANALYSIS FOR ASSUMPTIONS MADE FOR OPTION ^{5e} (PROPOSED OPTION)

Test	Present Value of Base Total Cost	Present Value of New Total Cost Under Test Assumption	Change in Present Value
50% prior notices changed	\$5,258,695,269	\$6,355,779,211	\$1,097,083,942
15% prior notices changed with amendment	\$957,198,397	\$1,139,875,988	\$178,677,588
5% lost value for produce, 12% lost value for seafood	\$957,198,397	\$1,177,557,426	\$220,359,029
Retail value is 200% of wholesale value	\$957,198,397	\$1,066,617,783	\$44,419,386
Prior notice entries increase 3% in second year	\$957,198,397	\$985,384,988	\$28,186,586
3% Discount rate	\$957,198,397	\$2,208,933,673	\$1,252,737,276

see attached new table 19, next pages

Table 18-Sensitivity Analysis for Assumptions made for

Option Five (proposed option)

<u>Test</u>	<u>Annual Cost Under Base Assumption</u>	<u>Annual Cost Under Test Assumption</u>	<u>Change in Annual Cost (or value)</u>
50% prior notices changed	\$370,516,823	\$447,312,699	\$76,795,876
15% prior notices change with amendment	\$69,798,077	\$71,727,578	\$1,929,501
5% lost value for produce, 12% lost value for seafood	\$69,798,077	\$84,837,174	\$15,039,097

Amendment time is 4 hours	\$69,798,077	\$123,843,623	\$54,045,546
Retail value is 200% of wholesale value	\$69,798,077	\$73,030,451	\$3,232,374
Prior notice entries increase 3% in second year	\$69,798,077	\$71,588,777	\$1,790,700

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Table 19-Present Values for Sensitivity Analysis for
Assumptions made for Option Five (proposed option)

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

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.

PAGE 80

PAGE 81

(SEE NEXT PAGE FOR P. 81)

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.

20
TABLE 28.—SUMMARY OF FIVE FOODBORNE OUTBREAKS

Pathogen	Location and year	Vehicle	Confirmed or reported cases	Estimated number of cases	Total illness cost
<i>Salmonella enteritidis</i>	Minnesota, 1994	Ice cream	150 cases; 30 hospitalizations	29,100 in MN 224,00 Nationwide	\$3,187,744,000 to \$5,629,792,000
<i>Shigella sonnei</i>	Michigan, 1988	Tofu salad	3,175 cases	Not available	\$45,183,000 to \$79,795,000

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 in table 16.

TABLE 16. SUMMARY OF FIVE FOODBORNE OUTBREAKS

Pathogen	Location and year	Vehicle	Confirmed or reported cases	Estimated number of cases	Total illness cost
<i>Salmonella enteritidis</i>	Minnesota, 1994	Ice cream	150 cases; 30 hospitalizations	29,100 in MN 224,00 Nationwide	\$3,187,744,000 to \$5,629,792,000
<i>Shigella sonnei</i>	Michigan, 1988	Tofu salad	3,175 cases	Not available	\$45,183,425 to \$79,747,275
Outbreaks resulting from deliberate contamination					
<i>Salmonella Typhimurium</i>	Dalles, Oregon 1984	Salad bars	751 cases; 45 hospitalizations	Not available	\$10,687,481 to \$18,874,887
<i>Shigella dysenteriae type 2</i>	Texas, 1996	Muffins and doughnuts	12 cases; 4 hospitalizations	All cases identified	\$82,808 83,000
Outbreaks resulting from imported foods					
<i>Cyclospora cayatanensis</i>	United States and Canada, 1996	Raspberries (probably imported from Guatemala)	1465 cases identified, less than 20 hospitalization	Not available	\$3,941,462

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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 17, 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.

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 TABLE 11.—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						
<i>Regression Approach</i>						
Short-Term	1.26%	5.41	\$3,391	\$100	\$44	
Long-Term	2.40%	2,613.12	\$452,554	\$7,322	\$11,048	
<i>Direct Survey Approach</i>						
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	\$14,231
					Direct Survey Approach	\$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

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 ^e In estimating the cost of this outbreak ~~in table 18~~, 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 18~~ 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		<u>\$82,808</u> correct

~~83,000~~ 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 18.—SUMMARY OF COSTS OF AN OUTBREAK OF CYCLOSPORIASIS

Severity	Number of cases	Cost per case	Total cost
Mild	879	\$1,650	\$1,450,350 ⁰⁰⁰
Moderate	586	\$3,748	\$2,196,328 ⁰⁰⁰
Severe	19	\$15,516	\$294,804 ⁰⁰⁰
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.

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 ~~15~~¹⁷ above). 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 time frame 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 time frame. We discuss the various costs associated with this possibility in the options outlined above (~~see table 15~~). 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.} ~~covered facilities~~. 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} ~~facilities~~ 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.

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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 constitute a significant rule under the Unfunded Mandates Reform Act. See table 16 for the total costs.

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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} importers; 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} importers will spend 45,193 hours notifying FDA of secure storage locations; 18,077 hours in subsequent years.

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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 (see **ADDRESSES**).

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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.

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page 93

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