seller of futures who is the buyer of the corresponding commodity or derivatives position. A third party could be permitted to facilitate the purchase and sale of the commodity or derivatives position as long as the commodity or derivatives position is passed through to the party that receives the futures position. The transaction would have to result in an actual transfer of ownership of the commodity or derivatives position. It also would have to be between parties with different beneficial owners or under separate control, who had possession, right of possession, or right to future possession of the commodity or derivatives position prior to the trade, the ability to perform the transaction, and resulting in a transfer of title.

(B) Pricing. The price differential between the futures leg and the commodities leg or derivatives position should reflect commercial realities, and at least one leg of the transaction should be priced at the prevailing market price.

(C) Transitory exchange of futures for commodities or for derivatives positions. Parties to an exchange of futures for commodities or for derivatives positions could be permitted to engage in a separate but related cash transaction that offsets the cash leg of the exchange of futures for commodities or for derivatives positions. The related cash transaction would have to result in an actual transfer of ownership of the commodity or derivatives position and demonstrate other indicia of being a bona fide transaction as described in paragraph (a). The cash transaction must be able to stand on its own as a commercially appropriate transaction, with no obligation on either party that the cash transaction be dependent upon the execution of the related exchange of futures for commodities or for derivatives positions, or vice versa.

(D) Reporting. Exchanges of futures for commodities or for derivatives positions should be reported to the contract market within a reasonable period of time.

(E) Publication. The contract market would publicize daily the total quantity of exchanges of futures for commodities or for derivatives positions that are included in the total volume of trading, as required by § 16.01 of this chapter.

(iv) *Office trades.* [Reserved]

(v) *Transfer trades.* [Reserved]

Issued in Washington, DC on September 12, 2008 by the Commission.

David Stawick,

Secretary of the Commission.

[FR Doc. E8–21865 Filed 9–17–08; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2007–N–0465]

RIN 0910–AF61

Label Requirement for Food That Has Been Refused Admission into the United States

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed rule that would require owners or consignees to label imported food that is refused entry into the United States. The label would read, ''UNITED STATES: REFUSED ENTRY.'' The proposal would describe the label's characteristics (such as its size) and processes for verifying that the label has been affixed properly. We are taking this action to prevent the reintroduction of refused food into the United States, to facilitate the examination of imported food, and to implement part of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

DATES: Submit written or electronic comments on the proposed rule by December 2, 2008. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 October 20, 2008, (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments, identified by Docket No. FDA–2007–N–0465, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *FAX:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and docket number and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy and Planning (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0587.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. How Did the Idea of Marking Refused Food Imports Originate?

Section 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 381) authorizes us to examine foods, drugs, devices, and cosmetics that are imported or offered for import into the United States and to refuse admission to products that appear, from examination or otherwise, to be (among other things) adulterated or misbranded.

Our examination of food imports usually begins with an electronic prior notice and then an entry review to determine whether additional scrutiny at arrival or thereafter is warranted. We may, based on our review, permit the goods to proceed without further examination. We may take additional steps to determine whether the shipment appears to comply with the act, including: (1) Visually examining the goods; (2) taking samples of the goods for laboratory analysis; (3) verifying the registration, declarations, and certifications for the goods; and/or (4) requesting supporting documentation. If our additional

examination shows that the food appears to be in compliance with the act, we allow the shipment to proceed. If the food appears not to be in compliance, we issue a notice that the shipment has been detained, and the owner or consignee has an informal opportunity to provide evidence or testimony that the food complies with the act or to submit a plan to recondition the food (21 CFR 1.94 and 1.95). If the importer is unable to demonstrate that the food complies with the act and reconditioning has failed to bring the food into compliance, we refuse admission to the food. Section 801(a) of the act provides that, if refused foods are not re-exported within 90 days of refusal (or such other time as Customs and Border Protection (CBP) permits), CBP ensures that the food is destroyed.

In the **Federal Register** of January 22, 2001 (66 FR 6502), we published a proposed rule (the 2001 proposed rule) that would require importers or consignees whose food is refused entry into the United States for safety reasons to mark the refused foods. The mark would state, ''UNITED STATES REFUSED ENTRY.'' The proposed rule also would prohibit persons from refusing to affix this mark on refused food, from importing or offering to import a previously refused food, and from altering, removing, tampering with, or concealing a mark.

We issued the 2001 proposed rule to address a practice known as ''port shopping.'' In general, when FDA refuses to admit a food into the United States, the food must be exported from the United States or destroyed. However, instead of simply exporting or destroying the refused food, some unscrupulous persons attempt to bring the refused food back into the United States by shipping it to another port in hopes that the food will be admitted into the United States at that other port.

The 2001 proposed rule also was in response to an April 1998 report by the General Accounting Office (GAO), 1998 hearings held by the Senate Committee on Governmental Affairs' Permanent Subcommittee on Investigations, and a July 3, 1999, Presidential memorandum (see GAO, ''Food Safety: Federal Efforts to Ensure the Safety of Imported Foods are Inconsistent and Unreliable'' (GAO/RCED–98–103); *The Safety of Food Imports: Fraud & Deception in the Food Import Process; Hearings Before the Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations*, September 10, 1998; ''Memorandum on the Safety of Imported Foods,'' *Weekly Compilation of Presidential Documents, Administration of William J. Clinton, 1999*, July 3, at pages 1277 through 1278). The GAO report and the Senate subcommittee hearings discussed marking refused foods as a way to enhance the safety of imported foods (see 66 FR 6502 at 6503). The July 3, 1999, memorandum from then-President Clinton to the Secretary of Health and Human Services and the Secretary of the Treasury also discussed imported food safety. The memorandum identified food safety as a high priority and directed the Secretaries to take all actions available to ''prohibit the reimportation of food that has been previously refused admission and has not been brought into compliance with United States laws and regulations (so called ''port shopping''), and require the marking of shipping containers and/or papers of imported food that is refused admission for safety reasons'' (id.).

B. What Happened to the Previous Effort to Require Marking of Refused Food?

We received 13 comments on the 2001 proposed rule and were nearing completion of a final rule when, on June 12, 2002, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Public Law 107–188) became law. Section 308(a) of the Bioterrorism Act created a new section 801(n) of the act, which provides additional express authority to require labels on refused foods. Section 801(n)(1) of the act states that we may require the owner or consignee of a food that had been refused admission into the United States to ''affix to the container of the food a label that clearly and conspicuously bears the statement: 'UNITED STATES: REFUSED ENTRY'.'' Section 801(n)(2) of the act requires the owner or consignee of the food involved to pay all expenses in connection with affixing the label. Section 801(n)(3) of the act states that a requirement under section 801(n)(1) of the act remains in effect until we determine that the food has been brought into compliance with the act.

The Bioterrorism Act made clear that the new provisions were not intended to detract from our existing authority to require refused food imports to be marked as such. Section 308(c) of the Bioterrorism Act states that, ''nothing in this section shall be construed to limit the authority of the Secretary of Health and Human Services or the Secretary of the Treasury to require the marking of refused articles of food under any other provision of law.'' Nonetheless, the new statutory requirements differed from our 2001 proposed rule in several ways, and these differences led us to withdraw the 2001 proposed rule on August 21, 2002 (67 FR 54138), and re-examine how we should implement this authority.

We summarize the principal differences between our earlier 2001 proposed rule and the requirements in section 801(n) of the act here.

TABLE 1—PRINCIPAL DIFFERENCES BETWEEN FDA'S JANUARY 22, 2001, PROPOSED RULE AND SECTION 801(N) OF THE ACT

Provision in the January 22, 2001 Proposed Rule	Provision in Section 801(n) of the Act
Would authorize marking of food that was refused admission into the United States for safety reasons	Authorizes labels on the container of food that was refused admission into the United States, except for food that is required to be destroyed
Would require the mark to be at least 2.5 centimeters or 1 inch high and to be clear, conspicuous, and permanently affixed	Requires the label statement to be clear and conspicuous
Mark would state, ''UNITED STATES REFUSED ENTRY''	Label states, ''UNITED STATES: REFUSED ENTRY''
No express provision regarding fees	Requires owner or consignee of the food involved to pay all expenses in connection with affixing the label and authorizes liens in event of default of such payment

TABLE 1—PRINCIPAL DIFFERENCES BETWEEN FDA'S JANUARY 22, 2001, PROPOSED RULE AND SECTION 801(N) OF THE ACT—Continued

Provision in the January 22, 2001 Proposed Rule	Provision in Section 801(n) of the Act
Would require the mark to go on the food's packing container, if possible, and to an invoice, bill of lading, and any other shipping document accompanying the food when it is exported	Label to be affixed to the container
Would prohibit altering, tampering with, or concealing a mark	Food is misbranded if: it fails to bear a label (concerning the fact that the food has been refused admission); the food presents a threat of serious adverse health consequences or death to humans or animals; and, upon or after notifying the owner or consignee involved that a label is required, the owner or consignee is informed that the food presents such a threat.

On July 18, 2007, President George W. Bush established an Interagency Working Group on Import Safety to conduct a comprehensive review of import safety practices and to determine areas for improvement. On November 6, 2007, the Working Group submitted its report, *Action Plan for Import Safety: A Roadmap for Continual Improvement*, to the President. Publishing this proposed rule by mid-2008 was a planned action in the report.

This proposed rule would, among other things, implement section 801(n) of the act and address labeling the documents associated with foods that have been refused admission, whether or not the foods have ''containers'' as we propose to define that term for purposes of section 801(n) of the act.

II. Description of the Proposed Rule

A. Introduction

We are proposing to amend our import regulations to create a new § 1.98, entitled ''Label requirement on food imports refused admission into the United States.'' The proposal would require all owners or consignees to label the shipping container of food refused admission into the United States under section 801(a) of the act, as well as any documents (including electronic documents) accompanying the food. The label would make it more difficult for imported food that has been refused admission into the United States to evade import controls and would complement our other efforts to monitor food imports.

There is no direct counterpart to section 801(n) of the act with respect to food that has been produced domestically rather than imported. Food produced domestically that is not in compliance with the act is subject to a range of regulatory and enforcement actions. For example, we may seek to seize the food under section 304 of the act (21 U.S.C. 334), seek an injunction under section 302 of the act (21 U.S.C. 332), or request that a firm voluntarily initiate a recall.

B. Who Is Subject to the Label Requirement? (Proposed § 1.98(a))

In general, proposed § 1.98(a) would state that you are subject to the rule if you are an owner or consignee of an imported food (including food for animals) which we have refused to admit into the United States (other than a food which must be destroyed). The proposal would require you to affix labels stating, ''UNITED STATES: REFUSED ENTRY,'' as described in proposed § 1.98(b) and (c) (which we discuss later in part II.C and II.D of this document).

Under our pre-existing import program, when an FDA-regulated food product is offered for import, we review electronic information about the product provided under the prior notice procedures described in 21 CFR 1.276 through 1.285. If prior notice requirements are satisfied, we then conduct an admissibility review to determine whether the food meets the safety and quality standards under the act and its implementing regulations that likewise apply to food produced or grown in the United States. If our review of that information determines that further evaluation of the information or article is unnecessary, we notify CBP that the article may proceed without further FDA examination. If further evaluation is deemed necessary, our staff may request additional information to make an admissibility determination or may examine or sample the product. Finally, if our review indicates that the product appears ''by examination or otherwise'' to be subject to refusal of admission under section 801(a) of the act (e.g., appears to be adulterated or misbranded), we will take appropriate action, and notify the owner or consignee and customs broker that we are detaining the shipment by sending a ''Notice of FDA Action.''

The Notice of FDA Action specifies the nature of the violations identified through our evaluation and designates an address where the recipient may present information to us. If the person receiving the Notice of FDA Action accepts the refusal of admission or if our district office determines, after reviewing the information provided to it, that the imported food continues to appear to be in violation, we then issue a ''Notice of Refusal of Admission.'' The Notice of Refusal of Admission finalizes the charges and provides for the food's exportation or destruction within 90 days of the notice's date or within timeframes set by CBP. We intend to modify these types of notices to state that a refused food import is subject to the labeling requirements described in this proposal and to indicate whether a refused food presents a threat of serious adverse consequences or death to humans or animals because of the misbranding requirement seen at section 403(v) of the act (21 U.S.C. 343(v)). Under section 403(v) of the act, a food is misbranded if: (1) It fails to bear a label required by regulation under section 801(n)(1) of the act; (2) we find that the food presents a threat of serious adverse consequences or death to humans or animals; and (3) upon or after notification that the label is required, we inform the owner or consignee that the food presents such a threat.

Proposed § 1.98(a) reference to owners and consignees of an imported food reflects the language in section 801(n)(1) of the act. However, for purposes of proposed § 1.98, we intend to interpret ''owner'' and ''consignee'' to include persons acting on the owner's or consignee's behalf, such as the owner's employees and agents. This practical and common sense interpretation would preclude arguments we have seen in other regulatory contexts where parties have argued that a particular statutory or regulatory requirement is too burdensome because only the specific

individual owner, and not any employee or agent retained by the owner, can satisfy the requirement. Here, if an owner instructs its employee or agent to affix the label to a shipping container or documents, we would consider the employee or agent to be acting on the owner's behalf and the employee's or agent's action to be consistent with section 801(n)(1) of the act and proposed § 1.98(a).

Proposed § 1.98(a) also would state that imported food includes ''food for animals.'' This reflects the fact that animal food or feed falls within the definition of ''food'' in section 201(f) of the act (21 U.S.C. 321(f)).

C. What Does the Label Look Like? (Proposed § 1.98(b))

Proposed § 1.98(b) would require the label to state, ''UNITED STATES: REFUSED ENTRY'' in capital letters and in black ink on a white background. For labels that are to be affixed to shipping containers, proposed § 1.98(b)(1) would require the label's letters to use either an Arial or Univers font style and be at least 72 points in size. The label would use uppercase letters only. (We discuss shipping containers and documents in greater detail in part II.D of this document.)

For labels that are to be affixed to documents (including electronic documents), proposed § 1.98(b)(2) would require the label's letters to be in black ink, use either an Arial or Univers font style, and be at least 36 points in size. The label would use uppercase letters only. We tentatively have decided to specify the label's fonts and sizes in proposed § 1.98(b)(1) and (b)(2) because such a requirement would make the label clear, conspicuous, and easy to read and identify and would minimize uncertainty about what the terms ''clear'' and ''conspicuous'' mean.

Based on our experience with the 2001 proposed rule, we expect that some individuals may want the rule to require some indication of why the food was refused entry rather than limit the label to the language specified by section 801(n)(1) of the act. We tentatively have decided against requiring such explanations in the proposed rule because the words, ''UNITED STATES: REFUSED ENTRY,'' are specified in section 801(n)(1) of the act. Unlike our 2001 proposed rule, the label would be applied to all foods that are refused entry. If we were to require the label to explain the reasons for refusing to admit the food into the United States, importers, owners, and consignees would have to have multiple labels (to cover the various possible reasons for refusing entry) or would have to use ''fill in the blank'' labels which could then be illegible (if the reasons are handwritten) or difficult to use (if the reasons are machine-printed). Such a result would be inconsistent with the statutory requirement that the label ''clearly and conspicuously'' bear the statement. Consequently, proposed § 1.98(b) would only require the label to say, ''UNITED STATES: REFUSED ENTRY.'' Nonetheless, neither the act nor this proposed rule would prohibit further statements as long as they are not false or misleading and do not prevent the label from being both clear and conspicuous.

Although the proposal would specify the label's text, font style, size, and color(s), it would not specify any particular type of label. In other words, use of adhesive labels, ink stamps, paint and stencils, or any other tool or device would satisfy the rule's requirements as long as the label is permanent, is the correct size and color, and otherwise complies with the rule.

As for the ink used for the label, we expect that, based on our experience with the 2001 proposed rule, we may receive comments requesting a rule that would require the label to use ''invisible ink'' that could be seen only by using some unspecified scanning device. In the past, some comments have expressed concern about how a visible label might affect the refused food's ability to enter a foreign country or return to the exporting country. We believe that the use of ''invisible ink'' would be inconsistent with the statutory requirement that the label's text be clear and conspicuous. If the labels were invisible to the human eye, we would be obliged to scan every food product offered for import into the United States, and implementing section 801(n)(1) of the act in such a manner would be contrary to the statutory intent of enabling FDA to identify previously refused food quickly and easily.

D. Where Does the Label Go? (Proposed § 1.98(c))

Proposed § 1.98(c) would require the label to be affixed to the shipping container of refused food and on invoices, bills of lading, and other documents accompanying the imported food. By ''shipping container,'' we mean ''an individual container designed for shipping one or more immediate containers of the refused food, and an immediate container is any container that holds an imported food for retail sale.'' This definition of ''shipping container'' would include items such as boxes, bags, bottles, jars, tanks, drums, barrels, and totes because such items are individual containers designed for shipping food. The definition would exclude items such as railroad cars, truck trailers and truck trailer bodies (also referred to as ''containers'' or ''intermodal shipping containers'' and including International Organization for Standardization (ISO) standard containers or ''ISOtainers'' and other standardized containers that can be attached to a vehicle body), ship holds, and similar transportation-related items because those items are not individual containers designed for shipping food.

Section 801(n)(1) of the act requires the label to be affixed to ''the container of the food,'' but the act, the Bioterrorism Act, and the legislative history for the Bioterrorism Act do not define or otherwise explain what constitutes a ''container.'' By referring to the ''shipping container,'' the proposal would require placement of the label on the container that would normally be used in commerce to ship food. For example, assume that an imported food shipment consists of cardboard cartons containing 24 cans of food and that we have refused to admit the food into the United States. The ''shipping containers'' would be the cartons containing the cans rather than each can, so the label would go on each carton. As another example, assume that an imported food shipment consists of plastic drums, each drum containing five gallons of vegetable oil, and that we have refused to admit the food into the United States. In this example, the ''shipping container'' is the individual plastic drum, so the label would go on the drums. Note, too, that, in this example, the plastic drums are also immediate containers, because it is likely that the plastic drums are the containers that hold the oil for sale to others.

Consistent with section 801(n) of the act, the proposal also would require the label on the shipping container to be clear and conspicuous. While we believe that the specifications in proposed § 1.98(b) will establish what we mean by ''clear,'' we invite comment on whether the rule should attempt to explain what ''conspicuous'' means or does not mean. Our concern is that individuals may attempt to comply with the letter, but not the spirit, of the law by placing the labels on the bottom of the shipping container. However, it may be difficult to describe what ''conspicuous'' means for the range of shipping containers. For example, if we stated that the label cannot go on a shipping container's bottom to prevent the label from being obscured, such detail might tempt individuals to put the label on the container's top, and then stack containers so that the label is

obscured. Consequently, we invite comment on whether the final rule should define or explain what ''conspicuous'' means in terms of the label's placement on a shipping container and, if so, what that regulatory requirement would be.

The proposal also would require the label to be permanently affixed to the shipping container, in addition to being clear and conspicuous. Although section 801(n)(1) of the act does not state that the label must be ''permanent,'' we believe that proposing to require the label to be permanently affixed to the refused food is consistent with the underlying statutory intent. Congress's goal, in enacting section 801(n) of the act, was to identify refused foods and to preclude the reintroduction of refused foods into the United States. Without a requirement that the label be permanently affixed, then the statutory intent could be undermined easily because unscrupulous importers, owners, or consignees could simply use removable labels and remove them before attempting to bring the refused food back into the United States. We do not believe that Congress intended to create legal requirements that could be so easily defeated, and so the proposal would require the label to be permanent.

To illustrate what we mean by ''permanent,'' printing ''UNITED STATES: REFUSED ENTRY'' on the shipping container in indelible ink would constitute a ''permanent'' label. In contrast, printing the same words in pencil on the shipping container would not be ''permanent'' because an individual could erase the words. As another example, using adhesive labels that cannot be removed from the shipping container after being affixed would be ''permanently'' affixing the label. In contrast, using hang tags would not be ''permanent'' because the tags can be removed easily.

Based on our experience with the 2001 proposed rule, we anticipate that some individuals may argue that ''container'' should include cargo containers or vehicle components, such as railroad cars and trailers (which are often referred to as ''containers'') that are attached to trucks and that are used to transport large quantities of imported food. It would be both impractical and inappropriate to interpret or implement section 801(n)(1) of the act to require that the label be affixed to a railroad car, truck, ship, or other vehicle, vehicle component, or vehicle attachment rather than a food's shipping container. By specifying that the label be clear and conspicuous, Congress intended to make it difficult for a person to ''port shop'' or to conceal previously refused food. If the label were placed on a large, reusable cargo container (such as a tractor trailer or railroad car), one could easily defeat this statutory intent simply by transferring the refused food from the labeled cargo container to an unlabeled cargo container. For example, if the label is placed on a railroad car instead of the shipping containers holding the refused food inside the railroad car, the intent behind section 801(n)(1) of the act and this proposal could be defeated by shifting the refused food from the labeled railroad car to an unlabeled railroad car. In contrast, if the label is on the shipping containers (such as boxes or bags) holding the refused food, it would be more difficult or burdensome to unpackage and repackage the refused food. In addition, a cargo container generally is used to transport food to a specific location and, once it arrives at that location, the food is removed, and the cargo container is used to transport another product. Requiring labels on a cargo container also would inhibit typical business practices by requiring that the cargo container remain associated with the refused food until its exportation.

There may be situations where the imported food has no shipping container. In these situations, requiring that the label be affixed to the documents accompanying the refused food is an appropriate mechanism to ensure that the fact of refusal is communicated to us, CBP, and others. Proposed § 1.98(c) would require the label on all documents accompanying the refused food even when the shipping container is labeled. Examples of such documents include, but are not limited to, bills of lading, bills of sale, airway bills, packing lists, and invoices. This requirement would implement section 403(a)(1) of the act and provide additional protection against the re-importation of refused food because there are times when we, CBP, and others may see documents accompanying a shipment, but not examine the shipment itself. Section 308(c) of the Bioterrorism Act states that we retain authority to require the marking of refused food ''under any other provision of law.'' As we explain in section III of this document, section 403(a)(1) of the act, along with other provisions, gives us ample legal authority to require the label on documents accompanying the refused food.

In order for the label on the documents to be useful in notifying us, CBP, and any prospective purchasers of diverted food that the food has been refused admission into the United States, proposed § 1.98(c) also would require the label on the documents to be clear, conspicuous, and permanently affixed. Our concern is that unscrupulous importers may attempt to undermine a simple regulatory requirement that the label go on the documents by placing the labels on the back of documents or on one page of a multi-page document in an effort to conceal the label. As another example, if we stated that the label must go on the ''bill of sale,'' an individual might be tempted to place the bill of sale as page 37 in a 50-page set of documents to make the label more difficult to find or to refer to the bill of sale by ''sales receipt'' or other name and then argue that the label requirement is inapplicable because there is no ''bill of sale.'' Thus, we propose to require that the label be permanent and go on the top page of each document to ensure that the label on the document is clear and conspicuous. (By ''top page,'' we mean the page that is physically located at the top of any single or multi-page document. For example, if there are two documents accompanying the imported food, and one document consists of a single page and the other document consists of five pages, the label would go on the single-paged document and on the top page of the five-page document.) We also propose that the label be permanent because it would undermine the requirement that the label be affixed to the documents if importers could use labels that could be removed at any point before re-exportation or re-importation.

E. How Do You Show You Complied With the Label Requirements? (Proposed § 1.98(d))

Section 801(n)(1) of the act authorizes us to require owners and consignees to affix the label to a refused food. Consequently, the proposed rule would establish clear standards for when food must be labeled as ''UNITED STATES: REFUSED ENTRY.'' We note that neither of the misbranding provisions upon which we rely for the proposed labeling requirement hinges on whether the refused food is re-offered for import (compare section 403(a)(1) and (v) of the act with section 402(h) of the act (21 U.S.C. 342(h))). To ensure that we can track compliance with the label requirement efficiently, proposed § 1.98(d)(1) would establish several mechanisms for demonstrating that the label was properly affixed to the shipping containers and documents for the refused food. For example, the owner or consignee could contact the FDA district office responsible for the food's entry and:

• Arrange to affix the labels in our presence or under our supervision. This method would probably be used in situations where the refused food presents a public health hazard or where the owner or consignee has a history of violations of the act or the Public Health Service Act (PHS Act);

• Submit photographs or other visual evidence to us to show that it affixed the label to the shipping containers and documents. This method could, for example, be used in situations where the owner or consignee has a good record of compliance with the act and the PHS Act and the refused food does not present a public health hazard; or

• Develop another means to show that it affixed the labels to the shipping containers and documents to FDA's satisfaction. For example, we could agree to have commissioned State or Federal officials supervise the labeling process.

Proposed § 1.98(d)(1) is intended to ensure that the shipping container and documents for a refused food are identified and labeled correctly. The provision would give us the option to verify that the labels were affixed correctly to the shipping container and documents by supervision, by reviewing visual evidence, or by other means. This flexibility would reduce the potential burden on owners or consignees.

Proposed § 1.98(d)(2) would require that the labels be affixed promptly. We invite comment on how we might interpret ''promptly.'' Under section 801(a) of the act, the exportation of any refused article is require within 90 days of the date of notice of such refusal or within such additional time as may be permitted pursuant to CBP regulations. We invite comment on how to frame a regulatory requirement to ensure that the owner or consignee has a reasonable amount of time to affix the required labels and that FDA has sufficient advance time to make arrangements to verify that the labels are affixed properly in light of the 90-day deadline specified in section 801(a) of the act. Any regulatory standards established for compliance with the label requirements will establish an obligation under the CBP bond to label the merchandise.

Proposed § 1.98(d)(2) would also require that the food not be moved until the owner or consignee has complied with the labeling requirements. This requirement would mean that the labels must be affixed before the food leaves the port of entry or, if the food has already been moved from the port of entry to another location for storage, before the food leaves that storage area to be re-exported.

F. What Fees May We Impose Under the Rule? (Proposed § 1.98(e))

Section 801(n)(2) of the act expressly states that all expenses in connection with affixing a label under section 801(n)(1) of the act ''shall be paid by the owner or consignee of the food involved, and in default of such payment, shall constitute a lien against future importations made by such owner or consignee.'' Section 801(c) of the act also provides authority for imposing expenses on owners and consignees for labor with respect to any article refused under section 801(a) of the act. Consequently, proposed § 1.98(e) would allow us to seek reimbursement for our expenses when we impose the label on shipping containers or when we supervise an importer's affixing of labels on shipping containers and documents. These costs would normally consist of our inspector's time, the per diem allowance under government travel regulations, travel expenses (actual cost of travel for travel other than by automobile, or mileage, toll fees, etc. if travel was by automobile), and administrative support costs.

We currently operate a similar reimbursement program for costs associated with our supervision of reconditioning imported articles for possible admission into the United States (see 21 CFR 1.99); thus, the fees we would seek under proposed § 1.98(e) would be consistent with existing programs.

III. Legal Authority

Several sections of the act give us the legal authority to issue this rule. First, section 801(n) of the act states (among other things) that if a food, other than a food that is required to be destroyed, is refused admission under section 801(a) of the act, we may require the owner or consignee of the food to affix to the food's container a label that states, ''UNITED STATES: REFUSED ENTRY.'' Section 403(v) of the act provides that food is misbranded if: (1) It fails to bear a label required under section 801(n)(1) of the act (concerning the fact that the food has been refused admission); (2) the food presents a threat of serious adverse health consequences or death to humans or animals; and (3) upon or after notifying the owner or consignee involved that a label is required, the owner or consignee is informed that the food presents such a threat. In addition, section 801(a) of the act authorizes us to refuse to admit imported food into the United States if the imported food appears to have been manufactured, processed, or packed under insanitary conditions, is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or is adulterated or misbranded. Sections 402 and 403 of the act describe when a food is adulterated and misbranded, respectively.

Under section 403(a)(1) of the act, a food is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the act states that, in determining whether labeling is misleading, we look not only at the affirmative representations made in or suggested by the labeling, but also ''the extent to which the labeling * * * fails to reveal facts material in light of such representations or material with respect to consequences which may result from the use or the article * * *.'' We tentatively conclude that the failure to reveal, in each document accompanying the shipment of food, that the food has been refused admission would misbrand the food because otherwise the labeling would imply that the food may be sold legally in the United States when, in fact, we have determined that the food may not.

Section 701(a) of the act (21 U.S.C. 371(a)) also authorizes promulgation of regulations for the efficient enforcement of the act, and section 701(b) of the act specifically authorizes promulgation of regulations for the efficient enforcement of section 801 of the act. Because labeling refused foods would permit us and CBP to efficiently enforce sections 403 and 801 of the act and is expressly authorized under section 801 of the act, we are authorized to impose labeling requirements on such food. The label would help ensure that foods that fail to meet the conditions for admission into the United States are not re-imported and do not enter or reenter domestic commerce. Sections 801(c) and (n)(2) of the act also provide the authority to impose the costs of supervising compliance with such labeling requirements on owners and consignees.

Finally, the proposed rule also is authorized by section 361 of the PHS Act (42 U.S.C. 264). Section 361 of the PHS Act authorizes us to issue regulations to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States. Labeling food that has been refused entry into the United States will help prevent the introduction, transmission, or spread of communicable diseases into the United States by making it more difficult for such rejected food to enter the United States through a different port or to escape detection.

What Are the Consequences of Failing to Affix the Labels?

Under section 403(v) of the act, a food is misbranded if: it fails to bear a label required under section 801(n)(1) of the act (concerning the fact that the food has been refused admission); the food presents a threat of serious adverse health consequences or death to humans or animals; and, upon or after notifying the owner or consignee involved that a label is required, the owner or consignee is informed that the food presents such a threat. As discussed previously, we intend to provide notification of the label requirement and, when appropriate, notice that the refused food presents a threat of serious adverse health consequences when we issue notices of refusal. If you receive notice to label the shipping container along with a notice that the refused food presents a threat of serious adverse health consequences and you fail to label the shipping container as required, the refused food is misbranded under section 403(v) of the act, and we may administratively detain the food under section 304(h) of the act and seize the food before it is exported or after it is re-imported under section 304(a) of the act.

Two situations are not covered by the misbranding provision in section 403(v) of the act: (1) Failure to label refused food that we have not found to present a threat of serious adverse health consequences; and (2) failure to label the documents. As set forth previously, we believe that the failure to label the shipping container or documents in accordance with proposed § 1.98 would misbrand the food under section 403(a)(1) of the act. Accordingly, if you fail to label the shipping container or documents, the refused food would be misbranded under section 403(a)(1) of the act and subject to seizure under section 304 of the act. Furthermore, the prohibited acts pertaining to misbranded food in section 301 of the act (21 U.S.C. 331) would also apply, and anyone who commits a prohibited act with respect to the food would be subject to an injunction under section 302 of the act or prosecution under section 303 of the act (21 U.S.C. 333).

In addition, if the food has been conditionally released under a customs bond, the failure to comply with any requirement of this proposed rule may be a violation of that bond (see 19 CFR 113.62(e)), and we could ask CBP to pursue liquidated damages from the importer of record under 19 CFR 113.62(l).

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(a), 25.30(k), and 25.32(g) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1995

We tentatively conclude that the labeling requirements proposed in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Rather, the statements are ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

Interested persons are requested to fax comments regarding information collection by October 20, 2008, to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

VI. Federalism

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

VII. Analysis of Impacts

A. Preliminary Regulatory Impact Analysis

We have examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe that this proposed rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we do not expect this cost for any one small owner or consignee to be excessive, we certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any 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 one year.'' The current threshold after adjustment for inflation is $130 million, using the most current (2007) Implicit Price Deflator for the Gross Domestic Product. We do not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

1. Need for Regulation

We are taking this action to assist in the enforcement of our admissibility decisions. Without a label requirement for food that has been refused admission, owners or consignees whose shipments are refused admission could simply move their shipment to another port and attempt entry again. Without labeling violative food products, the importer or consignee knows that a shipment has been refused, but personnel in the next port where the food is offered for import would not readily know that the shipment has been refused. Labeling violative food products will help reduce this problem. In addition, as discussed in section VII.A.4 of this document, this rule would help correct both of these behaviors by making the importation of violative food relatively more expensive.

2. Proposed Rule Coverage

The proposed rule would require owners and consignees whose food has been refused admission into the United States to label such food as ''UNITED STATES: REFUSED ENTRY.'' This

would make it easier for us and CBP to detect attempts to introduce previously refused imported food into the United States.

By making importation of previously refused food more difficult and expensive for importers, we expect that reconditioning or destruction of refused food will become more favored alternatives. We also expect that with this system in place, importers would be less likely to attempt to import violative food into the United States in the first place.

3. Regulatory Options Considered

As described earlier, the proposed rule would require owners and consignees whose food shipments have been refused admission into the United States to label such products as ''UNITED STATES: REFUSED ENTRY.'' This would make it easier for us and CBP to detect attempts to introduce previously refused imported food into the United States. In drafting this proposed rule, we considered several regulatory alternatives in addition to the proposed rule. We considered: (1) No additional regulatory action; (2) selective enforcement that would allow the decision to affix the label to be made at the level of individual refused food shipments; and (3) the destruction of all shipments of food refused admission into the United States. Because this proposed rule would not be an economically significant regulatory action, we do not quantitatively estimate the benefits and costs of the regulatory alternatives to the proposed rule. In what follows, we qualitatively compare the costs and benefits of the regulatory options to the costs and benefits of the proposed rule.

The first option would be no action. This alternative would not affect current practices, such as port shopping, and would result in the introduction of previously refused food imports into the United States. Consumers who ingested those unsafe food imports would, in turn, be subject to the risk of foodborne illnesses.

A second option would be a selective enforcement mechanism that would allow the decision to label to be made at the level of individual shipments. This alternative would require fewer resources for labeling shipments, but would require more resources for deciding which shipments should be labeled. The decision to label would be based on factors other than refusal. For example, refused food might be labeled because it poses a safety risk. The decision to label an individual refused food shipment could be complex. For example, whether a shipment contaminated with mold constitutes a safety risk depends upon the identification of the mold, its toxicological properties, and the probability of illness resulting from exposure to the mold. Deciding whether or not the same shipment is adulterated and violative is a simpler process. Selective enforcement could also lead to inconsistent standards between ports of entry, which would exacerbate the problem of importers choosing ports of entry based on the likelihood their cargo will be accepted. Finally, the incentive for port shopping would be higher under this alternative than in the proposed rule. This option would be close to the proposed rule in costs but would generate smaller benefits.

A third option would be to order the destruction of food imports refused for safety reasons. While this would deter ''port shopping'' and similar practices, this alternative would be costlier than the proposed rule for three reasons. First, it would require more Federal resources for supervision of destruction than the proposed rule. Second, the standard of proof to support the destruction of violative products is greater than the standard of proof for refusing to admit imported products. Because the standard of proof is higher for destruction than for marking, this would lead to more challenges to the FDA's policy and require resources from FDA both in establishing the basis for its action and defending challenges to such action. Third, the costs of this proposed rule in destroyed shipments would be high. For fiscal year 2006, data drawn from the Operation and Administrative System for Import Support (OASIS) database (Ref. 1) show that 10,340 shipments were initially refused at the intended U.S. port of entry for safety or security reasons. The threat of destruction should deter importers to attempt to import violative food. If we assume the number of violative imports will decrease by 75 percent and value the shipments conservatively at an average value of $500,000, the cost of this alternative in destroyed cargo alone would be about 1.3 billion dollars ((10,340 shipments) x (25 percent) x ($500,000)).

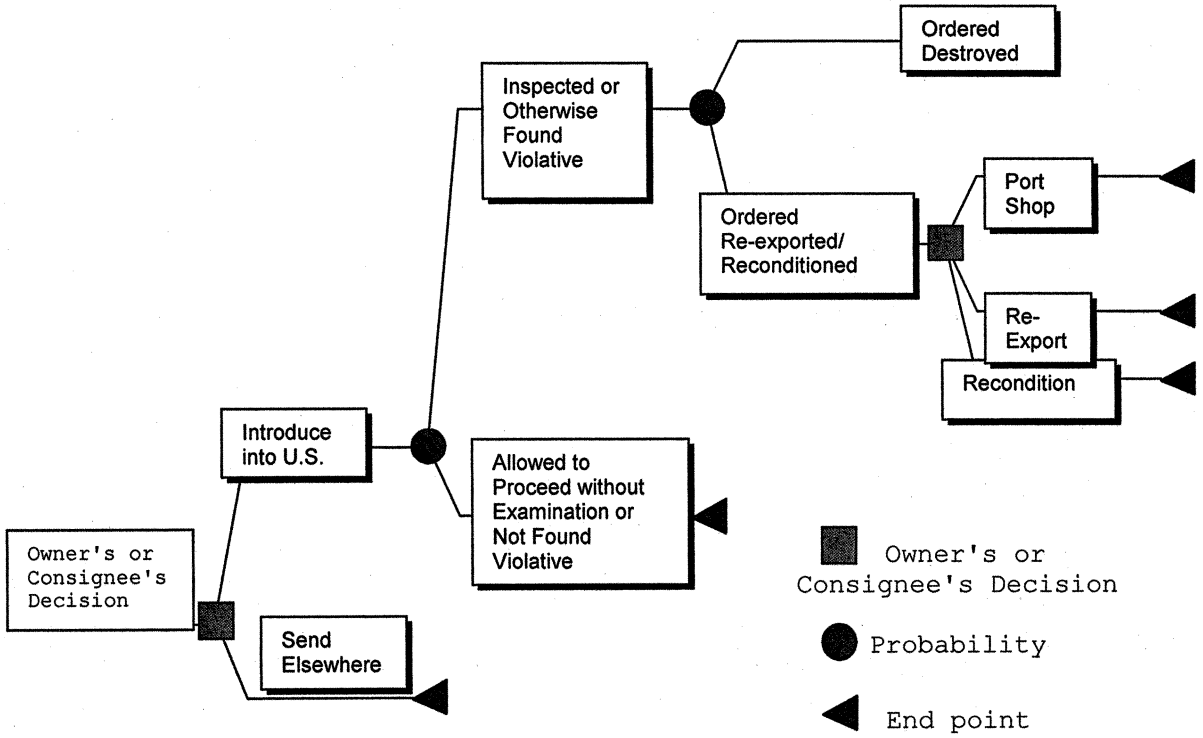
4. Strategic Action by Owners and Consignees

Although the vast majority of owners and consignees comply with the act, some attempt to circumvent Federal law and introduce violative food into United States commerce through means such as port shopping. For these owners and consignees, measures such as those contained in this proposed rule are necessary to deter port shopping.

An owner's or consignee's decision on how to dispose of its cargo is influenced by changes in the expected profits associated with each of its choices. Requiring owners and consignees to affix a ''UNITED STATES: REFUSED ENTRY'' label on imported food that has been refused admission would change the expected profits associated with the initial decision to attempt to import violative food. A label also would affect the expected profits associated with the decision to recondition, re-export, or port shop after a shipment is found violative.

The decision process of an owner or consignee of violative food can be represented visually by a decision tree (see Figure 1). This decision tree illustrates how requiring ''UNITED STATES: REFUSED ENTRY'' on refused imports would alter an owner's or consignee's incentives. The decision tree shows the possible outcomes and decisions an owner or consignee can make at each stage of the importation process. At point A, an owner or consignee of violative food first decides whether to attempt to import the food into the United States. This decision is influenced by the price the owner or consignee can get for the food if it is successfully imported, the probability the cargo will be inspected, and the cost to the owner or consignee if the food is inspected and found violative. At point B, whether the cargo is inspected is a function of factors such as the port of entry, FDA's inspection rate, and the type of product. At point C, FDA refuses admission of the food. If the food is not destroyed, at point D, the owner or consignee may have the option of exporting to a foreign country, reconditioning the food, or port shopping.

Figure 1: A Dynamic Representation of the Introduction of Food into Commerce in the United States



The proposed rule's effect on deterrence: Labeling refused imported foods as ''UNITED STATES: REFUSED ENTRY'' would alter the incentive structure that owners and consignees face when deciding whether to introduce their product into United States commerce. In particular, there are four ways that the proposed rule would increase the deterrence value of the FDA inspection system.

i. *Port shopping would be reduced.* One primary goal of this proposed rule would be to reduce port shopping. Requiring a label to be affixed to a refused imported food would reduce the probability that the refused imported food would be reoffered for import into the United States. The cost of port shopping would increase because resources would have to be expended to repackage a product that had been labeled. Thus, port shopping would become relatively less attractive to owners and consignees.

ii. *Decrease in the value of re-exported items.* The value of a product destined for re-export would decrease if it were labeled ''UNITED STATES: REFUSED ENTRY.'' After the product had been labeled, the owner or consignee has two costly choices: (1) After the product leaves the United States, relabel containers or repackage the product into containers that do not bear the label; or (2) sell the goods abroad with the label intact. It is likely that food with such a label would be viewed less than favorably by food safety inspectors and importers in international markets. Thus, the expected profit from selling goods that are labeled would be lower than if the label was not present, so this loss is in addition to the loss of value from refusal alone. Either of the owner's or consignee's choices (repackage or sell with the label intact) would lower the expected profit of re-exporting.

iii. *Reconditioning would become a more favored alternative.* The expected profit from reconditioning a refused food import would not likely change with this proposed rule. Consequently, because the expected profits from port shopping and re-exporting refused imported food would be expected to fall, reconditioning the food would become economically more attractive. We expect that more owners and consignees would choose to recondition their product.

iv. *Decrease in the introduction of violative food into the United States.* As with reconditioning, the expected profit from initially sending a violative and potentially unsafe or mislabeled product to a foreign port would not be expected to change significantly with this proposed rule. Therefore, as the expected profit from attempting to import violative food into the United States is lowered (because the cost of re-importing and re-exporting violative food is increased), the incentive to ship one's product directly to a foreign (non-United States) market would increase. The net result of such a dynamic would be that more violative food products would be either directly shipped to foreign markets or reconditioned at the point of export.

5. Benefits from the Proposed Rule

a. *Health benefits.* As described earlier, the proposed rule, if finalized, would decrease the number of refused imported food products reaching the United States consumer. The proposed rule would discourage attempts to offer or reoffer violative imported food into the United States and encourage the reconditioning of imported food which we have refused to admit. Consequently, United States consumers would benefit through a reduction in the number of foodborne illnesses due to unsafe or mislabeled imported foods. Because we cannot quantify the amount of re-importation of refused imported foods, we cannot make a definitive prediction of the value of the reduced illnesses

arising from this proposed rule. Although foods that represent a direct and serious danger to public health may be destroyed, refused food eligible for re-exportation may also present a health hazard. Typical reasons for refusing entry include illegal food or color additives, contamination by a pesticide residue or poisonous substance, foreign objects, poor sanitation in the manufacture of the food, improper labeling, and unregistered manufacturers. Each of these reasons for refusal may represent a health risk. Long term exposure to some illegal color additives has been linked to cancer. Sanitation problems indicate the food was held in unsanitary conditions, which may suggest more serious problems such as contamination with microbial pathogens. A single exposure to a violative pesticide level is very unlikely to result in cancer, but prolonged exposure over years may lead to increased risk of illness, including cancer. Improperly labeled food, among other things, may contain allergens without duly alerting the consumer. Sensitive individuals may experience allergic reactions ranging from mild contact dermatitis to a severe allergy attack.

Table 2 shows some possible illnesses and injuries that may result from violative foods and includes their symptoms and an average cost per case. The quality-adjusted life days (QALDs) (Ref. 2) column represents the lost utility per day to a consumer from an illness, essentially the loss to the consumer due to symptoms and problems associated with the illness. The QALDs are valued in dollars by multiplying the number of lost days by the value of a statistical life day, $622. This value of a statistical life day is drawn from the economic literature (Ref. 3). The medical cost column is the direct medical cost of illness, which includes hospitalization and doctor visits. Most illnesses arising from *E. coli* O157:H7 or *Salmonella* are self-limiting and short in duration, but some illnesses due to *Salmonella* or *E. coli* O157:H7 can be quite serious. *E. coli* in some cases can result in kidney damage or death. *Salmonella* can trigger chronic arthritis and, in a very small percentage of cases, can result in death.

TABLE 2.—COST OF SOME ILLNESSES POTENTIALLY AVERTED BY THE PROPOSED RULE

	Potential harm	Symptoms	QALD loss	Dollar value of lost QALDs	Medical Costs	Total cost
Allergens	Contact dermatitis	Reddening, swelling, itching of skin	2.1	$1,726	$125	$1,851
	Allergic reaction	Difficulty breathing, asthma, rash, possible shock	1.03	$847	$550	$1,397
Objects in food	Simple dental injury	Toothache, headache	0.23	$189	$0	$189
	Complex dental injury	Simple, plus infection	3.47	$2,852	$3,540	$6,392
	Oral emergency	Sharp pain in mouth, face, neck, bleeding, plus possible metastatic or local infection	4.27	$3,510	$3,540	$7,050
	Tracheo-esophageal obstruction	Choking, difficulty breathing, cyanosis, hypertension	0.48	$395	$0	$395
	Esophageal perforation	Pain in chest, bleeding aspiration pneumonia, requires surgery	13.93	$11,450	$14,160	$25,610
Canning processes	Botulism	Nausea, diplopia, blurred vision, lack of coordination, Can include loss of muscle strength, paralysis, death	667.94	$549,047	$29,526	$578,573
Filth	Salmonella	Vomiting, nausea, possible arthritis, low probability of death	72.04	$17,558	$321	$17,880
Filth	*E. coli*	Vomiting, nausea, bloody stools, possible kidney damage, low probability of death	19.56	$7,750	$485	$8,235

Sources: We calculated *E. coli* and *Salmonella* costs by assuming a QALD value of $822 and a value of a statistical life of $5 million. Objects in food, allergens and botulism costs were taken from RTI, Estimating the Value of Consumers' Loss from Foods Violating the Federal Food, Drug, and Cosmetic Act (Ref. 4).

b. *Other consumer benefits*. While problems such as insects or filth in food may not always represent a direct health threat, they call into question the conditions to which the food was exposed. Moreover, consumers who purchase food expect it to be clean and sanitary. Consumer research shows cleanliness is important to consumers. For example, the Food Marketing Institute found 89 percent of consumers surveyed ranked a clean, neat store as a very important factor in selecting their primary supermarket (Ref. 5). If consumers pay a premium because they believe that their food is sanitary and the food is not, this payment represents a social loss. However, we cannot quantify this economic loss because we do not know what percentage of the price of food is a ''cleanliness premium.''

6. Costs of the proposed rule

Costs would include both materials and time and would be incurred by both FDA and owners or consignees. The owners and consignees would bear the responsibility for affixing the labels; we would verify that the label is affixed. It is not clear which method owners and consignees would use to label refused food imports. Therefore, we have, for purposes of this analysis, used an

inexpensive and quick method of labeling to estimate costs.

a. *Materials*. Placing labels on all the packages would require the use of a label gun and printed labels. Label guns cost approximately $100, and three label guns would be needed at each of the 132 ports. Labels reading ''UNITED STATES: REFUSED ENTRY'' would also have to be printed at an approximate cost of $0.025 per label. We invite comment on the estimation that three label guns per port will be sufficient to accomplish the labeling necessary to comply with the rule.

b. *Time*. i. *Owner's or Consignee's Time*. The number of hours spent applying labels would be a function of the number of rejected shipments and their size. We assume that the average shipment consists of 500 cartons and would take approximately 3 hours to label. FDA requests comment on this assumption. We also assume that the owner or consignee would hire labor at the average wage rate for transportation and moving occupations published by the Bureau of Labor Statistics, $13.58, plus 30 percent in benefits (Ref. 6). Under these assumptions, it would cost approximately $53 in labor (3 hours x $17.65 per hour) to label each shipment. As a baseline, we estimate that 10,340 shipments would be refused annually. However, data drawn from the OASIS database (Ref. 1) show that in 2006, 6,318 of the refused shipments were destroyed and 438 were released, 176 due to successful reconditioning and 262 for another reason.[1] Most refused shipments would not have to be labeled. However, if the food is reconditioned at a different site, then the proposed rule would require that food to be labeled. In the absence of information, we assume that 50 percent of the reconditioned shipments would be subject to the proposed rule's label requirement. We invite comment on this assumption.

As shown in table 3 of this document, we estimate that roughly 3,672 shipments would need to be labeled initially. This number is used to calculate the ''static'' annual cost shown in table 4 of this document. The annual cost of labeling these shipments would be nearly $195 thousand in labor costs and nearly $46 thousand for labels. It would cost the government more than $55 thousand to confirm the labels had been affixed. The sum of these costs is about $296 thousand. The static annual cost should be viewed as the likely cost in the first few years after the proposed rule becomes final and as a high estimate for costs in later years. We invite comment on the data used in these calculations, including the percentage of reconditioned shipments subject to the label requirement and the labor cost to owners and consignees.

As discussed in part VII.A.4 of this document, because the relative price of refusal would increase due to this proposed regulation, we expect more owners and consignees would decide to recondition after refusal, or will not attempt to import potentially violative food. The ''dynamic'' annual cost is the ''static'' annual cost reduced by the expected percentage decrease (expected avoidance) in initial importation attempts and the increased number of successful reconditioning attempts. We do not have the data to predict the precise reaction of importers to this proposed rule. However, if we assume that owners and consignees would decrease attempts to import violative food by between 25 and 75 percent and that they would increase their attempts to recondition refusals by between 25 and 75 percent, we estimate that the number of shipments to require marking would drop to between 902 and 2,738 (1,814 for a mean change in imports and recondition attempts of 50 percent) annually.[2] This ''if-then'' scenario yields a mean ''dynamic'' annual cost of $146 thousand. We invite comment on our estimates of a 25 to 75 percent decrease in violative imports and of a 25 to 75 percent increase in reconditioning attempts. Added to these costs is a fraction of the cost of the label guns (shown in table 5 of this document). Because label guns are durable goods, the value of a label gun should not be added to the cost of marking each shipment.

TABLE 3.—ANNUAL NUMBER OF REFUSED SHIPMENTS TO BE LABELED

Refusals in 2006	10,340
Shipments Released After Refusal	
Total Recondition Attempts	185
Reconditioned Unsuccessfully	9
Reconditioned and Released	176
Released After Initial Refusal for Other Reason	262
Total Released	438
Shipments Destroyed After Refusal	6,318
Static Total Number of Refusals to be Labeled[1]	3,672
Expected Increase in Reconditioning Attempts and Avoidance	50.0%
Mean Dynamic Total of Refusals to be Labeled[2]	1,814

[1] This number is calculated by subtracting the number of shipments destroyed, the number of shipments released for ''other reason'', and half of the shipments that were reconditioned and released from the total refusals in 2006.

[2] This number is calculated by decreasing the number of refusal by 50 percent and increasing the percentage of total reconditioning attempts by 50 percent.

ii. *FDA inspector's time*. The proposed rule would require us to confirm that the owner or consignee affixes the label to the refused food import or otherwise complies with the label requirement.[3] We estimate that this process would require approximately 30 minutes per shipment. We estimate the value of an FDA inspector's time based on a GS–10, step 5 rate, plus 30 percent in benefits. At this hourly rate, FDA's labor costs for each shipment would be $15 (0.5 hours x $30 per hour). We request comment on these estimates.

TABLE 4.—MEAN ANNUAL LABELING COST ESTIMATES

	Static	Dynamic
Number of Refusals to be Labeled	3,672	1,814
FDA Labor Cost per Refusal	$15	$15
Total FDA Cost	$55,080	$27,210

[1] There are many reasons a shipment may be initially refused and subsequently released. For example, a violative shipment may be reconditioned successfully, samples of food suspected to be in violation may test negative, or paperwork, originally insufficient, might be corrected.

[2] Given a 1 percent inspection rate, an importer has a 99 percent chance of getting violative shipment into the United States. One out of every 100 shipments gets caught. Without this rule, the odds of getting into the next port, given a refusal, are roughly the same as the first port. So if an importer plans to port shop a violative shipment at least once, they have a 99.9999 percent chance to successfully get the shipment into the United States. Therefore this proposed rule increases the risk of getting caught when shipping a violative shipment by a factor of 100 for those that plan on port shopping. FDA believes this would yield a heavy enough disincentive to warrant the use of 25 to 75 percent in an ''if-then'' scenario.

[3] There are several ways of verifying that the label has been affixed. For the purpose of this analysis, our estimates are based on a scenario where FDA inspectors supervise the labeling of refused food.

TABLE 4.—MEAN ANNUAL LABELING COST ESTIMATES—Continued

	Static	Dynamic
Owner/Consignee Labor Cost per Refusal	$53	$53
Total Owner/Consignee Labor Cost	$194,616	$96,142
Label Cost per Refusal	$12.50	$12.50
Total Label Cost	$45,900	$22,675
Total Owner/Consignee Cost	$240,516	$118,817
Total Annual Cost	$295,609	$146,040

TABLE 5.—FIXED LABELING COSTS

Number of Ports	132
Label Guns Needed per Port of Entry	3
Cost per Label Gun	$100
Total Label Gun Costs	$39,600

c. *Increased cost of shipments.* Foods labeled as ''UNITED STATES: REFUSED ENTRY'' would lose value due to diminished value in foreign ports, in addition to the loss of the United States market for the product. The owner or consignee would suffer an initial loss of value due to rejection of its cargo, regardless of the label. How the label decreases the value of the food would be a function of the initial value of the food, type of food, reason for refusal, and the reluctance of the new buyer to purchase previously refused merchandise. This cost represents a transfer from the owner or consignee to the ultimate purchaser of the product. However, there would be an additional cost of this proposed rule that is borne directly by the owner or consignee, but may be passed on to consumers in the form of higher food prices. This cost is difficult to quantify but it includes the increased cost of importing goods because of the increased likelihood of refusal. It also includes the costs of any additional preventive measures taken at the point of origin for the shipment.

7. Summary of Benefits and Costs

The uncertain nature of the number of illnesses prevented and the difficulty in quantifying the benefits to consumers of having clean foods, regardless of the danger, prevents a definitive statement about benefits and costs. We expect the static costs to be about $300,000; this sets a threshold value for the benefits. For two reasons, the annual benefits would probably be greater than these estimated annual costs. First, the costs are likely to decrease over time, perhaps to as low as $70 thousand, as owners and consignees decrease shipments of violative food and increase efforts to recondition refusals. Second, stopping just one violative shipment from entering the United States after refusal could cover the costs. For example, in 2006, nearly 800 food shipments were refused because the food contained *salmonella* (Ref. 1). For the period between 1996 and 2006, we calculate that *salmonella* outbreaks caused from 2 to 688 confirmed illnesses (with an average of 46 confirmed illnesses) per outbreak (Ref. 7). Therefore, if stopping just one of the 800 shipments refused for containing *salmonella* from entering the United States would avert an outbreak, the result would be a savings of over $822,000 ($17,880 per illness x 46 illnesses) in direct medical and health costs. This is simply an example, using a single reason for refusal, that illustrates how high the benefits from this proposed rule are likely to be. If multiple outbreaks are averted in a given year, or even a single outbreak involving fatalities, the benefits could easily reach the hundreds of millions.

B. Preliminary Regulatory Flexibility Analysis

As discussed in detail in section VII.A of this document, we find that this proposed rule would affect up to 1,184 owners or consignees annually.[4] Most of these owners or consignees are small businesses as defined by the Small Business Administration. For the purpose of this analysis, we assume that all 1,184 affected businesses are small.[5] These small owners or consignees would face a cost of approximately $65 per labeled violative food shipment in time and materials as calculated in section VII.A of this document. In addition, the value of their violative food shipment would fall. This cost is difficult to quantify, but can be bounded by the cost of repackaging the merchandise. FDA seeks comment on the estimates used to calculate the cost per labeled shipment. We do not expect this cost for any one small owner or consignee to be excessive, so we conclude that this proposed rule would not place a disproportionate burden on small businesses.

Regulatory Alternative Considered for Small Businesses

Exempting small businesses from the proposed rule would lift the burden on some small entities. However, because most entities affected by the proposed rule are small, such an exemption would effectively negate the proposed rule. We also note that the proposed rule would not prescribe any particular method for affixing the label, and owners and consignees whose shipments are refused admission may decide to re-condition, destroy, or re-export a violative food import. Given these flexible alternatives available to small entities and the small compliance cost of the proposed rule, we did not consider additional options.

C. Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 (Public Law 104–4), requiring cost-benefit and other analyses, in section 1531(a) defines a significant rule as ''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 (adjusted annually for inflation) in any 1 year.'' We have determined that this proposed rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

VIII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

IX. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons

[4] Using total shipments labeled as a proxy for the number of importers affected is an overestimate in the sense that some owners or consignees may accrue multiple violations.

[5] Unless the businesses are repeat offenders, the same business will not be affected each year. The rule does not affect all owners and consignees of shipments, but only those shipments that have been refused admission.

between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. U.S. Food and Drug Administration, Operational and Administrative System for Import Support (OASIS), Available at: *http://www.accessdata.fda.gov/scripts/ora/pcb/tutorial/les2_oasis.htm*.

2. Kaplan, R.M., J.P. Anderson, and T.G. Ganiats, ''The Quality of Well-being Scale: Rationale for a Single Quality of Life Index,'' in Walker, S.R. and Rosser, R.M., eds. *Quality of Life Assessment: Key Issues in the 1990s*, The Netherlands: Kluwer Academic Publishers, 1993.

3. Viscusi, W.K., ''The Value of Risks to Life and Health.'' *Journal of Economic Literature*, vol. 31, pp. 1912–1946, December 1993.

4. Mauskopf, J.A., Mt French, A.S. Ross, D.M. Maguire, R.W. Leukrith, Jr., and K.D. Fisher, ''Estimating the Value of Consumers' Loss from Foods Violating the Federal Food, Drug, and Cosmetic Act,'' Research Triangle Report to the Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration, September 1988.

5. Food Marketing Institute, 1999, Consumer Attitudes and the Supermarket. Research International USA.

6. Bureau of Labor Statistics, 2004 National Occupational and Wage Estimates, *http://www.bls.gov/oes/*, March 2006.

List of Subjects in 21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner, we propose to amend part 1 as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. Section 1.98 is added to subpart E to read as follows:

§ 1.98 Label requirement on food imports refused admission into the United States.

(a) *Who is subject to this label requirement and what does the label say?*—You are subject to this rule if you are an owner or consignee of an imported food, including food for animals, which has been refused admission into the United States (other than a food that must be destroyed). In such situations, you must affix a label stating, ''UNITED STATES: REFUSED ENTRY'', as described in paragraphs (b), (c), and (d) of this section.

(b) *What does the label look like*?—(1) *Labels for shipping containers*—For labels that are to be affixed to shipping containers (as required by paragraph (c) of this section), the letters in the label must be at least 72 points in size, appear in either an Arial or Univers font, and use black ink against a white background. The label must use uppercase letters only.

(2) *Labels for documents*—For labels to be affixed to documents (i.e., invoices, packing lists, bills of lading, and any other documents accompanying the refused food, as required by paragraph (c) of this section), the letters in the label must be in black ink, must use either an Arial or Univers font style, and must be at least 36 points in size. The label must use uppercase letters only.

(c) *Where does the label go?*—For foods that are packaged, the label described in paragraph (b)(1) of this section must be clear, conspicuous, and permanently affixed to the food's shipping container. For purposes of this section, the term ''shipping container'' is any container used to pack one or more immediate containers of the refused food, and an immediate container is any container that holds an imported food for retail sale. In some situations, the food's immediate container may be the same as the shipping container. The term ''shipping container'' excludes trailers, railroad cars, ships, and similar vehicles, vehicle components, and transportation-related items. For all foods, regardless of whether they are packaged in shipping containers, the label described in paragraph (b)(2) of this section must be clear, conspicuous, and permanently affixed to the top page of each document accompanying the refused food.

(d) *How do you show that you complied with the label requirements*?—(1) To comply with the label requirement described in paragraphs (a) and (b) of this section, you must contact the FDA district office responsible for the food's entry and arrange to:

(i) Affix the label(s) in our presence or under our supervision;

(ii) Submit photographs or other visual evidence to us to show that you affixed the label(s); or

(iii) Develop another means of showing, to FDA's satisfaction, that you affixed the label(s).

(2) You must affix the label(s) promptly, and you must not move the food until you have complied with the label requirements.

(e) *What fees may we impose*?—We may seek reimbursement from the owner or consignee for expenses connected to the affixing of a label under this section. These expenses will be computed on the basis of our inspector's time, the per diem allowance under government regulations, travel costs, and administrative support costs. We will submit a list of expenses incurred to the owner or consignee.

Dated: September 12, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–21813 Filed 9–17–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. OSHA–2008–0012]

RIN 1218–AC40

Tree Care Operations

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: OSHA is requesting data, information, and comment on tree care operations, including hazards, fatalities, and control measures, that the Agency can use in developing a proposed standard to control hazards and reduce injuries in those operations.

DATES: Comments must be submitted (postmarked, sent, or received) by December 17, 2008.

ADDRESSES: You may submit comments, identified by Docket No. OSHA–2008–0012, by any of the following methods:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Fax: If your comments, including attachments, do not exceed 10 pages, you may fax them to the OSHA Docket Office at 202–693–1648.

Mail, hand delivery, express mail, messenger or courier service: You must submit three copies of your comments and attachments to the OSHA Docket Office, Docket No. OSHA–2008–0012, Room N–2625, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone 202–693–2350 (TTY number 877–889–5627).