

The Death of “Port Shopping” and FDA’s Proposed Label Requirements for Food Refused Admission into U.S.

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On September 18, 2008, the Food and Drug Administration (FDA) published a proposed rule that would require owners or consignees of imported food that is refused entry into the United States to affix a label stating: “UNITED STATES: REFUSED ENTRY.” This article outlines the proposed label requirements that importers will need to follow.

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Introduction

On September 18, 2008, the Food and Drug Administration (FDA) published a proposed rule that would require owners or consignees of imported food that is refused entry into the United States to affix a label stating: “UNITED STATES: REFUSED ENTRY.”¹

The FDA issued the proposed rule to prevent the practice of “port shopping”, wherein unscrupulous importers attempt to bring previously refused food back into the United States by shipping it to another port where it may enter undetected.

Under the existing import program, food refused admission into the United States generally must be destroyed, or re-exported within 90 days of refusal.² The relatively lax port inspection system allows importers to circumvent this regulatory system by shipping rejected food to a different port.

The new labeling requirements are meant to curb port shopping, and thereby ensure the safety and integrity of our national food supply. Whether the final rule will eradicate this practice altogether, we will have to wait to see. It may be, as Mark Twain is reported to have said of himself, that the news of port shopping’s death is greatly exaggerated.³

Description of Proposed Rule

FDA’s proposed rule would require all owners or consignees to “clearly and conspicuously” label the shipping container of food refused admission into the United States, as well as any documents (including electronic documents) accompanying the food, with the following label: “UNITED STATES: REFUSED ENTRY.”⁴

Under the existing import program, if the importer is unable to demonstrate that detained food complies with the FFDCA, the FDA will issue a “Notice of Refusal of Admission”. Refused foods that are not re-exported within 90 days of refusal (or such later time as Customs and Border Protection (CBP) permits) must be destroyed. The proposed rule would also require that refused food is subject to the new labeling requirements.

The FDA stated that it intends 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.⁵

■ PRACTICE POINT

The proposed rule would also specify that imported food includes food for animals.⁶

■ PRACTICE POINT

“Shipping container” would therefore include items such as boxes, bags, bottles, jars, tanks, drums, barrels and totes because such items are individual containers designed for shipping food.

What Does The Label Look Like?

To minimize uncertainty about what “clear” and “conspicuous” mean, the proposed rule specifies the label’s text, font style, size and color.

Labels for Shipping Containers.

For labels that are to be affixed to shipping containers, the proposed rule would also require the label’s letters to use either an Arial or Univers font style, be at least 72 points in size, and use black ink against a white background.⁷

Labels for Documents.

For labels that are to be affixed to documents (including electronic documents), the proposed rule would require the label’s letters to use either an Arial or Univers font style, and be at least 36 points in size. The label must also only use uppercase letters.⁸

Where Does The Label Go?

The proposed rule would require the label to be affixed to the shipping container of refused food and on invoices, bills of lading, bills of sale, packing lists, and other documents accompanying the imported food.⁹

The new proposed rule defines “shipping container” to mean 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.¹⁰

The proposed rule would also require that the label be permanent and go on the top page of each shipping document to ensure that the label on the document is clear and conspicuous.¹¹

In situations where the imported food has no shipping container, the proposed rule requires the label to be only permanently affixed to the documents accompanying the refused food.¹²

When Should The Labels Be Affixed?

The proposed rule would require that the labels be affixed promptly.¹³

Under section 801(a) of the FFDCA, the exportation of any refused article is generally required within 90 days of the date of notice of such refusal. The regulatory labeling requirement should therefore ensure that the owner or consignee has a reasonable amount of time to affix the required labels and that the FDA has sufficient advanced time to confirm compliance in light of the 90-day deadline.

The proposed rule would also require that the food not be moved until the owner or consignee has complied with the labeling requirements.¹⁴ In other words, the labels would have to 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.

How Is Compliance With Label Requirements Demonstrated?

In order to demonstrate that the label was properly affixed to the shipping containers and documents for refused food, the owner or consignee can:

- Arrange to affix the labels in the presence, or under the supervision of the FDA;
- Submit photographs or other visual evidence to FDA confirming that the labels were properly affixed; or
- Develop another means of showing compliance (e.g., agree that commissioned State or Federal officials can supervise the labeling process)¹⁵

■ PRACTICE POINT

Reimbursed expenses would normally include: the cost of the inspector's time, the per diem allowance under government travel regulations, travel expenses, and administrative support costs.¹⁸

Who Pays For Costs?

Section 801(n)(2) of the FFDCA expressly provides that all expenses in connection with affixing a label under section 801(n)(1) "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."¹⁶

Further, the proposed rule would allow the FDA to seek reimbursement for its expenses when it imposes the label on shipping containers or when it supervises an importer's affixing of labels in shipping containers and documents.¹⁷

Public Comments To Proposed Rule

Public comments to the proposed rule were submitted by several organizations. Most comments expressed agreement with the overall goal of the proposed rule, but offered several suggestions to strengthen the rule's intended effect.

On December 2, 2008, the Grocery Manufacturers Association (GMA) submitted comments regarding the definition of "conspicuous" in terms of a label's placement on a shipping container, and suggested that one label should be visible from each side of the pallet load, if the containers are repacked on pallets.¹⁹

In its public comments submitted on December 2, 2008, the National Fisheries Institute (NFI), recommended greater collaboration between the various federal agencies overseeing importation of food. As noted by NFI, the FDA's Prior Notice of Imported Food Shipment regulations (21 CFR 1.276-1.285) already require specific information to be electronically submitted to the FDA prior to the food arriving at the U.S. port of entry, and such information (including shipper identification, country of origin, anticipated arrival information, and carrier and mode of transportation) could be analyzed in an attempt to identify previously refused shipments seeking to illegally re-enter.²⁰

Likewise, as noted by the NFI, the U.S. Custom and Border Protection's recently finalized regulations (published in the November 25, 2008 *Federal Register* – 73 FR 71730 – as an interim final rule) require an Importer Security Filing (ISF) containing eight elements to be electronically submitted generally no later than 24 hours before the cargo is laden aboard a vessel destined to the United States. An additional two data elements must also be submitted as early as possible, but no later than 24 hours prior to the ship's arrival at a U.S. port. The ISF's ten data elements (country of origin, manufacturer, importer of record, etc.) can therefore be analyzed to detect possible attempts at port shopping.²¹

The Center for Science in the Public Interest (CSPI) also submitted comments in support of the proposed rule, but requested two changes:

- For the final rule to include a prohibition on altering, removing, tampering with, or concealing a "United States: Refused Entry Label".
- For the final rule to require that importers affix the labels with direct FDA supervision.²²

CSPI stated that both changes would improve enforcement and prevent fraudulent entry of unsafe foods into the United States via illegal port shopping.

Conclusion

Ultimately, the practice of port shopping will not be laid to rest until the cost of attempting to reintroduce violative foods into the United States is too high.

We will continue to monitor FDA's regulations regarding imported food label requirements for further developments.

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Endnotes

- ¹ Label Requirement for Food that has Been Refused Admission to the United States, 73 Fed. Reg. 54106 (September 18, 2008) (to be codified at 21 C.F.R. pt.1.98).
- ² Federal Food, Drug, and Cosmetic Act (FFDCA) § 801(a) codified at 21 U.S.C. § 381(a).
- ³ Mark Twain, the American author and humorist, is alleged to have quipped, “The report of my death is an exaggeration”, after a reporter was sent to investigate whether he had died. In fact, it was his cousin who had fallen seriously ill.
- ⁴ Label Requirements for Food that has Been Refused Admission to the United States, 73 Fed. Reg. at 54108 *et seq.*
- ⁵ 73 Fed. Reg. at 54108.
- ⁶ Proposed § 1.98(a).
- ⁷ Proposed § 1.98(b)(1).
- ⁸ Proposed § 1.98(b)(2).
- ⁹ Proposed § 1.98(c).
- ¹⁰ Proposed § 1.98(c).
- ¹¹ Proposed § 1.98(c).
- ¹² Proposed § 1.98(c).
- ¹³ Proposed § 1.98(d)(2).
- ¹⁴ Proposed § 1.98(d)(2).
- ¹⁵ Proposed § 1.98(d)(1).
- ¹⁶ FFDCA § 801(n)(2) codified at 21 U.S.C. § 381(n)(2).
- ¹⁷ Proposed § 1.98(e).
- ¹⁸ Proposed § 1.98(e).
- ¹⁹ FDA-2007-N-0465-0024.1 (submitted on December 2, 2008).
- ²⁰ FDA-2007-N-0465-0025.1 (submitted on December 2, 2008).
- ²¹ FDA-2007-N-0465-0025.1 (submitted on December 2, 2008).
- ²² FDA-2007-N-0465-0023.1 (submitted on December 2, 2008).

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