July 28, 2011

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Information Required in Prior Notice of Imported Food [Docket No. FDA-2011-N-0179; RIN 0910-AG65]

The Center for Science in the Public Interest (CSPI)\(^1\) appreciates the opportunity to comment on the interim final rule to require prior notices of imported food to include the name of any country that has refused entry to the article of food [Docket No. FDA-2011-N-0179]. CSPI supports the rule as published in the May 5, 2011, Federal Register but makes the following observations.

Section 304 of the FDA Food Safety Modernization Act requires anyone submitting a prior notice to include the name of any country that has refused entry to the food item that it is importing. The change came about because of concern shippers are sending food rejected by other countries or regions to the United States. To the extent that importers comply with the requirement, it should help discourage such port shopping. CSPI applauds the Food and Drug Administration (FDA) for its timely implementation of this interim final rule.

Unfortunately, the agency has not moved as decisively under authority Congress provided in 2002 that would prevent criminal port shopping of food that has been rejected during an FDA border inspection. In spite of proposing a rule in 2008 on labeling rejected articles of imported food as “United States: Refused Entry” [Docket No. FDA-2007-N-0465, Sept. 18, 2008], consumers are still waiting for a final rule. Meanwhile, unscrupulous importers continue to engage in the practice of port shopping undetected. Port shopping occurs between U.S. ports 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 because of gaps in FDA’s system of import inspection. FDA does not staff every port, inspects approximately 2 percent or less of imported foods, and has an inadequate system for tracking rejected shipments. This clearly increases the risk that consumers are exposed to dangerous contaminants or unlabeled allergens in imported food.

FDA first proposed a rule in 2001 after the Government Accountability Office (GAO) 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.

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\(^1\) The Center for Science in the Public Interest is a nonprofit health advocacy and education organization focused on food safety, nutrition, and alcohol issues. CSPI is supported principally by the 850,000 subscribers to its Nutrition Action HealthLetter and by foundation grants. We accept no government or industry funding.

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. 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.)

FDA withdrew the 2001 rule after Congress included a provision authorizing use of a refused entry label in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. By this specific authorization, Congress could not have intended that a final rule should languish for a decade since first being proposed.

The proposed rule published in 2008 would 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. By labeling the food item, Customs and FDA inspectors would easily be able to detect rejected products that are shopped between ports. This is a critically important component in larger reforms needed to protect consumers from criminal misconduct by food importers. 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.

CSPI urges FDA to expedite publication of a final rule on labeling food as “United States: Refused Entry.” CSPI thanks the agency for taking these comments into consideration as it moves forward with its programs for assuring the safety of the U.S. food supply.

Sincerely,

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3 Id.
5 GAO, supra, note 2, at 5-6.
6 Id. at 8.
7 Id.