

# FDA Refusals of Food Imports by Exporting Country Group

Jean C. Buzby and Anita Regmi

*JEL Classifications: F1, I18, Q17*

U.S. food imports grew rapidly in recent years, and some of the fastest growing imports came from the developing countries. Brooks, Buzby, and Regmi (2009) found that the share of total U.S. food imports from high-income countries declined from 51% in 2002 to 47% in 2007. In general, four-fifths of the total U.S. food imports from high-income countries are sourced either from Canada or the European Union. The loss of market share for these countries was accompanied by a growth in U.S. import market share for developing countries, particularly middle-income countries, such as Mexico, Chile, and China. In many cases, lower-income countries may not have as extensive or effective food safety standards, practices, and regulations in place as those in the United States or in other more developed countries. This challenges their food safety systems to keep pace with the growth in their food exports.

Buzby, Unnevehr, and Roberts (2008) analyzed U.S. Food and Drug Administration (FDA) refusals of food imports between 1998 and 2004 due to violations of the laws FDA enforces. These laws mostly cover product adulteration, such as unsafe chemical residues and microbial contamination, and misbranding, such as inadequate labeling. Given the growth in food imports, particularly from developing countries, there is a need to closely examine the nature of U.S. food import growth and the correlation between FDA import refusals and different levels of economic development of exporting countries.

## How Was the Study Conducted?

We analyzed FDA data on refusals of food offered for importation into the United States during 1998 to 2004 by food industry group and by type of violation to see if there was a correlation between import source and FDA import refusals. Here, the term *violation* refers to products that ap-

pear to violate one or more of the laws enforced by FDA. Imports of most meat products fall under the jurisdiction of USDA's Food Safety and Inspection Service (FSIS) and not FDA's, so only a few meat products are recorded in the FDA import refusals data.

In order to properly interpret the FDA data, it is important to understand that import violations do not necessarily imply that a particular product posed food safety or other risks but rather they highlight problems associated with certain products, manufacturers/shippers, and countries that appear to recur in trade and where the FDA has focused its import alerts and monitoring efforts (see Figure 1). FDA relies on risk-based criteria to guide its actions, including data on products and manufacturers with a history of violating U.S. import regulations. Because FDA looks more closely where there have been problems in the past, there will be a higher incidence of refusals for some products, manufacturers/shippers, and countries. A violation or a refusal of a shipment does not necessarily mean that there was a violative product, but rather that the product appeared to be violative in FDA's judgment. According to England (2000): Section 801(a) of the Food, Drug, and Cosmetic act, "gives the authority to FDA to refuse admission of any article that "appears" to be in violation" of one of the laws enforced by FDA. "The significance of the appearance standard under FDA law is that the Government is NOT required to prove an ACTUAL VIOLATION of law or the regulations has occurred. Rather, the FDA must be able to show that there exists an "appearance" of a violation to refuse admission of goods. The appearance of a violation may arise by the examination of physical samples, a field examination, review of entry documents, or based upon the history of prior violative shipments made from the same shipper."

**Figure 1. Import Alerts and Detention without Physical Examination**

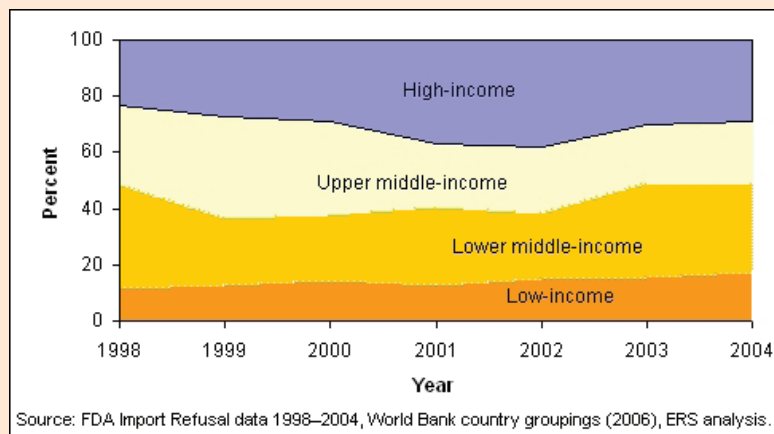
**Import alerts** were developed by the FDA to communicate guidance for import coverage to FDA personnel in field offices, as well as to identify and disseminate import information on problems and violative trends. Import alerts facilitate uniform and effective import coverage. They identify problem products and/or manufacturers/shippers, such as those that have met the criteria for detention without physical examination. These alerts are posted on FDA's Import Alert Retrieval System (FIARS) on their website ([www.fda.gov/ora/fiars/ora\\_import\\_alerts.html](http://www.fda.gov/ora/fiars/ora_import_alerts.html)).

*Example: Import Alert 21-03 calls for increased surveillance of all dried apricots and apricot paste from all countries because of historical problems with insect and rodent filth.*

**Detention without physical examination (DWPE)** is a notice in an import alert that means that subsequent shipments for a specific product and manufacturer/shipper will be refused entry into U.S. commerce unless evidence is presented, such as test results, to FDA proving the item meets safety requirements (FDA, CFSAN, Feb./March 2002).

*Example: Import Alert 16-81 calls for detention without physical examination of specific seafood products due to Salmonella contamination from specific manufacturers/shippers in several countries, including, frozen rock lobster tails from a specific firm in Brazil and frozen shrimp from a specific firm in Vietnam.*

**Figure 2. Share of Total FDA Import Violations by Country Groups**



The World Bank's list of economies (July 2006 version) was used to identify the distribution of all import violations among low-, lower middle-, upper middle-, and high-income countries. We consider high-income countries to represent *developed* countries and the other three groups to represent *developing* countries. We examined commodity and country level trade data from the U.S. Department of Commerce for fiscal years 1998–2007 to understand the volume and value of food trade from different countries and to estimate the number of violations per billion dollars of imports.

### What Did We Find?

Of the 70,366 FDA violations for food during 1998–2004, 70,333 identified the country of origin for the food shipment. In general, there were roughly twice as many violations in each of the last three years of the data than in each of the previous four years. Some of this growth may reflect the strengthening of the reporting system in later years. The distribution of FDA violations across the country groups somewhat mirrors the distribution for the value of total U.S. food imports across similar groups of source countries. As the

developed country share of food import value started to decrease in 2002, their share of the total number of FDA import violations also began to decline from 38% in 2002 to 29% in 2004 (Figure 2). The share attributed to low-income countries increased fairly consistently over the period, from 12% in 1998 to 15% in 2002, and 18% in 2004, while the share for lower middle-income countries has generally been rising since its low in 2000. Meanwhile the share of total FDA violations for upper middle-income countries appears to be on a declining trend, perhaps indicative of improving food standards, regulations, and practices.

In addition to higher growth in the number of import refusals during 2002–04, developing countries also registered a greater number of FDA refusals per billion dollars of U.S. food imports during 1998–04 (Table 1). The estimate is highest for low-income countries at 605 import refusals per billion dollars, followed by lower middle-income countries at 264 refusals per billion dollars. This finding helps support the need to target capacity building and technical assistance to less-developed countries that export food to the United States. For example, the number of violations due to package labeling that were incomplete or not in English could be reduced in the future with greater clarity of U.S. import requirements and greater capacity building. Additionally, information sharing on good agricultural and manufacturing practices can help reduce the contamination of food with filth and microbial pathogens.

Total imports in billions of dollars and the number of import violations per billion dollars are also presented by country group for consumer-ready foods (Table 1). This is important for food safety reasons because these foods include items, such as fruit, vegetables, meat, seafood, and processed foods, that may not have a

further cooking step to destroy any pathogens should they be present in the food. Some might argue that consumer-ready foods should require a higher level of care than foods that will be cooked or otherwise treated in additional preparation steps.

Buzby, Unnevehr, and Roberts (2008) identified the three food industry groups with the most violations: vegetables (20.6% of total violations), fishery and seafood (20.1%), and fruits (11.7%). Brooks et al. (2009) found that these were the same food groups which registered the fastest import growth rates. Therefore, this study also looks more closely at the import refusals in these three food industry groups by country grouping.

Since middle-income countries, led by Mexico, China, India, and other countries in Central and South America are the biggest sources of vegetable and vegetable food product imports into the United States, it is reasonable to find that middle-income countries also account for a large share of total FDA violations on imports of these products (Figure 3). Although the shares of product violations have fluctuated among the four income groups over time, there has been little change between the distribution of shares at 1998 and 2004 levels. Upper and lower middle-income countries have jointly accounted for about 72–73% of total FDA violations in both 1998 and 2004.

Of the 14,463 violations cited by FDA in refusals of vegetable and vegetable product imports during 1998–04, the top three violations were for pesticide residues (27%), failure to file information on its scheduled process of a low-acid canned food or an acidified food (23%), and filth (14%). Vegetable and vegetable product imports had relatively few violations for microbial pathogens (for example, 139 *Salmonella* violations; 37 *Shigella* violations; 1 *Listeria* violation). Pesticide residue levels are set with very conservative thresholds and failure to file a scheduled process is a procedural violation. Most of the violations for vegetables do not suggest immediate food safety risks.

Rising imports of fish and seafood products from developing countries and declining market shares of developed countries are reflected in the shares of FDA import refusals by country group (Figure 4). The most notable change is the increased share of FDA fishery and seafood violations during 1998–04 for low-income countries. In 1998, low-income countries accounted for 17% of these violations, compared to over 30% in 2004. This increased violation share is probably due to both increased imports from these countries and because FDA has issued import alerts concerning fish and seafood products from certain countries based on past problems. Of the 14,107 violations in the FDA fishery and seafood product refusals during 1998–04, the top three violations were filth (31%), *Salmonella* (21%), and manufacturer failure to file requisite information on low-acid canned food or on acidified food (8%).

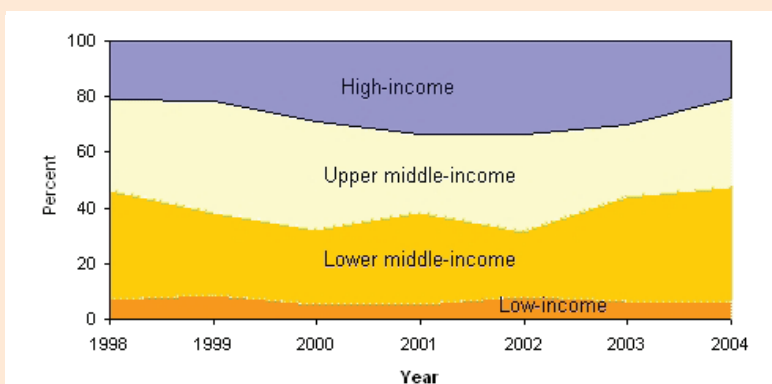
When looking at fruit and fruit product violations, the share attributed to the different income groups changed over time. Most notably, the share attributed to low-income groups more than doubled from 6% in 1998 to 14% in 2004, despite some fluctuation during this time pe-

**Table 1.** FDA Import Violations and U.S. Food Import by Country Grouping, 1998–2004

Country grouping	Total violations <sup>1</sup>	Imports		Violations/billion\$	
		Consumer-ready	Total	Consumer-ready imports	Total imports
	Number	Billion US\$		Number/Billion\$	
Low-income	10,693	11	18	1,001	605
Lower middle-income	20,534	54	78	379	264
Upper middle-income	17,030	63	73	272	234
High-income	22,087	135	165	163	134

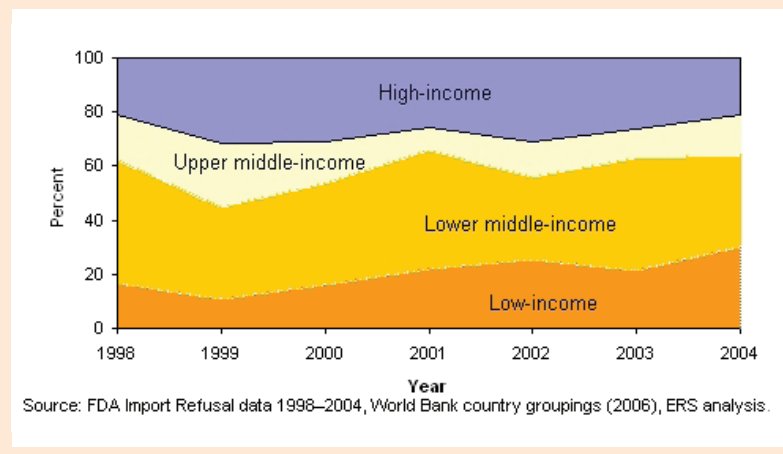
Source: FDA import violations are ERS calculations using FDA Import Refusal Reports, 1998–2004. Import figures are ERS calculations using data from U.S. Department of Commerce, Census Bureau. <sup>1</sup>22 violations for Anguilla, British Virgin Islands, Cook Islands, and Guadeloupe were omitted.

**Figure 3.** Vegetable and Vegetable Products FDA Violations by Country Groups

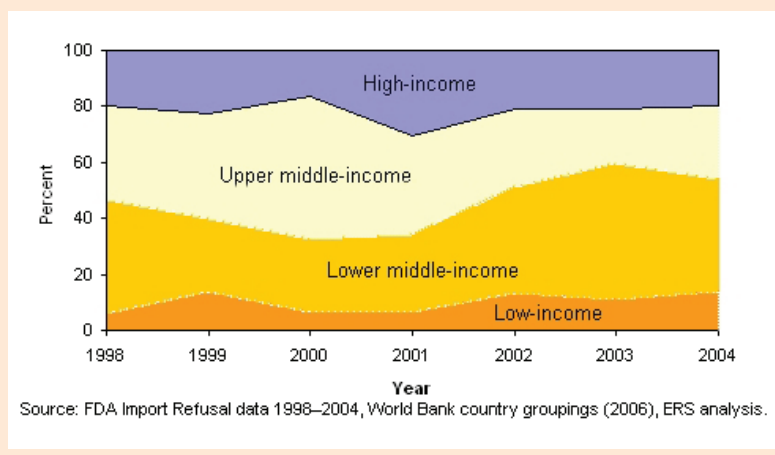


Source: FDA Import Refusal data 1998–2004, World Bank country groupings (2006), ERS analysis.

**Figure 4. Fishery and Seafood FDA Violations by Country Groups**



**Figure 5. Fruit and Fruit Products FDA Violations by Country Groups**



riod (Figure 5). Also, the share from lower middle-income countries grew from its low in 1999 while the share from upper middle-income countries shrank. This switch likely reflects increased imports of these products from low-income and lower middle-income countries, particularly fresh products from countries in Central and South America as noted in Brooks, Buzby, and Regmi (2009).

Of the 8,263 violations recorded for fruit and fruit product refusals during 1998–04, the top three violations were for filth (23.7%), manufacturer failure to file information on its scheduled process of a low-acid canned food or an acidified food (9%), and unsafe color (8%). The remaining violations were spread over a

wide variety of reasons, such as inadequate labeling, unsafe pesticide residues, and microbial pathogens. For example, there were 131 *Salmonella* violations, 270 *Listeria* violations, and 11 *Shigella* violations.

### Summary

A FDA violation means that the product appeared to violate one or more of the laws enforced by FDA, including adulterated or misbranded products. It does not necessarily imply an actual food safety or other risk was associated with the product. Nevertheless, the import refusals data are informative as they highlight food safety and other problems with certain products, shippers, and countries that appear to recur in trade and identify areas where

FDA has focused its import alerts and monitoring efforts.

There has been a noted increase in the share of FDA refusals of food imports from low-income countries. The products with the highest share of violations in imports refused entry by FDA are also those for which imports are rising most rapidly (that is, vegetables, fish/seafood, and fruit). Therefore, we closely examined the sources for these imports and found that the growth in the number of FDA violations among country groups is most evident for low-income countries for fish and seafood, and for fruit and fruit products. In addition to higher growth in the share of import refusals during 1998–2004, low-income countries also registered the most FDA refusals per billion dollars of U.S. food imports during this period. This is important because it provides information to target capacity building and technical assistance to low-income countries that export food to the United States, particularly for fish/seafood and fruit exports.

### For More Information

- Buzby, J.C., Unnevehr, L., and Roberts, D. (2008). *Food safety and imported food: An analysis of FDA food-related import refusal reports*, EIB 39, Washington, DC: U.S. Department of Agriculture, Economic Research Service.
- Brooks N., Buzby, J.C., and Regmi, A. (2009). Globalization and evolving preferences drive U.S. food import growth. *Journal of Food Distribution Research*, 40(1), 39–46.
- England, B.L. (2000, October 27). *Import operations, policies, and procedures*. Presented by the Regulatory Counsel to the Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration.

The World Bank. (2006). World Development Indicators. Available online: <http://devdata.worldbank.org/wdi2006/contents/index2.htm>

U.S. Department of Commerce, Bureau of the Census, Foreign Agricultural Service. (2008). U.S. trade internet system. Available online: <http://www.fas.usda.gov/ustrade/>.

U.S. Food and Drug Administration (FDA). (2009). *Import alert retrieval system (FIARS)*, Available online: [www.fda.gov/ora/fiars/ora\\_import\\_alerts.html](http://www.fda.gov/ora/fiars/ora_import_alerts.html).

U.S. Food and Drug Administration (FDA). (2007, April 1 revision). Code of federal regulations, Title 21, Volume 6, CITE: 21CFR582.20.

*Jean C. Buzby (jbuzby@ers.usda.gov) and Anita Regmi (aregmi@ers.usda.gov) are both economists with the U.S. Department of Agriculture's Economic Research Service, Washington, D.C.*