

May 5, 2016

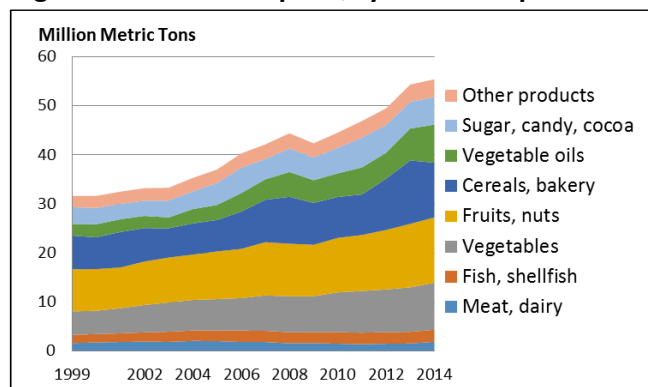
## Efforts to Address the Safety of FDA-Regulated Food Imports

High-profile foodborne outbreaks and incidents involving imported foods have generated growing concerns about whether current federal programs sufficiently ensure the safety of these imports. Safety concerns have been associated with imported products from China, Mexico, and nations in Central and South America, Southeast Asia, Europe, and elsewhere. Some imported products that have raised concerns include fish and seafood, fruits and vegetables, and pet foods. These products fall primarily under the responsibility of the Food and Drug Administration (FDA) at the U.S. Department of Health and Human Services and the Food Safety and Inspection Service (FSIS) at the U.S. Department of Agriculture (USDA).

Food imports have been steadily increasing over the past decade due to globalization and consumer demand for a wider variety of foods year-round. By volume, imports rose nearly 60% (2004 to 2014), driven in part by increased imports of fruits and vegetables and some processed foods (**Figure 1**). Imports now account for nearly one-fifth of all foods consumed in the United States and an even larger share of consumption of some foods, such as fish and seafood (97%) and fruits and nuts (49%), among other products (**Table 1**).

The sheer volume of imported foods each year further complicates efforts to secure the safety of imported foods and strains an already challenged U.S. food inspection and oversight system. For foods under FDA's jurisdiction (covering all foods except most meat and poultry products), more than 210,000 foreign food facilities are registered with FDA and are potentially subject to inspection. Each year FDA inspects about 25% of domestic food facilities and physically examines about 2% of all food imported during the year. Another 1,200 eligible foreign meat and poultry establishments fall under USDA's jurisdiction.

**Figure 1. U.S. Food Imports, by Food Group**



**Source:** CRS from USDA data. Excludes some product groups.

**Table 1. Import Share of U.S. Food Consumption**

Selected Food Groups	1993	2003	2013
	(percent)		
Total consumed food	12.8	16.0	19.4
Red meat	7.6	9.3	7.4
Poultry/eggs	0.0	0.1	0.4
Dairy products	1.9	3.6	1.9
Fish and shellfish	54.6	82.1	96.6
Grains	20.4	13.9	15.5
Fruits and nuts	30.3	36.8	48.7
Vegetables	7.9	14.8	20.0
Sweeteners	16.6	16.7	25.0
Spices	75.1	83.5	86.3

**Source:** CRS from USDA data based on volume.

### Data on FDA Refusals of Imported Food Products

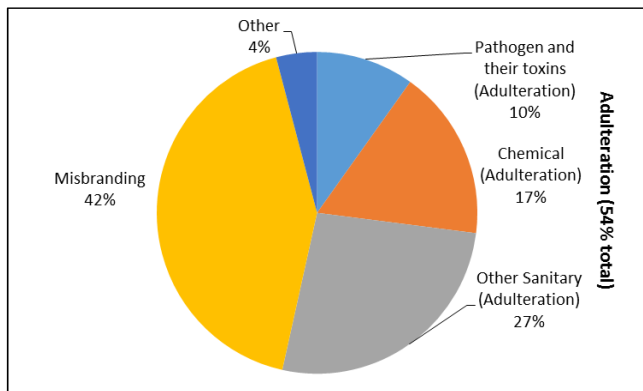
In recent years, FDA has issued import alerts on a range of imported foods, including pet food ingredients, seafood, and dairy products and ingredients, among other foods. Data on FDA import refusals by violation type, provided by FDA, indicate that adulteration accounted for more than half of all refusals during 2009-2013 (**Figure 2**). Refusals result from violations associated with misbranding and/or adulteration, among other types of violations. Most adulteration is attributable to pathogens and their toxins (such as *Salmonella*, *Listeria*, and aflatoxins), with the remainder attributable to chemical adulteration (such as unregistered pesticides or other illegal additives) and other sanitary adulteration (such as filthy or decomposed appearance or unregistered processes). Misleading or missing labels accounted for another 42% of FDA refusals.

Data on FDA import refusals by food group indicate that fish and seafood, vegetables and fruits, and processed snack foods and baked goods accounted for nearly 60% of all import refusals during 2009-2013 (**Figure 3**). Most produce refusals were due to violative residues (such as pesticides); filth, microbial pathogens, and bacterial contamination (mostly *Salmonella*); and improper process filing. Import violations were reported to be found in products mostly from Mexico and other Latin America and Caribbean nations. Refusals of fish and seafood were attributed to *Salmonella* and other pathogens (bacteria), residues (veterinary drugs), filth, and improper process filing. Violations were found in products from China, Vietnam, India, Bangladesh, and other Asian nations.

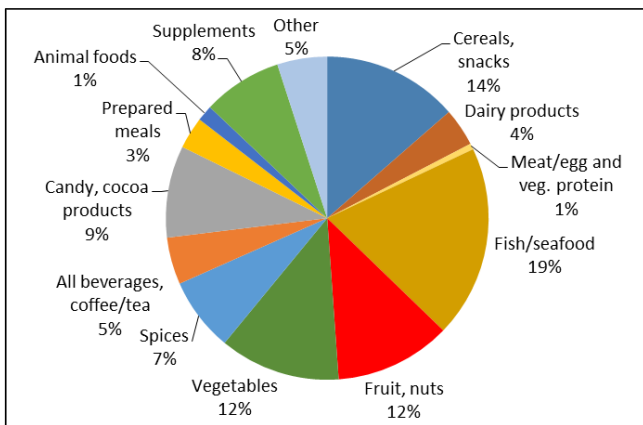
While attention has focused on the safety of imported foods, it remains unclear whether imported foods pose any greater safety risk than domestically produced foods.

Limited available data on foodborne outbreak investigations are published by the Centers for Disease Control and Prevention (CDC) in its *Foodborne Outbreak Online Database (FOOD) Tool*. FOOD data are a small convenience sample (i.e., not a random sample) of outbreaks in the United States each year. Also, outbreaks account for less than half of all foodborne illnesses each year. CDC has noted that the origin of a food—whether domestic or imported—is often difficult to determine. The FOOD system does not attempt to capture this information. CDC has previously commented that when it looked specifically at outbreaks that were attributed to imported foods, it found that fish and spices were the imported foods most often linked to outbreaks (which is consistent with the import shares of these foods in **Table 1**). Nearly 45% of the imported foods causing outbreaks came from Asia.

**Figure 2. FDA Import Refusals, by Violation**



**Figure 3. FDA Import Refusals, by Food Group**



**Source:** CRS from FDA import refusal data (September 2014). Data are calendar year and cover a five-year period (2009-2013). Percentages reflect share of the total number of refusals.

### Federal Food Safety Oversight

Numerous agencies share responsibility for ensuring the safety of the U.S. food supply. FDA and FSIS are the two primary federal food safety agencies: FDA is responsible for regulating the safety and labeling of most foods and beverages (excluding alcohol) and the manufacture and distribution of shell eggs, most seafood, and drugs and feeds for animals. FSIS is responsible for regulating the safety and labeling of meat, poultry, and some egg products and catfish. Other USDA agencies and the National Marine Fisheries Service at the Department of Commerce also

oversee quality and grading standards for some foods but do not strictly play a food safety role. The U.S. Customs and Border Protection at the Department of Homeland Security plays an important role regarding food imports as part of the agency's overall oversight role at U.S. borders.

The FDA Food Safety Modernization Act (FSMA, P.L. 111-353) includes several provisions on food imports imposing tighter controls, setting minimum entry requirements, requiring certification of imported foods, and raising importer accountability. FSMA created several new programs and requirements, including a program for expedited entry and capacity building in foreign countries. Other FSMA requirements establishing preventive controls and standards for produce also apply to both imported and domestically produced products. FDA has issued final FSMA regulations, which will be phased in over the next few years. FSMA's import requirements place more responsibility on U.S. trading partners. Some claim that FSMA requirements could influence food safety efforts worldwide once implemented. Key import requirements under FSMA are listed in the text box.

### FSMA's Requirements Related to Food Imports

- **Hazard Analysis and Risk-Based Preventive Controls (§103):** Mandatory preventive controls for both domestic and foreign food facilities.
- **Standards for Produce Safety (§105):** Mandatory minimum standards for fruits and vegetables (applies to both domestic and foreign operations).
- **Laboratory Accreditation for Analyses of Food (§202):** Program to test food by accredited labs.
- **Foreign Supplier Verification (§301):** Program for importer verification of imported foods.
- **Voluntary Qualified Importer Program (§302):** Program to provide for the expedited review and importation of foods from participating importers.
- **Import Certification (§303):** Requirements for food entities to provide certification concerning imported foods.
- **Prior Notice Requirements (§304):** Requirements for food entities to submit prior notice of imported food.
- **Building Capacity of Foreign Governments (§305):** Technical support to foreign governments.
- **Improved Enforcement Authorities (§306):** Federal inspection of registered foreign facilities.
- **Accredited Third-Party Certification (§307):** Program of qualified third-party auditors to certify that foreign food facilities are in compliance with U.S. standards.
- **Foreign Offices (§308):** Report on the selection of the foreign countries for established offices.
- **Smuggled Food (§309):** Strategy to identify and prevent entry of smuggled food.

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