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The Center for Science in the Public Interest (CSPI) appreciates this opportunity to comment on the Food and Drug Administration (FDA) proposed rule on labeling as “United States: Refused Entry” imported food that has been refused admission [Docket No. FDA-2007-N-0465, Sept. 18, 2008]. CSPI is a non-profit consumer advocacy and education organization that focuses largely on food safety and nutrition issues. It is supported principally by the more than 950,000 subscribers to its Nutrition Action Healthletter and by foundation grants.

CSPI supports the proposed rule for the reasons stated below, but urges the agency to consider additional changes to improve enforcement and prevent fraudulent entry of unsafe foods into the United States. Specifically, CSPI urges FDA to—

1. Include a prohibition on altering, removing, tampering with, or concealing a “United States: Refused Entry” label in the final rule; and,
2. Remove provisions from the rule that allow importers to affix the labels without direct FDA supervision.

I. Background and Reason for Support.

The proposed rule responds to concern that unscrupulous importers engage in a practice known as port shopping. Port shopping occurs when FDA inspectors refuse entry at an imported product’s initial destination and the shipper moves the product to a subsequent port where it may
enter undetected. It happens because of FDA’s lax system of import inspection. FDA does not staff every port, inspects 1.2 percent of imported foods, and has an inadequate system for tracking rejected shipments. This system clearly increases the risk that consumers are exposed to dangerous contaminants or unlabeled allergens in their food, even products that have been inspected. FDA proposes addressing one deficiency in its import inspection program by requiring importers to label rejected food shipments as “United States: Refused Entry” on their shipping containers and documents.

FDA first proposed this rule in 2001 after the Government Accountability Office (GAO)\(^1\) testified before Congress on conditions that allowed unsafe imported food to enter commerce.\(^2\) GAO identified as one condition FDA’s lack of an effective method for deterring port shopping. The testimony highlighted a long-standing practice at the Food Safety Inspection Service (FSIS) of using a “U.S. Refused Entry” stamp to mark rejected foods. This and other factors made it easier for FSIS to ensure a rejected product was either destroyed or re-exported. In contrast, GAO found that FDA could not ascertain the status of rejected products. Meanwhile, investigations demonstrated that importers engaged in a number of practices to circumvent refusals.\(^3\) GAO recommended five changes to address deficiencies in FDA’s import inspection system including use of a refused entry stamp. (Other changes were: require unique identifying marks on imported products, improve coordination with Customs, reduce the period for redelivery of rejected products from 90 to 45 days, and increase bond amounts.)

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1 Congress renamed the “General Accounting Office” the “Government Accountability Office” effective July 7, 2004. Although the GAO reports cited in this comment were issued under the original name, this comment uses the agency’s current designation for clarity.
3 \textit{Id}.
FDA withdrew the 2001 rule because Congress included a provision authorizing uses of a refused entry label in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). The reissued rule is intended to conform its requirements to the statute.

CSPI supports labeling rejected food imports as a proven method of protecting consumers from injury, illness or death that can occur when unsafe foods are allowed to reach the marketplace. FDA may require an importer to affix a label that clearly and conspicuously states “United States: Refused Entry” to any container of food that is refused admission. 21 U.S.C. § 381(n). FDA must refuse entry if the food appears to be produced under insanitary conditions, adulterated, misbranded, or prohibited in interstate commerce. 21 U.S.C. § 381(a). The refused entry labeling provision improves the ability of Customs and FDA inspectors to detect rejected products that are being shipped between ports. This is critically important. As GAO reported, unscrupulous shippers engage in a number of practices to enter potentially dangerous products into the United States. For example, investigations in the 1990s uncovered approximately 30 percent of importers substituting products for inspection or destruction. Additionally, GAO found that miscommunication between FDA and Customs meant the agencies could not ascertain the status of rejected products. These situations exist because importers know they are unlikely to be caught and if caught do not face serious criminal or civil sanctions for their actions. Such weak import controls clearly pose a serious threat to the health and safety of consumers, a fact that is evident from the record of outbreaks caused by unsafe imports. Most recently, imported

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5 GAO, supra, note 2, at 5-6.
6 Id. at 8.
7 Id.
peppers (and perhaps tomatoes) contaminated with *Salmonella* Saintpaul caused 1,400 illnesses and two deaths.

In supporting this rule, CSPI continues to note that it is one tool in a sparsely stocked food safety toolkit at FDA. The agency needs to improve its inspection rate, coordinate better with Customs inspectors, increase bond requirements and penalties, and seek statutory changes identified by GAO. CSPI has identified other steps that would improve import safety in its white paper “Building a Modern Food Safety System for FDA Regulated Foods.” Additionally FDA’s “Food Protection Plan” puts forward regulatory and statutory proposals that CSPI encourages the agency to continue pursuing.

With regard to the proposed rule, CSPI makes the following comments on areas where it should be strengthened and areas in which the agency specifically requested comment.

**II. Strengthen Rule to Prevent Tampering and Fraud.**

Authority under § 381(n) is broader than that provided by the 2001 proposed rule because it would allow marking any imported food that is refused admission. The 2001 proposed rule would have required the “United States: Refused Entry” mark only on foods refused admission for safety reasons. However, in conforming the rule to the statute, FDA has weakened it in two areas. First, it has removed a prohibition on altering, removing, tampering with, or concealing the label. Second, it would permit importers to affix the labels without supervision of an FDA official or designee. FDA should correct both these deficiencies in the final rule.

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A. Prohibit Altering, Removing, Tampering With, or Concealing Labels.

The proposed rule should be strengthened by restoring a specific provision to prohibit altering, removing, tampering with, or concealing labels. As drafted, the proposed rule, in its preamble, explains that refused products will be treated as mislabeled if the label is removed. This is different from the 2001 rulemaking, which included an explicit prohibition. While agreeing with FDA’s analysis of its authority, CSPI is concerned that the agency’s approach may not result in an enforceable rule except in very narrow circumstances, thus permitting some importers to flaunt the law.

FDA should not rely solely on misbranding as a basis for enforcing the labeling requirement. CSPI agrees with FDA’s analysis that any time an importer fails to affix or removes the “United States: Refused Entry” label that action renders the product misbranded under 21 U.S.C. § 343(a)(1) because the missing label conceals a material fact. However, the specific misbranding provision at 21 U.S.C. § 343(v) raises a question about whether Congress intended to preclude sanctions in other situations. This is an arguable claim because, as demonstrated by FDA’s analysis, the misbranding provision at § 343(v) is not needed otherwise, and the legislative history suggests Congress intended to narrow enforcement to circumstances where the threat to health was serious and the importer had received notice of this fact. It is reasonable to assume the court could bar enforcement based on § 343(a)(1), leaving FDA with enforcement authority under § 343(v) alone.

The authority provided in § 343(v) is inadequate on its own to protect the public. The statute declares a food is misbranded if (1) it fails to bear a refused entry label, (2) presents a

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9 Subsection (c) stated that an importer must not “[a]lter, remove, tamper with, or conceal a ‘United States Refused Entry’ mark. Id. at 6511.
10 For an example of a case where a specific statutory authority preclude exercise of a broader grant see, Halverson v. Slater, 129 F.3d 180, 185-86, (D.C. Cir. 1997) (“Congress cannot be presumed to do a futile thing.”)
threat of serious adverse health consequences or death, and (3) the owner or consignee of the food is informed it presents such a threat. By limiting prosecution to foods that present a threat of serious adverse health consequences or death, the law does not cover every instance where consumers can be exposed to illness or injury from illegally imported foods. Instead, enforcement under § 343(v) would apply only to those foods that are subject to a Class I recall if found on the market. A survey of FDA’s enforcement reports for 2008 discovered chili snacks from Mexico tainted with lead, anchovy dip from Thailand potentially containing *Clostridium botulinum*, mussels from New Zealand contaminated with *E. coli*, and pickled beets from Belgium contaminated with glass defined as Class II and III recalls, and, therefore, outside the scope of § 343(v)(2). From this, it is clear that enforcement through § 343(v) alone would leave instances where FDA could find a health-endangering violation but not be able to prosecute.

To address the problems with reliance on misbranding authority, FDA should include a specific prohibition against altering, removing, tampering with, or concealing the label, and base it on 21 U.S.C. § 342(h) and 21 U.S.C. § 371(a) and (b). In addition to the labeling provision covered by this proposed rule, the Bioterrorism Act included a prohibition on port shopping that deems food to be adulterated if it is reoffered for import after being refused entry. § 342(h). The agency has authority to issue rules as necessary to enforce provisions of the Federal Food, Drug, and Cosmetic Act and in particular its section 801 (21 U.S.C. § 381). § 371. GAO found in 1997 that up to 30 percent of importers will circumvent FDA inspections to bring illegal imports into the country.\(^\text{12}\) Therefore, it is a reasonable exercise of FDA’s rulemaking authority under § 371(a) and (b) to issue a regulation that prohibits actions such as removing or concealing a

\(^{12}\) GAO, *supra* note 2, at 5-6.
refused entry label required under § 381(n) that may prevent FDA from determining whether a food is adulterated within the meaning of § 342(h).

For the reasons provided above, FDA should amend the rule to add a subsection that prohibits altering, removing, tampering with or concealing a “United States: Refused Entry” label.

**B. Require Labels to be Affixed Under Government Supervision.**

The rule should be strengthened by requiring government officials to supervise the person who affixes a “United States: Refused Entry” label. As drafted, subsection (d) of the rule would permit an importer to affix the label provided FDA is given photographic or visual proof it was done, or the importer provided proof by another satisfactory method. These two alternatives open the door to fraud.

Neither the proposed rule’s preamble nor referenced documentation provides support for FDA’s decision to permit unsupervised importers to affix labels. It is well established that unscrupulous importers will cheat in order to avoid detection of an unsafe food shipment. Customs operations in the 1990s found 30 percent of importers engaged in practices such as banking, substitution and document fraud to illegally import and avoid exporting unsafe foods. FDA seems to recognize this penchant for cheating in the proposed rule’s preamble. The agency rejects recommendations to mark packages with invisible ink, speculates on efforts to thwart the conspicuous labeling requirement, emphasizes the meaning of permanent, identifies methods for defeating an overly-broad definition of container, and worries that unscrupulous importers may use various techniques to hide document labels. Meanwhile, FDA does not provide any rationale for trusting importers not to doctor photographs or develop self-serving proofs to circumvent the

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13 *Id.*
law. Even FDA’s concession that it would supervise labeling by importers with a history of violating the law does not bear close scrutiny. In one operation, Customs and FDA found that 30 of the 40 violators had been considered reliable until the investigation.  

Meanwhile, FDA cannot argue that supervising every labeling event would be prohibitive because the law and rule provide for reimbursement of the agency’s expenses, which the agency itself estimates as less than $60,000 annually. The only conclusion is that the agency has acted in an arbitrary manner in its drafting of subsection (d).

The agency should delete subsections (d)(ii) and (iii) and restore the language of the 2001 proposed rule so that “United States: Refuse Entry” labels may only be affixed under supervision of an FDA employee or designee.

III. Response to Specific Requests for Comments.

FDA specifically requested comments on how it should define “conspicuous” and “promptly,” and on its assumptions regarding its costs estimates for implementing the regulation. CSPI provides the following comments in response to that request.

A. Conspicuous.

FDA requested comment on whether the rule should explain what “conspicuous” means. CSPI believes the better approach is to include an explicit statement that importers must not conceal the labels, as was contemplated in the 2001 proposed rule. If FDA decides to define conspicuously in the final rule, it should apply the common meaning.

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14 Id.
The requirement that the labels be “clear and conspicuous” prohibits placing them on a container so that they would be concealed from an observer. Conspicuous means “clearly visible or obvious,”17 “obvious to the eye or mind,” and “attracting attention.”18 These definitions would exclude any label that is affixed to the top, bottom, or in a way that obscures it from an inspector. It is difficult to see how an importer could believe otherwise because commercial law defines conspicuous in a manner consistent with its dictionary definitions. The Uniform Commercial Code (UCC) defines conspicuous to mean “it is so written that a reasonable person against whom it is to operate ought to have noticed it.”19 While the definition applies to commercial contracts and forms, it is easily applied to interpret “conspicuous” for the purpose of labeling containers in commerce. The UCC has been adopted into many state codes that would be familiar to persons in the shipping business. Therefore, shippers may not reasonably argue that labels affixed in a fashion that allows them to be concealed or obscured meets the requirement of the statute and rule. Even so, FDA may wish to clarify its intention to rely on the plain meaning of the term conspicuous. It could do this, for example, by issuing a guidance that the agency will not accept easily concealed labels, but will treat this as a violation.

B. Promptly.

FDA requested comment on the interpretation of the term “promptly” under proposed § 198(d)(2). This request highlights a core problem with FDA’s import program. Under 21 U.S.C. § 381(a) and (b) importers may retain custody of food shipments while a decision on their status is pending and have 90 days to re-export or destroy rejected product. In contrast, importers of products subject to FSIS inspection cannot take custody until a shipment is inspected and only

19 Uniform Commercial Code § 1-201(10), (2001 Ed.).
have 45 days to re-export or destroy rejected product. GAO recommended strengthening the bonding requirement and reducing the amount of time an importer has to re-export or destroy rejected shipments as a means of preventing practices such as substitution. CSPI agrees and believes the agency should seek administrative and legislative changes to put into effect all of GAO’s recommendations for improving FDA’s food import program. With regard to the proposed rule, CSPI believes FDA should require an importer to affix the label immediately upon an inspector’s decision to refuse admission. This is consistent with proposed § 198(a), and with the common definition of promptly as “performed readily or immediately.”

C. Assumptions in Cost Estimates.

FDA requested comment on its cost-benefit estimates. In general, CSPI agrees that the benefits of labeling rejected food imports as “United States: Refused Entry” outweigh the costs this rule may impose on society. This is especially true since importers may easily avoid the costs by ensuring food they import meets U.S. standards for safety. Nonetheless, CSPI believes FDA has misclassified its costs and omitted substantial benefits, thus underestimating the full value of the program.

The analysis improperly classifies labor costs associated with supervising the labeling of refused food as a cost to government. FDA should not bear any costs for the labeling program since it may recover its labor and administrative expenses under § 198(e). Therefore, this “cost” is more in the nature of a transfer payment that should not be included in a cost-benefit analysis. This reduces the static costs by $55,080 and the dynamic costs by $27,210.

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20 GAO, supra note 2, at 13-14.
FDA’s analysis includes the health benefits of reducing illnesses, but fails to account for the benefit to domestic growers and processors of avoiding the economic repercussions of outbreaks. This benefit can be substantial as demonstrated in the recent *Salmonella Saintpaul* outbreak. After FDA issued a warning for tomatoes imported from Mexico, and grown in the Southwest and in Florida, consumers stopped buying tomatoes generally. Georgia tomato farmers estimated their losses at $15 million\(^{23}\) and California farmers lost an estimated $30 million.\(^{24}\) Nationally, domestic growers and processors may have suffered $500 million in lost sales.\(^{25}\) These costs not only fall on industry, but are likely passed on to consumers in the form of higher prices. To more accurately reflect the real benefits of avoiding outbreaks caused by unsafe imports, FDA should include avoidance of substantial economic losses in its benefits calculation.

**V. Conclusion.**

CSPI congratulates the agency on proposing this rule which will help end illegal port shopping of imported foods. It cannot be ignored that port shopping occurs because of the inadequacies in FDA’s port inspection system. Implementation of the proposed rule addresses an effect of that inadequate system, but does not mitigate the need to increase the rate of inspection and hire sufficient personnel to provide FDA inspectors at all ports of entry. While CSPI recognizes the changes necessary to fix FDA’s port inspection system are outside the scope of this rule, we call attention to it as a means of urging the agency to seek adequate funding and


\(^{24}\) *Review of legal and technological capacity for full traceability in fresh produce*, hearing before the House Agriculture Subcomm. on Horticulture and Organic Agriculture, 110\(^{th}\) Cong. (July 30, 2008) (statement of Henry Giclas Vice President of Strategic Planning, Science and Technology, Western Growers Assn.).

\(^{25}\) *Florida Counties Poised to Begin Shipping Tomatoes Again After Being Added to FDA’s “Safe to Eat” List*, Press Release from the Florida Fruit & Vegetable Association (June 11, 2008).
authorities to support improvements. With regard to the rule, CSPI recommends including specific provisions to prohibit removal or tampering with labels, and to prevent fraudulent actions intended to circumvent the purpose of the rule. These changes will ensure the rule operates as intended to protect consumers from importation of foods that fail to meet U.S. safety standards.

Respectfully submitted,

[Signature]

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