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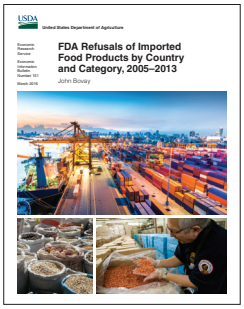

Find the full report at *www.ers.usda.gov/publications/eib-economic-information-bulletin/eib151*

FDA Refusals of Imported Food Products by Country and Category, 2005–2013

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What Is the Issue?

The U.S. Food and Drug Administration (FDA) is responsible for overseeing the safety of most food sold in the United States, including food imported from foreign countries. FDA has the resources to inspect only a handful of foreign facilities, and physically examines less than 1 percent of shipments offered for import. FDA uses a risk-based prediction algorithm to prioritize inspections. To better understand the countries and products that pose the greatest risk for U.S. consumers, ERS researchers have analyzed FDA import refusal patterns. This report reviews import refusal patterns over 2005-13 for a variety of subgroups (e.g., product categories, violations) while paying special attention to shipments from the three exporting countries with the most shipments refused (Mexico, India, and China). For many countries, the most commonly refused products are correlated with the most commonly exported products.

What Did the Study Find?

The number of food shipments refused by FDA inspectors has remained relatively stable, despite an increasing volume of food imports over 2005-13. Thus, the number of shipments refused declined relative to the volume of imports. This decline may reflect improvements in compliance with U.S. laws among foreign producers and importers, or it may reflect FDA's limited resources and capacity to inspect, detain, and refuse imported food. This is difficult to determine because FDA does not randomly sample import shipments for inspection. Instead, FDA uses a risk-based prediction algorithm to determine whether shipments should be inspected in the field or a laboratory, and also relies on *Import Alerts*, which provide guidance on firms and products that meet the criteria for detention without physical examination and require the importer to produce evidence that no violation is present, before the shipment may enter general commerce.

The following food product categories accounted for the majority of shipments refused:

1. Fishery and seafood products (20.5 percent of all refusals);
2. Vegetables and vegetable products (16.1 percent);
3. Fruit and fruit products (10.5 percent);

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4. Spices, flavors, and salts (7.7 percent); and
5. Candy without chocolate and chewing gum (7.2 percent).

For both fishery/seafood products and fruit/fruit products, the most common reason for a shipment to be refused was sanitary violations or, specifically, "filth." Vegetables/vegetable products were most commonly refused because of unsafe pesticide residues. The most common violation for spices, flavors, and salts was the presence of *Salmonella* bacteria. The use of an unsafe color additive was the most common violation for non-chocolate candies and gum.

Of the 142,679 violations reported, 57 percent were for adulteration (i.e., a problem relating to safety issues, packaging integrity, or sanitation), and 41 percent were for misbranding, which may include untruthful or misleading labels or labels that lack English. Although adulteration generally poses a greater risk to human health than misbranding, improper labeling, such as a failure to identify an allergen, may lead to illness and fatalities in some cases.

The countries with the most food shipments refused by FDA—Mexico, India, and China—have distinct sets of product categories (vegetables, spices, and seafood, respectively) that have been subject to the most refusals. The persistence of the same problems, year after year, in food import shipments indicates that FDA's inspection regime has not completely deterred producers and importers from offering food shipments for import that violate U.S. laws. Overall, the patterns of refused import shipments correlate with the volumes of imports (of various product categories and from various countries), but data are unavailable to perform a more precise analysis of this relationship.

How Was the Study Conducted?

ERS researchers analyzed FDA data on food shipments offered for import into the United States and refused entry over 2005–2013. Researchers tabulated refusals by country, industry group, and type of violation, and assessed patterns in refusals. Patterns in adulteration violations and violations for pathogen and toxin adulteration were examined closely because of their clear links to foodborne illness in humans. Special attention is given to persistent patterns in import refusals for shipments from Mexico, India, and China, the three countries with the most shipments refused over the period of analysis.

The nonrandom nature of FDA sampling means that researchers cannot draw inferences about the relative safety of food produced in various countries or the relative risk of certain food products. Instead, the conclusions drawn in this report highlight FDA refusals that reveal recurring patterns of import violations in food products, which have repeatedly attracted the attention of FDA inspectors.