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U.S. Food and Agricultural Imports: Safeguards and Selected Issues

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SUMMARY

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July 1, 2020

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U.S. Food and Agricultural Imports: Safeguards and Selected Issues

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. Imports of fish and seafood, fruits and vegetables, and pet foods are among those that have been associated with foodborne outbreaks and incidents. It is unclear whether imported foods pose a greater safety risk than domestically produced foods. Available data on foodborne illness outbreak investigations do not readily identify whether the food is domestic or foreign sourced.

A steady increase in the volume of food imports—a result of globalization and consumer desire for a wider variety of foods year-round—complicates efforts to secure the safety of imported foods and strains already-challenged U.S. food inspection and oversight services. Overall, imported foods account for about one-fifth of all foods consumed in the United States, but an even larger share for some foods, such as fish and seafood, and fruit and vegetable products.

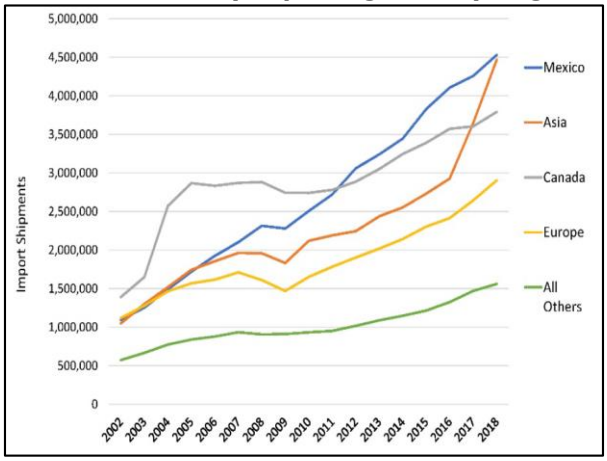
Numerous federal, state, and local agencies share responsibilities for regulating the safety of the U.S. food supply. State and local authorities are thought to account for as much as 90% of all the food inspections in the United States through their routine sampling, inspection, and food-testing work.

Federal responsibility for food safety rests primarily with the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). FDA, an agency of the Department of Health and Human Services, is responsible for ensuring the safety of all domestic and imported food products (except for most meats and poultry). FDA also has oversight of all seafood, fish, and shellfish products. More than 210,000 foreign food facilities are registered with FDA and are potentially subject to inspection. USDA's Food Safety and Inspection Service (FSIS) regulates most meat (including catfish) and poultry and some egg products. Roughly 1,300 eligible foreign establishments fall under FSIS jurisdiction.

In FY2019, FDA inspected more than 1,700 foreign facilities and examined 17.7 million import lines (referring to separate product lines on an entry document) of FDA-regulated foods. For meat and poultry imports, FSIS audits the meat inspection systems of foreign countries that are approved to export meat and poultry products to the United States. Upon entry into the United States, FSIS reinspects the imported products.

Changes enacted in the FDA Food Safety Modernization Act (FSMA, P.L. 111-353) gave FDA new tools and authorities to ensure imported food meets the same safety standards as food produced in the United States. However, FDA continues to examine about 1% of the total number of food import lines each year—rates similar to that prior to FSMA. FSMA mandates requiring an increase in the number of facility inspections and an increase in the number of FDA inspectors have also not kept pace with targets set by Congress. As part of its ongoing oversight, Congress may wish to continue monitoring FDA's progress in implementing FSMA and examine the agency's ability to ensure the safety of imported foods. Some in Congress also continue to question the safety of imported foods under USDA's jurisdiction and have scrutinized the agency's process for determining the

Number of Imported Food Shipments to the United States by Exporting Country/Region



Source: FDA, *FDA Strategy for the Safety of Imported Food,* February 2019.

eligibility of foreign establishments to export meat and poultry products to the United States, particularly for products originating from certain countries. Congress may consider whether tighter requirements are necessary regarding such imports.

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Over the past few decades, a number of high-profile foodborne illness incidents and outbreaks involving imported foods have generated growing concerns about whether current federal programs sufficiently ensure the safety of these imports. Foodborne illness incidents and outbreaks involving imported foods have been associated with products from China, Mexico, nations in Central and South America, Southeast Asia, Europe, and elsewhere. Compounding concerns about the safety of imported foods is the fact that the volume of imports continues to steadily increase, in part given increased globalization but also rising consumer demand for a wider variety of foods year-round. Food imports now account for a growing share of all foods consumed in the United States. The U.S. Department of Agriculture (USDA) reports that food imports account for about one-fifth of all U.S. food consumed (regardless of whether measured by volume or product value of trade). Imports account for an even greater share of total consumption for some foods, including fish and seafood, and fruit and vegetable products.

Numerous agencies share responsibility for ensuring the safety of the U.S. food imports. Federal responsibility for food safety—covering both imported and domestically produced foods—rests primarily with the Food and Drug Administration (FDA) at the Department of Health and Human Services (HHS) and the Food Safety and Inspection Service (FSIS) at USDA. 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, drugs, and animal feeds. FSIS is responsible for regulating the safety and labeling of meat, poultry, egg products, and catfish.

Trends in U.S. Food Product Imports

Value of Trade

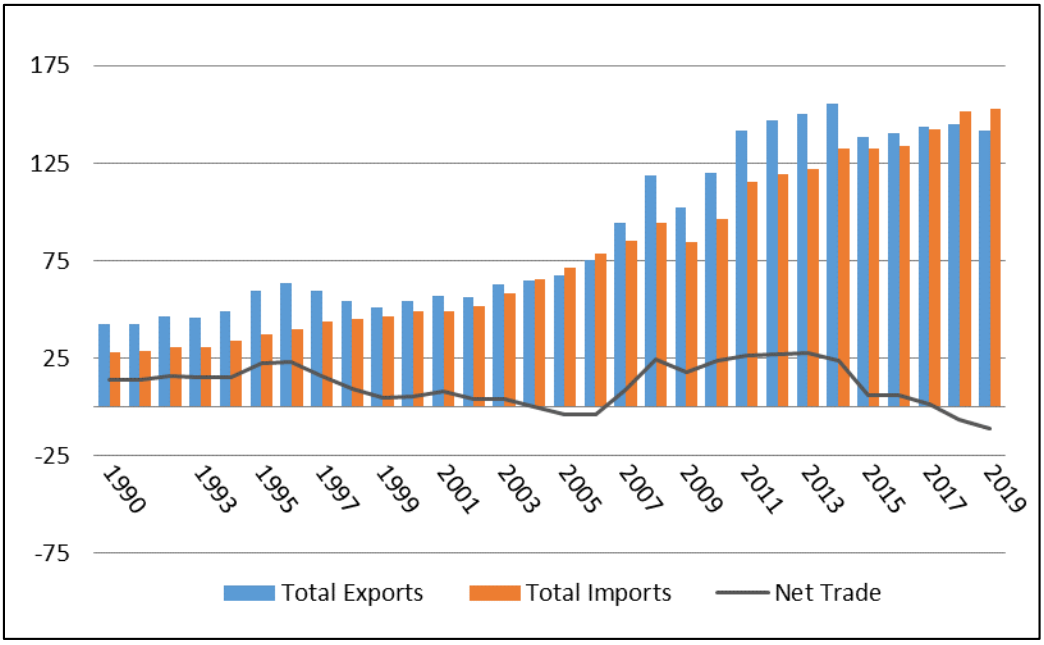
In 2018-2019, the United States was a net importer of agricultural and fish products, reversing a period of a U.S. trade surplus over the past decade (**Figure 1**). While U.S. agricultural exports have increased, so have imports. From FY2015 to FY2019, U.S. agricultural exports averaged about $142 billion per year, while U.S. imports averaged slightly higher at $143 billion per year.

Trade data presented here cover *agricultural products* as defined by USDA for the purposes of calculating U.S. agricultural exports and imports and the agricultural trade balance. This definition includes raw and bulk agricultural commodities (e.g., grains and oilseeds), meat and dairy products, fruits and vegetables, nursery products, wine, and cotton fiber products (see **text box**). USDA's definition typically does not include certain other *agriculture related products*, which cover fish and seafood, distilled spirits and other beverages, manufactured tobacco products, and forestry and bioenergy products. Fish and seafood are often not included in official U.S. agricultural statistics. This is consistent with the World Trade Organization's (WTO's) Agreement on Agriculture, which excludes fish and seafood products from its list of products covered by the agreement.[1] As the United States remains a net importer of fish and seafood products, the inclusion of fish and seafood data as part of the overall trade picture results in a net trade deficit (**Figure 1**). From FY2015 to FY2019, U.S. fish and seafood exports averaged about $6 billion per year, while U.S. imports averaged about $11 billion per year.

Table 1 provides additional detail on a range of *agricultural products* and other *agriculture related products*, including fish and seafood, and forestry products. It excludes distilled spirits and agriculture-derived bioenergy products.

[1] WTO, Agreement on Agriculture, Annex 1, https://www.wto.org/english/docs_e/legal_e/14-ag.doc. See also USDA, *Profiles of Tariffs in Global Agricultural Markets*, AER-796, Appendix, January 2001, https://www.ers.usda.gov/publications/pub-details/?pubid=41257.

Figure 1. Value of U.S. Agricultural and Fish/Seafood Trade, 1990-2019



Source: CRS from USDA's Global Agricultural Trade System data (FATUS product group). As defined by USDA, "Agricultural" trade including selected (non-ag) fish and seafood products (excluding fertilizer and agricultural chemicals, farm machinery, and tobacco products). Alt also excludes distilled spirits.

Notes: Agricultural products exclude re-exports and reflect USDA-revised data for domestic exports and imports for consumption, customs value basis.

USDA's Definition of Agricultural Products in U.S. Trade

USDA's definition of *agricultural products* (often referred to as "food and fiber" products)—for the purposes of calculating U.S. agricultural exports and imports and the agricultural trade balance—covers a broad range of goods from unprocessed bulk commodities, intermediate products, and consumer-oriented products. This includes grains for human consumption and animal feed; raw cotton; meat and poultry products; milk and dairy foods; fresh and processed specialty crops (fruits, vegetables, tree nuts, nursery products, honey, and wine); highly processed high-value foods and beverages (such as sausages, bakery goods, ice cream, beer, and condiments); tropical products (such as sugar, cocoa, and coffee); fats and oils; hides and skins; wool and mohair; and unmanufactured tobacco. Generally, most of the products in Chapters 01-23 of the U.S. Harmonized Tariff Schedule (HTS) include agricultural products. Exceptions include fishery products (Chapters 03 and 16) and distilled spirits (Chapter 22). Other products are also considered agricultural products. These include essential oils (Chapter 33), raw rubber (Chapter 40), raw animal hides and skins (Chapter 41), and wool and cotton (Chapters 51-52). These data exclude manufactured tobacco products such as cigarettes and cigars (Chapter 24).

Some products derived from plants or animals are considered to be nonagricultural because of their manufactured nature, such as cotton thread and yarn, fabrics and textiles, clothing, leather and leather goods, cigarettes and cigars, and distilled spirits. Others are considered to be agricultural related products, such as fishery and seafood products (given their food value) and solid wood products (given that USDA promotes U.S. exports of these products). USDA's definition of *agricultural related products* included fish and shellfish products, distilled spirits, forest products, and ethanol and biodiesel blends.

Source: USDA, "GATS Agricultural Products Definition," https://apps.fas.usda.gov/gats/AgriculturalProducts.aspx. See also, for example, USDA, *Profiles of Tariffs in Global Agricultural Markets*, AER-796, Appendix, January 2001, https://www.ers.usda.gov/publications/pub-details/?pubid=41257. The exclusion of fish and seafood products is consistent with coverage under the WTO's Agreement on Agriculture (Annex 1).

Table 1. U.S. Imports of Agriculture, Fish and Forest Products, 1990-2019

Product	1990	2000	2010	2015	2018	2019	2019
	($billions)						
Ag, Fish & Forest Prods	**33.24**	**64.32**	**107.77**	**148.49**	**171.67**	**170.39**	**100.0%**
Consumer-Oriented	13.95	25.97	51.93	75.90	90.29	93.85	55.1%
Fruit, Vegetable, Tree Nut Products	5.46	9.05	20.58	29.75	36.19	37.23	21.8%
Cheese and Dairy Products	0.87	1.55	2.17	3.02	2.95	3.16	1.9%
Red Meats	2.93	3.77	4.78	9.44	8.67	9.10	5.3%
Wine and Beer	1.83	4.42	7.80	10.09	11.78	12.12	7.1%
Snack Foods	0.88	2.47	5.80	8.03	9.88	10.49	6.2%
Other Consumer-Oriented Products	1.98	4.72	10.80	15.57	20.81	21.75	12.8%
Intermediate Total	4.08	7.00	16.71	23.12	24.94	24.30	14.3%
Live Animals, Hides and Skins	1.32	2.03	2.39	3.38	2.63	2.87	1.7%
Vegetable and Tropical Oils	0.67	1.29	4.11	5.47	6.49	5.81	3.4%
Sugars, Sweeteners, Cocoa Paste	0.63	0.62	2.69	2.38	2.26	2.37	1.4%
Essential Oils	0.22	0.33	2.46	3.45	4.30	4.10	2.4%
Other Intermediate Products	1.25	2.72	5.06	8.44	9.26	9.15	5.4%
Bulk Total	4.89	6.00	13.22	14.62	13.49	12.89	7.6%
Coffee, Tea, Cocoa	2.28	3.01	5.89	7.27	6.41	6.25	3.7%
Other Bulk Products	2.60	2.99	7.33	7.35	7.08	6.64	3.9%
Seafood and Fish Products	5.2	9.9	14.6	18.6	22.3	21.9	12.8%
Tuna and Salmon	0.8	1.0	2.0	1.9	2.6	2.6	1.5%
Shrimp	1.7	3.8	4.3	5.4	6.2	6.0	3.5%
Other Seafood and Fish Products	2.7	5.2	8.3	11.2	13.5	13.3	7.8%
Forest Products	5.15	15.45	11.35	16.29	20.60	17.48	10.3%

Source: CRS from USDA's Global Agricultural Trade System data (BICO-HS10 product group). As defined by USDA, "Agriculture, Fish, and Forest Products" includes bulk and intermediate agricultural products, consumer-oriented products, fish and seafood, and forest products. It excludes and other related agricultural products such as distilled spirits and biodiesel blends.

Notes: May not add due to rounding. Data are not adjusted to account for inflation.

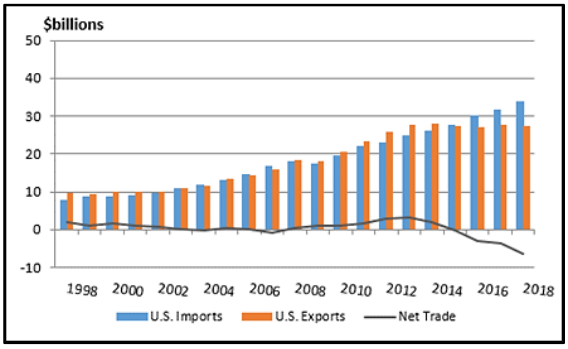
USDA aggregate agricultural trade surplus data often mask trade imbalances for certain traded goods, including fish and seafood (**Figure 2**) and fresh and processed fruits and vegetables (**Figure 3**). Currently, by value, the United States imports more fish and seafood and more fruit and vegetables than it exports, resulting in a deficit in trade for these broad product categories.[2]

[2] The deficit for fruits and vegetables cannot be solely explained by imports of bananas and other tropical fruits, which are generally not grown in the United States. For more information, see CRS Report RL34468, *The U.S. Trade Situation for Fruit and Vegetable Products.*

Figure 2. Value of Trade, Selected Fish and Shellfish Products

Source: CRS from USDA Global Agricultural Trade System, calendar year data, https://apps.fas.usda.gov/gats/default.aspx.

Figure 3. Value of Trade, Fresh and Processed Fruits and Vegetables



Source: CRS from U.S. International Trade Commission's Trade DataWeb, calendar year data, https://dataweb.usitc.gov/. Excludes fresh nuts (HTS 801 and 802).

Across all product categories—including fish and shellfish and other agriculture related products—more than one-third of the value of U.S. agricultural imports in 2018 were supplied by Canada and Mexico, with another 17% supplied by the European Union. China accounted for about 5% of the value of U.S. agricultural imports, while Chile, India, and Indonesia supply roughly 3% each. **Table 2** lists other leading U.S. food importing countries.

Figure 4 shows the number of imported food shipments by exporting country or region.[3] These data further indicate that the number of shipments to the United States from all major suppliers has risen sharply over the past several years.

Not all agricultural imports enter the human food supply; some products are used as ingredients in pet food and animal feed, in manufactured goods (e.g., rubber), and in the nursery plant trade.

Volume of Trade

By volume, food imports have steadily increased in all food product categories since the 1990s (**Figure 5**). From 1999 to 2017, volume imports of selected foods rose from 32 million metric tons (MMT) to nearly 60 MMT.[4] Increases were greatest for imports of fruits and vegetables, prepared grain and bakery goods, and other ready-to-eat products. By value, these types of consumer-oriented products account for more than half of all U.S. food imports (**Table 1**).

Other more detailed data also show increases in volume imports of fish and shellfish products, which have increased since the 1990s, reaching over 2.8 MMT in 2018.[5] Fish products accounted for about 60% of this total import volume in 2018, with shellfish accounting for the remainder (**Figure 6**).

[3] FDA, "FDA Strategy for the Safety of Imported Food," February 2019. Data are reported by FDA from data in its Operational and Administrative System for Import Support (OASIS), 2018.

[4] USDA's U.S. Food Imports data (https://www.ers.usda.gov/data-products/us-food-imports/). Data through 2017 are the most recent available.

[5] Converted from reported pounds. USDA, "Aquaculture Data," http://www.ers.usda.gov/data-products/aquaculture-data.aspx. The volume of total U.S. aquaculture exports totaled about 0.2 MMT in 2018 (excluding trade in live trout and ornamental fish).

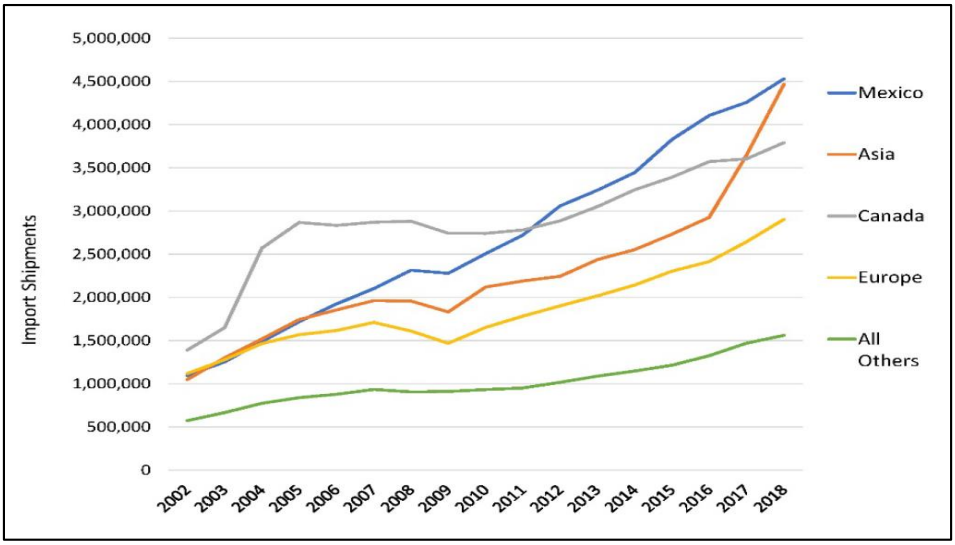
Table 2. Leading Food Exporting Countries to the United States, 2018

Exporting Country	Value ($billion)	Share (%Value)	Major Food Product Imports (based on value)
Mexico	27.2	18.0%	Fresh/prepared fruits/vegetables, spirits/beverages, sugar/confectionary
EU-28	26.0	17.2%	Wine/spirits, baked goods, fats/oils, dairy products, prepared fruits/vegetables
Canada	25.6	16.9%	Meat products, cereals/baked goods, seafood, fats/oils
China	7.5	5.0%	Fresh/prepared fish/seafood, prepared fruits/vegetables
Chile	5.2	3.4%	Fruit, seafood, wine/beverages
India	4.8	3.1%	Fresh/prepared fish/seafood, gums/resins, tea/spices, oilseeds/legumes
Indonesia	4.2	2.8%	Fresh/prepared fish/seafood, fats/oils, coffee/spices, cacao products
Vietnam	3.8	2.5%	Fresh/prepared fruits, fresh/prepared fish/seafood, coffee
Brazil	3.8	2.5%	Coffee, beverages, processed fruits vegetables
Thailand	3.6	2.4%	Fresh/prepared fish/seafood, cereals animal feed, prepared fruits
Australia	3.2	2.1%	Meat products, wine, grains
Colombia	2.7	1.8%	Coffee, nursery plants, fruits
New Zealand	2.5	1.7%	Meat, beverages, dairy products, fruit, fresh fish/seafood
Peru	2.5	1.7%	Fresh/prepared fruits/vegetables, coffee/tea/spices, fresh fish/seafood
All Other	28.8	19.0%	

Source: CRS, from trade data posted at the U.S. International Trade Commission's Interactive Tariff and Trade DataWeb database, covering HTS codes in chapters 1-24 (includes fish, seafood, distilled spirits, and tobacco products). Shares based on a subtotal of $151.5 billion.

Notes: EU-28 includes the current 28 member states of the European Union, including the United Kingdom.

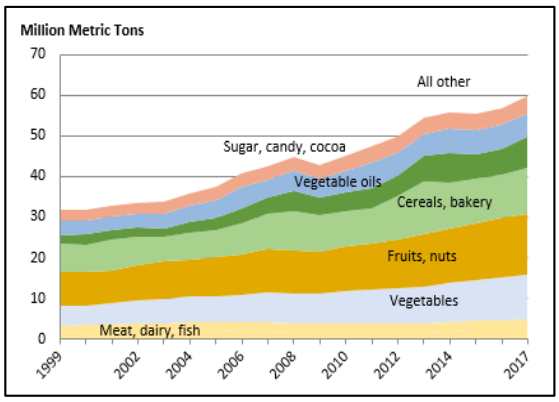
Figure 4. Number of Imported Food Shipments by Exporting Country/Region



Source: FDA, *FDA Strategy for the Safety of Imported Food*, February 2019. Data are reported by FDA from data in its FDA's Operational and Administrative System for Import Support (OASIS), 2018.

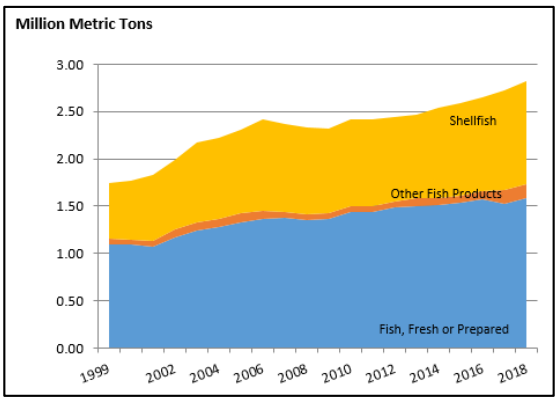
Notes: All products offered for entry into the United State must be declared to the U.S. Customs and Border Protection, including commercial shipments (or imported goods brought into U.S. commerce for sale or distribution) and items for personal use.

Figure 5. Volume of U.S. Food Imports, by Food Group



Source: CRS from USDA U.S. Food Imports data (fiscal year, most recent available data), https://www.ers.usda.gov/data-products/us-food-imports/. Excludes some product groups, including live meat animals and beverages.

Figure 6. Volume of Trade, Selected Fish and Shellfish Products



Source: CRS from USDA Global Agricultural Trade System, calendar year data, https://apps.fas.usda.gov/gats/default.aspx.

Food Imports as a Share of U.S. Consumption

Available data reported by USDA indicate that imports account for a growing portion of American diets and the U.S. food supply. **Table 3** and **Table 4** show two sets of USDA estimates of import shares based, respectively, on the volume of food consumed and the value of food products. Regardless of the measure, imported foods account for an average of about one-fifth of all foods consumed or marketed in the United States each year. There are notable differences, however, between these two USDA datasets and estimates for individual food products.

Table 3 shows import shares based on the volume of foods consumed from a discontinued USDA dataset that last reported estimates through 2013.[6] For 2016-2017, estimates shown are calculated using other limited available USDA data.[7] Based on the volume of food consumed, available USDA estimates of import shares are calculated based on the *commercial disappearance* of a food product, as measured by total production adjusted for changes in beginning and ending stocks and changes in trade (exports and imports). Estimates of import share vary widely depending on the type of food. Import shares are greater for fish and seafood,[8] tropical products[9] (imports account for more than 90% of food consumed by volume), spices (nearly 90%), tree nuts (more than 30%), fruit juices (more than 50%), and fresh fruits and vegetables (more than 20%). Import shares are lower for dairy (about 3% of all dairy products consumed) and meat (between 5% and 10%, depending on whether beef or poultry products). Compared to the 1990s, imports as a share of U.S. food consumption have risen sharply for most food and agricultural products.

[6] For more information, for example, see A. Jerardo, *The Import Share of U.S.-Consumed Food Continues to Rise*, FAU-66-01, Economic Research Service (ERS), July 2002.

[7] Calculated by CRS using ERS's Food Availability (Per Capita) Data System, available at http://www.ers.usda.gov/topics/international-markets-trade/us-agricultural-trade/import-share-of-consumption.aspx.

[8] Other estimates by the National Oceanic and Atmospheric Administration (NOAA) report that imported seafood as a share of consumption was 94% in 2018. See NOAA, *Fisheries of the United States 2018*, Current Fishery Statistics No. 2018, p. 116, https://www.fisheries.noaa.gov/resource/document/fisheries-united-states-2018-report. NOAA says its existing model overestimates this percentage and that the agency is investigating improvements.

[9] Includes coffee, cocoa, and tea—products not widely grown in the United States.

Table 3. Imports as a Share of Consumption Based on Volume of Foods Consumed

Product Category	1990	2000	2005	2012	2013	2016	2017
	(percentage based on estimated commercial disappearance)						
Total Consumed Food	**12.1**	**14.2**	**17.1**	**18.3**	**19.1**	**N/A**	**N/A**
Beef	9.8	11.1	13.0	8.7	8.9	11.4	11.0
Pork	5.6	5.2	5.4	4.4	4.7	5.1	5.2
Poultry and eggs	0.0	0.1	0.1	0.4	0.4	0.4	0.4
Dairy products	1.9	2.7	4.2	2.2	2.1	3.2	2.7
Fish and shellfish	56.3	68.3	84.3	87.8	96.2	96.3	91.7
Grains	10.1	14.4	13.2	12.5	15.5	NA	NA
Rice, milled	8.6	13.7	21.1	26.4	27.5	NA	NA
Sugar, cane and beet	32.1	16.6	21.5	30.6	28.8	21.8	20.2
Spices	77.7	84.7	87.7	88.8	86.3	NA	NA
Tropical products	99.8	99.2	102.0	97.5	96.4	NA	NA
All fresh fruits	34.9	20.5	21.5	24.5	24.1	NA	NA
All fruit juices	37.9	31.1	40.6	48.1	55.6	NA	NA
All tree nuts	31.5	39.9	54.5	39.2	44.7	31.4	34.0
All fresh vegetables	8.6	11.2	14.9	20.8	22.0	NA	NA

Source: 1990-2013 (USDA/ERS, discontinued dataset); 2016-2017 calculated by CRS using available limited data from ERS as part of its Food Availability Data System (http://www.ers.usda.gov/topics/international-markets-trade/us-agricultural-trade/import-share-of-consumption.aspx). *Commercial disappearance* is estimated based on production and changes in stocks and trade (imports and exports). Tropical products include coffee, cocoa, tea, and spices. More recent data are not available.

Table 4 shows USDA estimates based on the value of food products, both imported and domestically produced.[10] Based on product value, available USDA estimates are measured from the combined value of both imported and domestically produced foods. As such, these estimates may be influenced by differences in relative prices between imported and domestic products. Price differences may skew import shares lower in the case of lower-cost raw commodity imports; alternatively, price differences may result in higher import shares in the case of higher priced value-added processed foods. Among processed (manufactured) food products, grain and oilseed milling products and sugar and confections are among the highest share imported products (based on value). Sweeteners (sugarcane, sugar beets, honey), vegetables and melons, and fruits and tree nuts are the highest share products of raw (nonmanufactured) goods. Compared to 2008, these data show mostly slight increases in import shares over time.

Compared to import shares based on the volume of foods consumed, estimates shown in **Table 4** often differ significantly from estimates shown in **Table 3**. For example, based on the volume of food consumed, import shares for dairy products are estimated at 3%, and import shares for meat products are estimated to range from 5% to 10%. In contrast, based on value, import shares are much higher for these products, estimated at 9% to 11% for dairy products and 18% to 22% for meat products. Estimates of import shares based on value are not available for fish and seafood products. These discrepancies, along with the likelihood that differences in relative prices might

[10] Available at https://www.ers.usda.gov/topics/international-markets-us-trade/us-agricultural-trade/data/.

influence differences in these estimates, raise questions about the potential usefulness of USDA's estimates based on import value for tracking imports as a share of the U.S. market.

Table 4. Imports as a Share of Consumption Based on Product Value

Product Category	2008	2010	2012	2013	2014	2015	2016
	(percentage based on value)						
Total Food and Beverages	**12.0**	**11.8**	**13.0**	**13.1**	**13.5**	**14.6**	**14.8**
Grain/oilseed milling products	31.7	31.3	43.3	48.9	54.6	47.3	45.2
Sugar and confections	31.6	33.7	37.3	36.2	37.1	36.0	36.2
Preserved fruit and vegetables	24.4	22.5	25.5	24.9	26.1	25.7	26.5
Dairy products	9.7	6.8	9.1	9.9	11.1	10.1	9.0
Meat products	14.4	13.8	18.8	18.4	21.0	21.8	18.0
Bakery products	8.2	8.5	10.4	10.4	10.4	10.7	11.4
Beverages	12.7	13.6	22.2	19.1	18.1	17.3	16.0
Food grains	28.3	18.4	14.6	29.0	22.1	24.1	21.9
Feed grains	2.0	1.0	1.6	2.3	1.6	1.9	1.7
Oilseeds	7.2	3.4	4.2	5.3	9.8	6.4	4.2
Fresh vegetables and melons	26.0	29.1	31.2	31.7	32.8	31.7	36.1
Fresh fruits and tree nuts	35.9	37.2	34.8	36.3	39.6	44.5	45.3
Sweeteners	38.4	45.0	44.1	38.9	45.8	46.9	44.5
Livestock	3.6	2.9	2.6	2.5	2.9	2.9	2.8

Source: USDA/ERS; U.S. Department of Commerce (available at https://www.ers.usda.gov/topics/international-markets-us-trade/us-agricultural-trade/data/). More recent data are not available.

Federal Food Safety Agencies and Authorities

Numerous federal, state, and local agencies share responsibilities for regulating the safety of the U.S. food supply, including imported foods.[11] Federal responsibility for food safety rests primarily with FDA and USDA. FDA is responsible for ensuring the safety of all domestic and imported food products (except for most meats and poultry). FSIS regulates most meat and poultry and egg products and catfish. For imported foods, FDA and FSIS rely on different regulatory systems, including how each agency determines whether foreign food suppliers have safety systems and standards comparable to those in the United States (see **text box**).

The **Appendix** describes the role of other federal agencies in ensuring the safety of imported food and agricultural products. For example, USDA's Animal and Plant Health Inspection Service (APHIS) is responsible for protecting plant and animal resources from domestic and foreign pests and diseases. The Department of Homeland Security (DHS) is responsible for coordinating agencies' food security activities, including border inspections by DHS's U.S. Customs and Border Protection (CBP). Other federal agencies—such as USDA's Agricultural Marketing Service (AMS) and the National Marine Fisheries Service at the National Oceanic and

[11] For more background information, see CRS Report RS22600, *The Federal Food Safety System: A Primer*.

Atmospheric Administration (NOAA)—are involved in various food quality and inspection programs.[12]

FDA Systems Recognition Assessment Versus FSIS Equivalence Determination

Globally, there is substantial variation in the robustness of food safety systems, according to FDA, ranging from systems in the early stages of development to highly mature food safety systems. This variability presents a challenge to U.S. food safety regulators at both FDA and FSIS providing assurances of the safety of food and feed imported to the United States from foreign countries.

Statutory and regulatory differences governing FDA and FSIS, along with differences in the types of products and scale of imports shipped to the United States under each agency's jurisdiction, has resulted in two distinctly different approaches between FDA and FSIS when assessing the safety of imported food and feed.

FDA Systems Recognition Assessment

Following enactment of the FDA Food Safety Modernization Act (FSMA), FDA considered a range of approaches for assessing the safety of imported foods obtained from recognized food systems or countries with an equivalent system to that in the United States. FDA's *systems recognition assessment* refers to the process used by the agency to assess the capability of foreign food safety systems to help ensure the safety of foods produced under the oversight of that country's food safety authority/authorities. This process also provides a means for FDA to establish closer regulatory partnerships and leverage work conducted by FDA and foreign food safety authorities. As part of this process, FDA relies on information obtained from facility registrations, border examinations, foreign facility inspections, and import certificates, among other information.

For more information, see FDA, "Frequently Asked Questions on Systems Recognition for Foreign Governments," https://www.fda.gov/food/international-interagency-coordination/frequently-asked-questions-systems-recognition-foreign-governments.

FSIS Equivalence Determination

At FSIS, *equivalence* refers to the process of determining whether a country's food safety inspection system achieves an FSIS-appropriate level of public health protection as applied domestically in the United States and provides "standards equivalent to the FSIS to ensure other non-food safety requirements (such as humane handling, accurate labeling, and assurance that meat, poultry, or egg products are not economically adulterated) are met." The country is not required to develop and implement the same procedures as those in the United States, but rather the country must objectively demonstrate how its procedures meet U.S. levels of protection. Countries wishing to become eligible to export meat, poultry, or egg products to the United States must demonstrate that they have a regulatory food safety inspection system that is equivalent to that of the United States.

For more information, see FSIS, "Equivalence Process Overview," https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/Equivalence/equivalence-process-overview.

Both of these approaches comply with U.S. international commitments and obligations under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures, under which countries may adopt and enforce public health and safety measures "necessary to protect human, animal or plant life or health," so long as such measures are not applied in an arbitrary or discriminatory manner.

The following focuses on the role of federal agencies only and does not discuss the role of state and local authorities, which reportedly account for as much as 90% of all the food inspections in the United States through their routine sampling, inspection, and food testing work.[13]

[12] Guidance and information for importers and foreign suppliers who wish to ship food products into the United States is available from FDA (https://www.fda.gov/food/food-imports-exports/importing-food-products-united-states), FSIS (https://www.usda.gov/topics/trade/importing-goods; https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products), APHIS (https://www.aphis.usda.gov/aphis/ourfocus/importexport), and CBP (https://help.cbp.gov/s/article/Article-83?language=en_US). The Automated Commercial Environment is the "single window" electronic system that went into effect in 2016, per Executive Order 13659, Streamlining the Export/Import Process for America's Businesses (79 *Federal Register* 4263, January 24, 2014).

[13] *Food Chemical News*, "FSVP to Change Not Only FDA, but States' Role in Regulating Imports," June 23, 2017.

Food and Drug Administration

FDA's food regulatory authority comes chiefly from the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended (21 U.S.C. §301 et seq.). FFDCA requires, among other things, that all domestic and foreign food manufacturing facilities adhere to FDA's requirements for Current Good Manufacturing Practices (CGMPs)[14] and prohibits the adulteration and misbranding of food.[15] The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act, P.L. 107-188) amended FFDCA to require that all domestic and foreign food facilities register with FDA. The Bioterrorism Act also imposed prior notification requirements for FDA-regulated imported foods, as well as requirements for maintenance and submission of records sufficient to identify the immediate supplier and subsequent recipient of these products.[16]

Congress further amended the FFDCA in 2010 by passing a comprehensive food safety law, the FDA Food Safety Modernization Act (FSMA, P.L. 111-353), which gave FDA new tools and authorities to ensure imported food and feed meet the same safety standards as food and feed produced in the United States.[17] For example, FSMA amended the FFDCA to require that all high-risk domestic facilities be inspected within five years of the law's enactment and at least once every three years after that.[18] FSMA also authorized FDA to suspend food facility registrations if there is reasonable probability of the food causing illness or death to humans or animals.[19] Pursuant to FSMA, FDA implemented regulations covering all domestic and foreign food manufacturing facilities, as well as certain farming operations. FSMA Title III specifically addressed imported foods, tightening general inspection and administrative requirements regarding imports. FSMA's import provisions are described in more detail in the sections below.

More than 300,000 domestic and foreign food facilities are registered with FDA.[20] Of the total number of registered FDA-regulated facilities, about 88,000 are U.S.-based facilities and another 212,000 are foreign facilities that are potentially subject to FDA inspection and reporting requirements.[21]

Table 5 provides a summary of available data regarding FDA-regulated imported food and feed for selected years from FY2010 through FY2018.

Of the more than 212,000 foreign food facilities that are potentially subject to FDA inspection and reporting requirements, more than 15% are located in the European Union.[22] Japan is the single country with the most number of foreign facilities registered to ship food products into the United States, with close to 7% of registered facilities. Another 5% of registered foreign facilities

[14] 21 C.F.R. Part 110. Exempt are establishments such as farms engaged solely in harvesting, storing, or distributing raw agricultural commodities normally cleaned or otherwise treated before consumption.

[15] 21 U.S.C. §§301(a)-(c), 342, & 343.

[16] 21 U.S.C. §350d and 21 U.S.C. §381(m). Regulations are at Title 21, Part 1, Subpart I, of the *Code of Federal Regulations*. FSMA further expanded prior notice requirements for food imports (FSMA §304).

[17] FSMA further applies to ingredient suppliers of dietary supplements. FFDCA Section 201(ff) (21 U.S.C. §321(ff)) states that dietary supplements are deemed to be foods, aside from a few exceptions.

[18] 21 U.S.C. §350j(a)(2).

[19] 21 U.S.C. §350d(b).

[20] FDA, "Registration Statistics" (as of February 2016), http://www.fda.gov/food/guidanceregulation/foodfacilityregistration/ucm236512.htm. More recent data are not available.

[21] In 2012, FDA's registration renewal removed foreign facilities that had ceased operations, even though their registration had remained in FDA's system. This resulted in substantial changes in the reported data over the period. (Based on CRS communication with FDA, September 5, 2014.)

[22] FDA, "Registration Statistics," http://www.fda.gov/food/guidanceregulation/foodfacilityregistration/ucm236512.htm.

are located in China, with another 6% of facilities located in other Asian nations, including South Korea, India, Taiwan, Vietnam, and Thailand. Nearly 8% are located in Mexico and Canada.

FDA has 13 foreign offices intended to enable FDA staff and U.S. border officials to make informed decisions about products entering the United States. Foreign offices are located in China (posts in Beijing, Shanghai, and Guangzhou); India (posts in New Delhi and Mumbai); Latin America (posts in San Jose, Costa Rica; Santiago, Chile; and Mexico City, Mexico); Europe (posts in Brussels, Belgium; London, UK; and Parma, Italy); South Africa (Pretoria); and Jordan (Amman).[23] Decisions to establish a foreign post are based on the volume of imported products and the magnitude of problems associated with imported products, among other factors. FDA in-country activities include conducting foreign inspections, assisting foreign governments and industry to understand FDA standards and requirements, and obtaining information about products destined for the United States.[24]

Table 5. FDA Food Safety Inspections of Imported Foods, FY2010-FY2018

	FY2010	FY2012	FY2014	FY2015	FY2016	FY2017	FY2018	FY2019
FDA-Regulated Foreign Facilities	254,088	285,977	NA	212,183	NA	NA	NA	NA
Foreign Inspections	354	1,347	1,339	1,357	1,269	1,548	1,638	1,747
Import Physical Exam Subtotal	200,766	201,749	207,764	266,932	276,502	252,903	206,656	159,675
Import Field Exams/Tests	170,392	171,783	183,224	245,804	252,766	229,129	185,761	141,905
Import Lab Samples Analyzed	30,374	29,966	24,540	21,128	23,736	23,774	20,895	17,770
Import Line Decisions (million)	9.7	10.8	12.2	13.1	14.0	15.3	16.9	17.7
% Lines Physically Examined	2.06%	1.87%	1.71%	2.04%	1.98%	1.66%	1.23%	0.9%
Prior Notice Reviews	81,618	81,888	82,821	80,990	87,817	81,035	84,113	80,013
FDA Import (Line) Refusals	17,080	16,386	15,709	15,223	NA	NA	NA	NA
% Refusals (Total Import Decisions)	0.18%	0.15%	0.13%	0.12%	NA	NA	NA	NA

Source: CRS from various sources. The number of FDA-regulated facilities is from FDA, "Registration Statistics," http://www.fda.gov/food/guidanceregulation/foodfacilityregistration/ucm236512.htm. Inspections data are from FDA Congressional Justifications (https://www.fda.gov/about-fda/reports/budgets) and updates data for FY2010-FY2012 reported in FDA, *Annual Report on Food Facilities, Food Imports, and FDA Foreign Offices*. FDA import refusals are from J. Bovay, *FDA Refusals of Imported Food Products by Country and Category, 2005-2013*, March 2016. Most recent reported available data on the number of FDA-regulated facilities is for February 2016.

Notes: *Import lines* refers to separate product lines on an entry document of FDA-regulated foods. *Prior notice* refers to notification to the FDA that an article of food, including food for animals, is being imported or offered for import into the United States in advance of the arrival of the article of food at the U.S. border. In 2012, FDA's registration renewal removed foreign facilities that had ceased operations, even though their registration had remained in FDA's system, resulting in a decrease in the number of registered foreign facilities.

FSMA Provisions Addressing Imports

Concerns about low FDA inspection rates of imported foods and available federal resources to ensure the safety of these imports were widely highlighted during the debate leading up to

[23] FSMA provided the authority for FDA to establish foreign offices related to food and feed (P.L. 111-353, §308). FDA had requested permission to establish an additional post in Brazil but currently has no plans for additional posts.

[24] For more information, see FDA, *2012 Report to Congress on the FDA Foreign Offices*, February 2012, https://www.fda.gov/food/food-safety-modernization-act-fsma/2012-report-congress-fda-foreign-offices.

Congress' enactment of FSMA. The Government Accountability Office (GAO) conducted a number of studies critical of FDA's food safety oversight of both domestic and imported foods.[25] Regarding imported foods, GAO noted FDA's limited authority to ensure that food imports meet the same food safety requirements as those for domestically produced foods. GAO also noted FDA's limited authority to take certain enforcement actions as well as a number of resource gaps involving border inspections of imported foods and that federal law provided limited authority for FDA to inspect foreign facilities. FDA only periodically visited foreign facilities to inspect their operations, usually in response to a concern and only with the permission of the foreign government.[26] Widely cited estimates indicated that FDA inspected about 1% of the food imported under its jurisdiction.[27] Among the cited reasons for this low incidence in inspections were limited resources, including too few inspectors covering U.S. ports of entry in the face of ever-increasing import volumes.[28] Moreover, import requirements were mostly voluntary, according to FDA's draft guidance on Good Importer Practices. A 2011 report by FDA's Office of the Inspector General further indicated that the agency's guidance for handling recalls of imported foods prior to FSMA "was not adequate to ensure the safety of the nation's food supply because it was not enforceable" and that the recall process did not always operate efficiently and effectively.[29] (For other related background, see "Food Safety Concerns Involving Imports.")

FSMA was enacted to address these types of concerns and limitations. Leading authorities and mandates involving imported food and feed under FSMA include the following:[30]

- **Importer Accountability and Verification:** Established that food importers have an explicit responsibility to verify that their foreign suppliers have adequate preventive controls in place to ensure that food for human and animal consumption meets applicable FDA safety standards.
- **Third-Party Certification:** Provided that qualified third parties can certify that foreign food facilities comply with U.S. food safety standards. This certification may be used to facilitate the entry of imports.
- **Certification for High Risk Foods:** Authorized FDA to require that high-risk imported foods be accompanied by a credible third-party certification or other assurance of compliance as a condition of entry into the United States.

[25] See, for example, GAO, *FDA Has Provided Few Details on the Resources and Strategies Needed to Implement Its Food Protection Plan* (GAO-08-909T; June 2008); *Food Safety: Selected Countries' Systems Can Offer Insights into Ensuring Import Safety and Responding to Foodborne Illness* (GAO-08-794; June 10, 2008); *Food Safety: FDA Could Strengthen Oversight of Imported Food by Improving Enforcement and Seeking Additional Authorities* (GAO-10-699T; May 6, 2010); *Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food* (GAO-09-873; September 15, 2009); and GAO, *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable* (RCED-98-103; April 1998).

[26] For example, in 2010, FDA conducted 354 inspections of foreign facilities. This compares to 1,747 foreign facility inspections in FY2019. See **Table 5**.

[27] GAO, *Fundamental Changes Needed to Ensure Safe Food*, GAO-02-47T, October 10, 2001.

[28] See, for example, testimony of Caroline Smith DeWaal, Center for Science in the Public Interest, before the House Energy and Commerce Committee's Subcommittee on Oversight and Investigations, July 17, 2007, and testimony of Jean Halloran, Consumers Union, before the House Committee on Ways and Means, October 4, 2007.

[29] FDA, Office of the Inspector General, *Review of the Food and Drug Administration's Monitoring of Imported Food Recalls*, A-01-09-01500, June 2011. The review examined recalls of imported foods from July 2007 to June 2008.

[30] See, for example, FDA, "Background on the FDA Food Safety Modernization Act," *FSMA Facts*, July 2011.

- **Authority to Deny Entry:** Authorized FDA to refuse entry into the United States of food from a foreign facility if FDA is denied access by the facility or entry to the country in which the facility is located.

Aside from provisions that address imported food in FSMA's Title III, other requirements apply to imported foods and feed. These include mandatory preventive controls for food facilities and on-farm production standards under FDA's Produce Safety Rule that apply to both imported and domestically produced fruits and vegetables.[31] The **text box** provides a summary of FSMA's provisions related to FDA-regulated food and feed imports. The section that follows discusses selected topics related to imports.

FSMA's import provisions have been described as a "paradigm" shift for foreign suppliers with the potential to impact global food trade.[32] Since enactment, FSMA has resulted in the implementation of a series of regulations and reporting requirements for foreign countries, U.S. importers, and FDA. FSMA placed tighter controls on food imports, set minimum entry requirements, required certification of imported foods, raised importer accountability, and placed more responsibility on U.S. trading partners. Some stakeholders have expressed resistance to FDA's rulemaking requirements.[33]

FSMA created the Foreign Supplier Verification Program (FSVP) for importers to verify that foreign suppliers of food for human and animal consumption provide the same level of food safety standards and public health protection as required of U.S. companies. Under FSVP, importers are responsible for developing and maintaining a food safety plan and for conducting supplier verification activities, as well as implementing corrective actions and maintaining records. The appropriate verification activities and their frequency vary depending on the food, the foreign supplier, and the types of control actions. Hazards in a food will be controlled if there is a reasonable probability that exposure to the hazard will result in "serious adverse health consequences or death to humans or animals," which may result in an annual onsite audit of the foreign supplier.[34] Verification activities include onsite auditing, sampling and testing of a food, review of the foreign supplier's relevant food safety records, and other activities based on the evaluation of the risk posed by the food and foreign supplier performance. FDA is able to audit an importer's food safety plan and can stop imported food from entering the United States if the plan and/or its implementation is determined to be inadequate. FDA estimates that FSVP will result in total average annual costs of $435 million.

FSMA also established the Voluntary Qualified Importer Program (VQIP), a voluntary, fee-based program for the expedited review and importation of foods from importers who achieve and maintain a high level of control over the safety and security of their supply chains. By allowing expedited review to some foreign suppliers, VQIP may help FDA manage the sheer volume of

[31] See FDA, https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-produce-safety. The National Association of State Departments of Agriculture (NASDA) has also emphasized the need to ensure appropriate food import activities as part of FDA's Produce Safety Rule and the need to develop national and regional information sharing networks and processes on producer audits and inspections, recalls, import alerts, and other procedures. See NASDA, "Model Produce Safety Implementation Framework" February 22, 2019, https://s3.amazonaws.com/nasda2/media/NASDA-Model-Produce-Safety-Implementation-Framework_2-22-2019.pdf?mtime=20190906154302.

[32] Comments from Michael Taylor, former FDA Deputy Commissioner for Foods, February 17, 2011. See also B. L. Booren, "The Relatively Unknown FSMA Rule," OFWLAW.com blog, April 27, 2017.

[33] See, for example, H. Bottemiller, "FDA Releases Two Major Rules to Boost Oversight of Imported Foods," Food Safety News, July 26, 2013. See also postings from FDAImports.com blog posts available at https://www.fdaimports.com/blog/category/food-safety-modernization-act-2/.

[34] 80 *Federal Register* 74226-74351, November 27, 2015.

food imported to the United States each year and free up agency resources to better focus on high-risk imports. FSMA further required that FDA increase the number of inspections of foreign facilities it undertakes and established programs for building technical, scientific, and regulatory food safety capacity in foreign countries.

FSMA Provisions Relating to FDA-Regulated Imported Food and Feed

- **Section 103 (Hazard Analysis and Risk-Based Preventive Controls):** Established mandatory preventive controls for domestic and foreign food facilities (21 U.S.C. §350g).
- **Section 105 (Standards for produce safety):** Established mandatory science-based, minimum standards for the safe production and harvesting of fruits and vegetables. Requirements apply to both domestic and foreign operations (21 U.S.C. §350h).
- **Section 202 (Laboratory accreditation for analyses of food):** Established a program for the testing of food by accredited laboratories and for FDA to submit a progress report on its implementation of a national food emergency response laboratory network (21 U.S.C. §350k).
- **Section 301 (Foreign Supplier Verification Program):** Established a foreign supplier verification program (FSVP) for importers to share responsibility for ensuring safety of imported foods according to types of hazards, importers, and suppliers (21 U.S.C. §384a). Under FSVP, food importers are required to develop and maintain systems for verifying that their foreign suppliers are manufacturing or growing food in a manner that provides the same level of public health protection as required of U.S. companies.
- **Section 302 (Voluntary Qualified Importer Program):** Established a Voluntary Qualified Importer Program (VQIP) to expedite review and importation of foods from participating importers. Eligibility is limited to, among other things, importers offering food from certified facilities (21 U.S.C. §384b).
- **Section 303 (Authority to require import certifications for food):** Authorized FDA to require that high-risk imported foods be accompanied by a credible third-party certification or other assurance of compliance as a condition of entry into the United States (21 U.S.C. §384c).
- **Section 304 (Prior notice of imported food shipments):** Established requirements for submitting prior notice of imported food, including food for animals (21 U.S.C. §381).
- **Section 305 (Building capacity of foreign governments with respect to food safety):** Required HHS to develop a comprehensive plan to expand the technical, scientific, and regulatory food safety capacity of foreign governments and their food industries that export foods to the United States.
- **Section 306 (Inspection of foreign food facilities):** Authorized FDA to enter into agreements with foreign governments to facilitate inspections of registered foreign facilities and to direct resources to inspections of foreign facilities, suppliers, and higher risk foods (21 U.S.C. §384c).
- **Section 307 (Accreditation of third-party auditors):** Required HHS to develop model standards and recognized accreditation bodies to ensure that third-party auditors and audit agents meet such standards to qualify third-party auditors as accredited auditors (21 U.S.C. §384d).
- **Section 308 (Foreign FDA offices):** Required HHS to submit a report to Congress regarding the selection of the foreign countries for established FDA offices.
- **Section 309 (Smuggled food):** Required HHS, coordinating with DHS, to develop and implement a strategy to identify smuggled food and prevent its entry into the United States.

Information on the requirements and implementation status of FDA's FSMA rules and guidance for industry is available at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-rules-guidance-industry. For other background, see CRS Report R43724, *Implementation of the FDA Food Safety Modernization Act (FSMA, P.L. 111-353)*.

As of 2020, FDA has mostly completed implementation of many of the requirements under FSMA pertaining to food and feed imports. FDA's prior notice requirements became effective May 30, 2013.[35] FSVP regulations were finalized in 2016, and the first compliance dates began in

[35] 78 *Federal Register* 32359-32362, May 30, 2013 (Docket Folder FDA-2011-N-0179); 21 C.F.R. 1. See also FDA, "Guidance for Industry: Prior Notice of Imported Food Questions and Answers," Edition 3, June 2016,

May 2017.[36] FDA regulations providing for accreditation of third-party certification bodies to conduct food safety audits of foreign food entities (including registered foreign food facilities) and to issue food and facility certifications were also finalized in 2015 and became effective in January 2016.[37] FDA's VQIP guidance was finalized in February 2020.[38]

FSMA regulations affecting foreign suppliers as well as domestic producers and manufacturers—including preventive controls for food and feed facilities, producer standards for growers, and protections against intentional adulteration, among other requirements—have been mostly implemented. Information on the specific requirements and current implementation status of FSMA rules and guidance for industry is available at FDA's website.[39]

FDA's 2019 *Strategy for the Safety of Imported Food* outlines the agency's approach to ensuring the safety of food imported into the United States. The strategy focuses on four goals: (1) ensuring that imports meet U.S. food safety requirements, (2) ensuring that border surveillance prevents entry of unsafe foods, (3) maintaining a rapid and effective response to unsafe imported food, and (4) maintaining an "effective and efficient" food import program.[40] According to FDA, ensuring that imported food is as safe as that produced domestically requires foreign facility inspections, cooperation with international regulatory counterparts through facility systems recognition, food safety partnerships, and screening and examination (and sampling) at the port of entry.[41]

FDA Foreign Facility Inspections

FSMA required that FDA inspect at least 600 foreign food facilities in 2011, doubling each year for the next five years.[42] Two possible responses to what this mandate required have been put forward. One assumes 600 facility inspections in the base year (FY2011) with the number of inspections doubling each year, rising to 19,200 inspections in the fifth year (FY2016).[43] Some view this goal as unrealistic.[44] An alternative response, as noted by GAO, has FDA inspecting

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https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-prior-notice-imported-food-questions-and-answers-edition-3.

[36] 80 *Federal Register* 74225-74352, January 26, 2016 (Docket Folder FDA-2011-N-0143); 21 C.F.R. 1, 11, and 111. See also FDA's fact sheet at https://www.fda.gov/media/94746/download.

[37] 80 *Federal Register* 74569-74667, November 27, 2015 (Docket Folder FDA-2011-N-0146); 21 C.F.R. 1, 11, and 16. See also FDA's fact sheet at https://www.fda.gov/media/94753/download.

[38] *Guidance for Industry: FDA's Voluntary Qualified Importer Program* (Docket Number: FDA-2011-N-0144, February 2020). See also FDA's fact sheet at https://www.fda.gov/food/food-safety-modernization-act-fsma/fact-sheet-final-guidance-industry-fdas-voluntary-qualified-importer-program.

[39] See FDA's website at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-rules-guidance-industry.

[40] FDA, *Strategy for the Safety of Imported Food*, February 2019, https://www.fda.gov/food/importing-food-products-united-states/fda-strategy-safety-imported-food. FDA's previous strategy for improving the quality of imports more broadly focused on developing partnerships with regulatory counterparts, developing international information systems, increasing data collection and risk-based analysis, and using qualified public and private third-party audits to certify that food facilities comply with U.S. requirements (FDA, *Pathway to Global Product Safety and Quality*, June 2011).

[41] See, for example, statement by former FDA Commissioner Scott Gottlieb, in a letter to State Agriculture Commissioners, Secretaries, and Directors, July 31, 2018, https://www.fda.gov/media/114883/download.

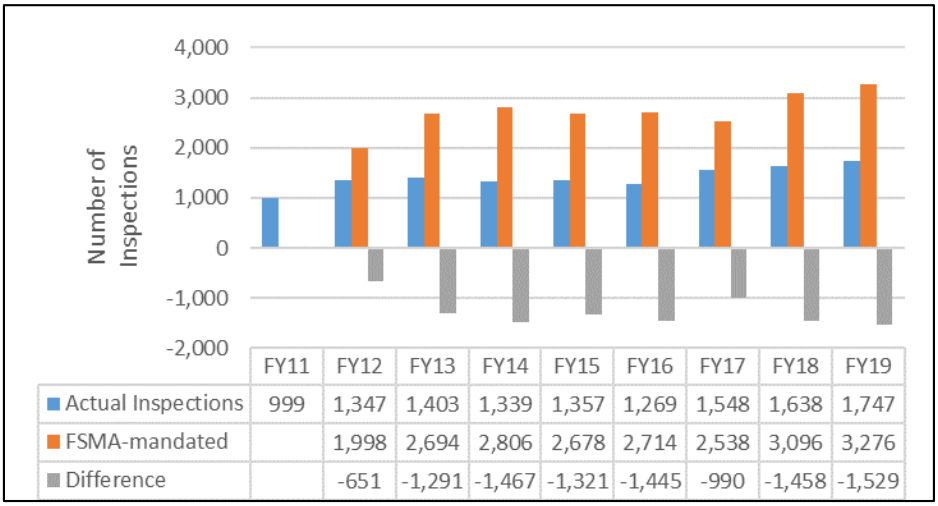
[42] FSMA, P.L. 111-353, §201. FDA is also required to identify high-risk facilities.

[43] This assumes 600 facility inspections in the base year (FY2011); there would have been 1,200 inspections in year 1 (FY2012), 2,400 in year 2 (FY2013), 4,800 in year 3 (FY2014), 9,600 in year 4 (FY2015) and 19,200 in year 5 (FY2016).

[44] See, for example, GAO, *Additional Actions Needed to Help FDA's Foreign Offices Ensure Safety of Imported Food*, GAO-15-183, February 27, 2015; and C. Smith DeWaal, "FSMA: Import Rules May Foster Global Food Safety," *Food*

twice the actual (or planned) number of foreign food facilities compared with the previous year, starting with the roughly 1,000 inspections FDA completed in 2011, reaching a target of at least twice as many inspections—about 2,000—in 2012 as FDA actually inspected in 2011 and continuing to double the previous year's actual inspections through 2016.[45] Updated estimates based on FDA-reported actual inspections data and assuming the approach reported in GAO's 2015 report are shown in **Figure 7**, indicating that FDA's annual inspections of foreign food establishments have not kept pace with targets set by Congress in FSMA. In FY2019, FDA conducted 1,747 foreign facility inspections, compared to nearly 3,300 facility inspections that would have been expected under FSMA under the GAO approach. More than 212,000 foreign facilities are registered with FDA and are potentially subject to FDA inspection.

Figure 7. Actual versus FSMA-Mandated Inspections of Foreign Food Facilities



	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19
Actual Inspections	999	1,347	1,403	1,339	1,357	1,269	1,548	1,638	1,747
FSMA-mandated		1,998	2,694	2,806	2,678	2,714	2,538	3,096	3,276
Difference		-651	-1,291	-1,467	-1,321	-1,445	-990	-1,458	-1,529

Source: CRS, updating data and approach reported in GAO, *Additional Actions Needed to Help FDA's Foreign Offices Ensure Safety of Imported Food*, GAO-15-183, February 27, 2015.

Notes: Assumes FSMA mandated targets indicate a doubling for FY2012 to 1,998 foreign facility inspections (from 999 actual inspections in FY2011) and again doubling from FY2012 actual inspections (1,347) to a target of 2,694 inspections for FY2013, and so on.

Compared to the number of foreign facility inspections prior to FSMA, however, the number of inspections in the wake of FSMA has been higher. Available data indicate that FDA conducted 1,034 inspections of foreign food firms over the seven-year period from FY2001 to FY2007.[46] In FY2010, FDA conducted 354 inspections of foreign facilities, which compares to 1,747 foreign facility inspections in FY2019 (**Table 5**).

Safety News, February 14, 2011.

[45] See also GAO, *Additional Actions Needed*. Numbers shown here are updated from those cited in GAO's report.

[46] GAO, *FDA Has Provided Few Details on the Resources and Strategies Needed to Implement its Food Protection Plan*, GAO-08-909T, Appendix I, June 2008. Individual annual totals were 211 (2001), 169 (2002), 148 (2003), 153 (2004), 132 (2005), 125 (2006), and 96 (2007).

FSMA also required that FDA increase the number of food safety inspectors within the agency and stated a goal of not fewer than 5,000 staff members by FY2014.[47] In FY2019, FDA reports total actual staffing levels at 3,905 full-time equivalents.[48]

FDA has continued to experience recruitment challenges in its foreign offices, and inspections by country may vary. The most recent available data indicate that FDA food facility inspections in China and India accounted for about one-fifth of all foreign facility inspections.[49] Most recent available data indicate that the average cost of a foreign high-risk food facility inspection is $23,600 per inspection, according to FDA.[50]

The cost of recruiting, training, and retaining inspectors, as well as the cost of conducting the actual inspection of registered facilities (along with continued monitoring and auditing of registered facilities), represents a resource challenge for both oversight agencies and policymakers. GAO reports that, according to FDA officials, the cost of inspections is the main reason that the agency is not keeping pace with the FSMA mandate for foreign food facility inspections.[51] GAO has recommended that FDA revise its approach for assessing the comparability of a country's food safety system to one that includes assessing foreign food safety systems for particular food products and not just a country's food safety systems as a whole.[52] A 2020 report by the National Academies of Sciences, Engineering, and Medicine (NASEM) further describes strategies to address safety challenges in low- and middle-income countries.[53]

FDA's Center for Food Safety and Applied Nutrition (CFSAN) has issued a number of warning letters to foreign facilities that export food to the United States. FDA general warning letters notify a manufacturer when it has significantly violated FDA regulations, usually by identifying the violation and making clear that the company must correct the problem.[54] In 2019, CFSAN issued nearly 60 warning letters, of which about one-third were issued to foreign facilities, mostly regarding imported fish and seafood.

Another tracking measure is FDA's documentation during inspections conducted by agency staff and its representatives (so-called *Form 438*s).[55] Under FSMA, food importers are required to develop and maintain FSVPs for their foreign suppliers. However, according to FDA reports on FY2019 data based on the number of *Form 438*s issued, failing to develop an FSVP is the most commonly cited violation during a FDA food facility inspection (accounting for about two-thirds of the nearly 440 issued forms).[56] Other FSVP-related violations include failing to follow or

[47] FSMA, P.L. 111-353, §401. By fiscal year, staff level increases were authorized to a total of not fewer than 4,000 staff members (FY2011); 4,200 staff (FY2012); 4,600 staff (FY2013); and 5,000 staff (FY2014).

[48] FDA, *FDA Justification if Estimates for Appropriations Committees*, FY2021, p. 43.

[49] GAO, *Additional Actions Needed*, Figure 3.

[50] FDA, *Annual Report on Food Facilities, Food Imports, and FDA Foreign Offices*, November 2013 https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-reports-studies. Most recent data available.

[51] GAO, *Additional Actions Needed*.

[52] GAO, *FDA Can Better Oversee Food Imports by Assessing and Leveraging Other Countries' Oversight Resources*, GAO-12-933, September 28, 2012. Among its recommendations, GAO suggests that FDA's comparability assessments adopt certain equivalence measures used by FSIS regarding imported meat and poultry, as well as measures used in the European Union before specific food products can be imported.

[53] NASEM, *Stronger Food and Drug Regulatory Systems Abroad*, 2020, https://doi.org/10.17226/25651.

[54] Warning letters are posted at FDA's website at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/about-warning-and-close-out-letters.

[55] FDA, "Inspection Observations," FY2019 data, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-observations.

[56] FSVP violations cover Title 21, Sections 1.500-1.514, of the *Code of Federal Regulations*.

maintain the FSVP, failing to translate the FSVP into English when applicable, failing to sign and date the FSVP upon modification, and failing to make adequate assurances of a supplier's food safety under FSVP. FDA cited food facilities for other violations relating to food safety and good manufacturing practices, including violations for failing to take reasonable measures and precautions related to personnel practices (21 C.F.R. §117.10), pest control (21 C.F.R. §117.35(c)), sanitation monitoring (21 C.F.R. §120.6), sanitary operations and plant maintenance (21 C.F.R. §117.35(a)), and Hazard Analysis and Critical Control Point (HACCP) plan implementation (21 C.F.R. §123.6(c)).[57]

FDA Foreign Systems Recognition Assessment

FSMA addressed limitations in FDA's abilities to inspect foreign food facilities by authorizing FDA to enter into agreements with foreign governments to inspect registered foreign facilities and by directing resources to inspections of foreign facilities, suppliers, and food types. When the FDA inspects a food facility, the agency checks for compliance with Current Good Manufacturing Practices (CGMPs) and any other applicable food safety regulations. Failure to comply can result in FDA issuing warning letters, citations, or detentions. Under FSMA, FDA may further recognize a country's food safety system as comparable to that in the United States if it provides similar protections, oversight, and monitoring as U.S. requirements. To assess the capability of foreign food safety systems, FDA implemented a *systems recognition assessment*—a process used by the agency to assess the capability of foreign food safety systems to help ensure the safety of foods produced under the oversight of that country's food safety authority/authorities. The assessment relies on a range of available information, including facility registrations, border examinations (including testing of samples and compliance), foreign facility inspections, import certificates, and accredited laboratories, as well as information from in-country export programs, bilateral agreements, and other systems of recognition or equivalence assessments of foreign food safety systems.[58] Other information is obtained from programs established in FSMA, such as the FSVP and VQIP, and through third-party certification.[59]

FDA's systems recognition assessment further provides a means for FDA to establish closer regulatory partnerships and leverage work conducted by FDA and foreign food safety authorities. Available guidance provides information to foreign food facilities subject to FDA's facility inspection as well as to foreign governments, as authorized under FFDCA.[60]

To date, FDA has recognized as being comparable to that in the United States the foreign food safety regulatory systems of Australia, Canada, and New Zealand.[61] Entering into such agreements with some countries allows FDA to focus its resources on other countries that may present a relatively greater safety risk. FDA has also entered into international partnerships with

[57] FDA, "Inspection Observations," FY2019 data. See also *Food Safety News*, "Foreign Supplier Verification Most Common Violation in FDA Food Facility Inspections," February 26, 2020.

[58] See FDA's FAQs at https://www.fda.gov/food/international-interagency-coordination/frequently-asked-questions-systems-recognition-foreign-governments. Previously, FDA used the term *comparability assessment* to describe the process of food safety systems evaluation.

[59] VQIP was authorized in FSMA Section 302 (21 U.S.C. §384b).

[60] 21 U.S.C. §384c(b). FDA, "Draft Guidance for Industry: Refusal of Inspection by a Foreign Food Establishment or Foreign Government," December 2017, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-refusal-inspection-foreign-food-establishment-or-foreign-government.

[61] As of December 2019. FDA, "International Cooperation on Food Safety," https://www.fda.gov/food/international-interagency-coordination/international-cooperation-food-safety#systems_recognition. Alternatively referred to as a comparability agreement or systems recognition by FDA.

several counterpart foreign government agencies and international organizations through Cooperative Arrangements (or Memoranda of Understanding) or through Confidentiality Commitments. FDA's partnerships include the countries of the European Union, as well as Argentina, Australia, Brazil, Canada, Chile, China, India, Israel, Japan, Mexico, New Zealand, the Philippines, Russia, and Switzerland.[62]

Technical Assistance for Foreign Food Suppliers

FSMA required FDA to develop a comprehensive plan to expand technical, scientific and regulatory food safety capacity of foreign governments and their respective food industries in countries exporting foods to the United States.[63] FDA issued its report to Congress in 2013, which provides a strategic framework for how FDA can expand the technical, scientific, and regulatory capacity of foreign governments and their food industries as part of its international food safety capacity-building activities.[64] Despite this technical assistance, some foreign food suppliers in low- and middle-income countries may face challenges meeting user fees associated with imported foods, especially among smaller-sized suppliers.[65] VQIP fees for FY2020 are set at $16,681 per facility.[66] Foreign facility reinspection, recall, and importer reinspection fees are based on the number of direct hours spent on any actions taken and are assessed at an hourly rate ranging from $253 to $282, plus any foreign travel costs.[67] Costs incurred by third-party certification entities that are responsible for conducting food safety audits and issuing food and facility certifications to eligible and registered foreign food facilities that meet U.S. food safety standards and requirements might also contribute to costs faced by foreign suppliers.[68]

Food safety regulations and standards are often implemented through a variety of sanitary and phytosanitary (SPS) measures and other technical regulations—such as testing, registration, and certification, as well as quality, packaging, and labeling requirements. In certain instances, these may be considered non-tariff barriers that may restrict trade.[69] As Congress has important legislative, oversight, and advisory responsibilities with respect to U.S. trade negotiations, issues regarding both tariff and non-tariff barriers to agricultural trade are regularly part of trade policy considerations.

Differences in food safety regulations and standards between the United States and its trading partners could, in some cases, heighten trade tensions about potential non-tariff barriers to trade

[62] As of December 2019. For more updated information, see FDA, "International Arrangements," https://www.fda.gov/international-programs/international-arrangements/cooperative-arrangements.

[63] FSMA §305. See also FDA's website at https://www.fda.gov/food/food-safety-modernization-act-fsma/international-capacity-building-under-fsma.

[64] FDA, Building Domestic Capacity to Implement the FDA Food Safety Modernization Act (FSMA), February 2013, https://www.fda.gov/media/124268/download.

[65] See, for example, J. Murphy, "Steep VQIP Fees Likely to Shut Out Small Importers, Says Specialty Food Association, *Food Chemical News*, August 17, 2015; and H. Bottemiller, "Food Importers Mobilize to Oppose FDA Fees," *Food Safety News*, August 29, 2011.

[66] 84 *Federal Register* 35680-35683, July 24, 2019 (Docket Number: FDA-2019-N-3406). Rates are for FY2020.

[67] 84 *Federal Register* 35659-35662, July 27, 2018 (Docket Number: FDA-2018-N-2775). Rates are for FY2019.

[68] For more information on the accreditation and annual fees incurred by a certification body, see 84 *Federal Register* 35395-35398, July 23, 2019 (Docket Number: FDA-2016-N-4119). Rates are for FY2020.

[69] For more background, see CRS Report R43450, *Sanitary and Phytosanitary (SPS) and Related Non-Tariff Barriers to Agricultural Trade*. WTO definitions for both *non-tariff measures* and *non-tariff barriers* are defined by their abbreviations at http://www.wto.org/english/thewto_e/glossary_e/glossary_e.htm.

and result in international trade disputes.[70] Food safety regulations and standards in the United States operate under the constraints of internationally accepted trade rules and norms, including safety and public health protections addressed in the multilateral Agreement on the Application of Sanitary and Phytosanitary Measures and the Agreement on Technical Barriers to Trade.[71] On the one hand, the United States itself has questioned whether certain U.S. trading partners are advancing science-based food safety regulations and standards, particularly those regulations and standards in some European Union countries. This situation has resulted in long-standing trade disputes that have had implications for ongoing and prior trade negotiations.[72] On the other hand, some low- and middle-income countries may have difficulty meeting what they perceive as increasingly complex and costly technical regulations and product standards implemented by developed-country trading partners, including the United States.[73] This could also have implications for future trade relations.

A 2019 World Bank report further highlights the need for investments in low- and middle-income countries to enhance global food safety management capacity.[74] A 2020 NASEM report also emphasizes the need for capacity building and improved monitoring in low- and middle-income countries.[75] FDA has a partnership with the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) to help establish food safety training programs in other countries.[76]

FDA Inspection of Imported Foods

FFDCA authorizes FDA examination of food and feed products offered for entry into the United States.[77] In addition, CBP regulations authorize FDA employees to examine or take samples of goods entering the United States that are released for delivery by CBP border agents.[78] FSMA provided FDA with additional authorities regarding inspection and oversight; however, FDA continues to physically examine about 1% of the total number of food import lines each year—rates similar to that prior to FSMA.[79] FSMA further authorized FDA to require that high-risk

[70] For examples of how different food safety requirements may lead to formal trade disputes, see WTO's website at https://www.wto.org/english/tratop_e/dispu_e/dispu_agreements_index_e.htm?id=A19.

[71] SPS measures refer to laws, regulations, standards, and procedures that governments employ as "necessary to protect human, animal or plant life or health" from the risks associated with the spread of pests, diseases, or disease-carrying and causing organisms or from additives, toxins, or contaminants in food, beverages, or feedstuffs. TBT measures in agriculture include SPS measures and other types of measures related to health and quality standards, testing, registration, and certification, as well as packaging and labeling requirements.

[72] See CRS Report R46241, *U.S.-EU Trade Agreement Negotiations: Trade in Food and Agricultural Products*.

[73] Organisation for Economic Co-operation and Development, *Analysis of Non-Tariff Barriers of Concern to Developing Countries*, June 2005, http://dx.doi.org/10.1787/223281783722. See also S. Henson and R. Loader, "Barriers to Agricultural Exports from Developing Countries: The Role of Sanitary and Phytosanitary Requirements," *World Development*, vol. 29, no. 1 (2001).

[74] S. Jaffee et al., *The Safe Food Imperative*, World Bank Group, 2019, https://openknowledge.worldbank.org/bitstream/handle/10986/30568/9781464813450.pdf?sequence=6.

[75] NASEM, *Stronger Food and Drug Regulatory Systems Abroad*, 2020, https://doi.org/10.17226/25651.

[76] For more information, see JIFSAN's website, https://jifsan.umd.edu/.

[77] 21 U.S.C. §381. FDA, *Investigations Operations Manual 2019*, Chapter 6—Imports, May 2020, https://www.fda.gov/media/75256/download. Other information is available at FDA, "Importing Food Products into the United States," https://www.fda.gov/food/food-imports-exports/importing-food-products-united-states.

[78] Regulations are at Title 19, Section 151.4, of the *Code of Federal Regulations*. FDA commissions CBP to assist with examinations and investigations related to prior notice requirements for imported goods (21 U.S.C. §381(m)) at ports and other facilities and locations subject to CBP jurisdiction under MOU 225-04-4001 (http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm115145.htm).

[79] See also rates cited in GAO, *Fundamental Changes Needed to Ensure Safe Food*.

imported foods be accompanied by a credible third-party certification or other assurance of compliance as a condition of entry into the United States.[80]

In FY2019, FDA examined more than 17.7 million import lines of FDA-regulated food and feed and physically examined—through field exams or analyzing samples—an estimated 0.9% of the total number of food import lines (**Table 5**). An *import line*—or *entry line*—refers to each portion of an import shipment that is listed as a separate item on an entry document. Items in an import entry having different tariff descriptions must be listed separately. Each entry line identifies a unique shipment or lot of a particular food by a particular shipper offered for admission into U.S. commerce at a particular place in time and furthermore references FDA product codes unique to a specific product.[81]

Since FY2010, available data indicate that the percentage of import lines physically examined in FY2019 reached its lowest point (0.9%, down from 2% in FY2010) before FSMA was enacted. The total number of import lines requiring a decision by FDA did increase dramatically during that time, rising from 9.7 million to 17.7 million from FY2010 through FY2019. Over the same period, the number of import field exams/tests and the number of import laboratory samples analyzed reportedly dropped (**Table 5**).

FDA does not randomly sample import shipments for inspection but instead uses a risk-based prediction algorithm to determine whether shipments should be inspected in the field or a laboratory. FDA electronically screens all import entries using an automated system known as Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT), which helps inspectors determine a shipment's relative risk and whether it needs closer scrutiny (i.e., a physical examination and/or testing).[82] PREDICT generates a numerical score using a database to analyze risk-based data, such as information about the product, manufacturers, importer, country of origin, historical data, lab results, facility inspections, recall events, and natural disasters (e.g., whether foods may have been subject to flooding, hot weather, or market conditions that could contribute to greater risk). If the PREDICT score exceeds an FDA-specified threshold, inspectors are directed to examine the product.

FDA's surveillance of imported foods consists of reviews of prior notice data, reviews of customs entry forms, physical or sensory analysis, sample collections for laboratory analysis, and detention without physical examination. Foreign facilities that manufacture/process, pack, or hold food must register with FDA unless food from that facility undergoes further processing (including packaging) by another foreign facility before it is exported to the United States.[83] Foreign facilities must also provide notice for imported food shipments into the United States prior to importation.[84] Prior notice is required to enable the food to be inspected at U.S. ports of

[80] FSMA §303 (21 U.S.C. §384c).

[81] See FDA's website at https://www.fda.gov/industry/import-program-resources/product-codes-and-product-code-builder.

[82] According to FDA, PREDICT "uses data analytics from the entire life cycle of a product to better identify and target high-risk products before they enter the country" and "helps field inspectors determine which products pose the greatest risk and, therefore, should be physically examined." For more information, see FDA's website (http://www.fda.gov/forindustry/importprogram/ucm172743.htm). For recommendations regarding PREDICT, see GAO, *FDA's Targeting Tool Has Enhanced Screening, but Further Improvements Are Possible*, GAO-16-399, May 26, 2016.

[83] Under the Bioterrorism Act, facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States were required to register with FDA by December 12, 2003 (http://www.fda.gov/food/guidanceregulation/foodfacilityregistration/default.htm).

[84] 21 U.S.C. §381(m) [FFDCA §801(m)]. For more information, see FDA's "Guidance for Industry: Prior Notice of Imported Food Questions and Answers," Edition 3.

entry, and FDA must refuse admission to food imported or offered for import if the notice was not submitted or if the notice was deficient. FSMA specified that prior notice submissions must include information regarding "any country to which the article has been refused entry."[85] FDA may hold food at the port of entry if it is imported or offered for import by a person who was debarred under FFDCA or if it was imported or offered for import from a foreign facility that has not registered with FDA. FDA screens the electronic shipping records of all imported food products before they enter the United States. From these records, the agency selects products for physical examination and/or testing to determine whether they contain adulterants.

In practice, import product inspections are relatively infrequent. Product perishability also presents a challenge, given that some types of testing services might not be available locally or may overwhelm locally available sources, especially seasonally during periods of peak production, requiring samples to be sent elsewhere. At some border facilities, mobile laboratories may be available.[86]

In March 2020, Congress passed the Protecting America's Food and Agriculture Act of 2019 (P.L. 116-122). The law authorizes CBP to hire and train 240 new agricultural inspectors and technicians, as well as 20 new canine units, to work at different U.S. ports of entry and to conduct additional border inspections of plants, food, animals and goods entering the United States. While increased border inspections augment FDA efforts, they do not provide the same type of food safety oversight provided by in-country foreign facility inspections and audits.

FDA's Authority to Refuse Import Shipments

FFDCA empowers FDA to refuse entry to any food import if it "appears," based on a physical examination or otherwise, to be adulterated, misbranded, or in violation of U.S. law.[87] In such cases, FFDCA generally provides that, with few exceptions, a food article must be refused admission into the United States "if it appears from the examination of such samples or otherwise" that it has been "manufactured, processed, or packed under insanitary conditions," or it is "forbidden or restricted in sale in the country in which it was produced or from which it was exported," or it is "prohibited from introduction or delivery for introduction into interstate commerce under section 301(ll)."[88]

FDA actions on suspect imported products may be affected by and implemented through FDA's "Import Alerts."[89] An import alert is a notification from FDA to signal field inspectors to pay special attention to a particular product or a range of products from a particular producer, shipper, or importer.[90] According to FDA, import alerts prevent potentially violative products from being distributed in the United States and place responsibility on the importer to ensure that the products imported into the United States are in compliance with FDA laws and regulations.[91]

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[85] 78 *Federal Register* 32359-32362, May 30, 2013.

[86] FDA, "On the Road Again: FDA's Mobile Laboratories," FDA Consumer Health Information, March 2009.

[87] 21 U.S.C. §381(a), FFDCA §801(a).

[88] 21 U.S.C. §381(a), FFDCA §801(a). In exercising its oversight, FDA relies on a system of prior notifications by importers and document reviews at points of entry (ports). Importers must have an entry bond and file a notification for every shipment.

[89] FDA's import alert database is at http://www.accessdata.fda.gov/cms_ia/default.html. Other information is at FDA's Import Alert website (https://www.fda.gov/industry/actions-enforcement/import-alerts#purpose).

[90] An alert can be issued for an import from a manufacturer, shipper, grower, geographical area, or country. For other background, see CRS Report R43609, *Enforcement of the Food, Drug, and Cosmetic Act: Select Legal Issues*.

[91] See FDA's website at https://www.fda.gov/industry/actions-enforcement/import-alerts. See also FDA, *Regulatory*

Import alerts are also a way for FDA to refuse entry of future shipments of an imported product that either have or could potentially violate FFDCA without physically examining the product. Such an action, known as detention without physical examination (DWPE), formerly known as automatic detention, was developed to address recurrent violations.[92] DWPE allows the agency to detain a product without physically examining it at the time of entry. If the problem or condition exists on a wide scale, federal inspectors may be instructed to detain all products of a certain kind coming from a country or a region of a country. Products that may be subject to refusal based on existing evidence (such as a history of violations) may be detained at the border and refused admission unless the importer is able to demonstrate that the products are in compliance.[93]

If FDA decides to detain a regulated product, the agency issues a "Notice of FDA Action" specifying the nature of the violation to the owner or consignee, who is entitled to an informal hearing in order to provide testimony regarding the admissibility of the product.[94] If the owner fails to submit evidence that the product is in compliance or fails to submit a plan to bring the product into compliance, FDA is to issue another notice thereby refusing admission to the product. At that point, the product then has to be exported or destroyed within 90 days.

FDA has issued import alerts on a range of imported foods, including pet food ingredients, seafood, and dairy products and ingredients, among other foods.[95]

FDA's Import Data Reporting Requirements

Pursuant to FSMA, FDA is required to annually report to Congress and make publicly available certain information about food facilities and foods imported into the United States, as well as information about foreign FDA offices.[96] Annual reports must include the number of registered facilities inspected (including the number of high-risk facilities inspected and those scheduled for inspection but not inspected), the number of registered facilities scheduled for inspection in the previous fiscal year that FDA did not inspect, and the average cost of FDA facility inspections.[97] Annual reports must also provide information about food imports, including the number of import lines examined/sampled (including those not examined/sampled) and the average cost of import examination/sampling.[98] FDA must also report on the number of foreign offices established and the number of personnel permanently stationed in each foreign office.[99]

Procedures Manual, Chapter 9—Import Operations and Actions, December 2017, https://www.fda.gov/media/71776/download.

[92] For more information, see C. Anderson, "Assistance with U.S. FDA's Detention Without Physical Examination," *Food Safety* magazine, May 21, 2013.

[93] If a shipment is refused admission, the importer may introduce evidence within 10 days to avoid the appearance of a violation. During that time, the product is held at a warehouse or with the importer and cannot be distributed. If the shipment is not proven to be safe, it must be destroyed or exported within 90 days.

[94] FDA, https://www.accessdata.fda.gov/scripts/importrefusals/. See also FDA, *Regulatory Procedures Manual*, Chapter 9—Import Operations and Actions, December 2017, https://www.fda.gov/media/71776/download.

[95] FDA, "Recalls, Market Withdrawals, & Safety Alerts," http://www.fda.gov/Safety/Recalls/default.htm.

[96] 21 §U.S.C. 393(h), as amended by P.L. 111-353, §201(b). Elsewhere, Section 1009 of the Food and Drug Administration Amendments Act of 2007 (P.L. 110-85) required annual reporting on the number and amount of FDA-regulated food products imported by country and type of food, the number of inspectors and inspections performed, and aggregated data on inspection findings, including violations and enforcement actions.

[97] 21 §U.S.C. 393(h)(1)(B)-(F) [FFDCA §1003(h)(1)(B)-(F)].

[98] 21 §U.S.C. 393(h)(2)(A)-(C) [FFDCA §1003(h)(2)(A)-(C)].

[99] 21 §U.S.C. 393(h)(3) [FFDCA §1003(h)(3)].

To date, however, FDA has made public annual reports for three years only, covering 2010, 2011, and 2012.[100] Annual reports are not publicly available for subsequent years. Some of the required data continue to be reported in public documentation submitted to Congress as part of the annual appropriations process (i.e., FDA's congressional budget justifications as shown in **Table 5**). FDA's congressional budget justifications do not include certain data, such as the number of high-risk facilities inspected (including those scheduled for inspection but not inspected), the number of registered foreign (and domestic) facilities scheduled for inspection in the previous fiscal year that FDA did not inspect, and the average cost associated with FDA facility inspections or import examination and sampling. FDA's congressional budget justifications also do not provide annual data on the number of foreign offices and personnel.

Measures of Effectiveness of FSMA Mandates

FDA maintains a *Food Safety Dashboard* portal to monitor progress and performance toward achieving key outcomes of FSMA-mandated controls for both domestically produced and imported foods and to report and analyze key performance data.[101] For imported foods, available data focus on the number of inspections and recall events related to imported human food and animal food subject to FSVP and FSMA preventive controls.[102] Reported inspection data are based on type of classification and class of recall event. Inspection data cover FY2017-FY2019, while recall data cover FY2018-FY2019 only.

Currently, FDA's dashboard tracks outcomes from three of the FSMA rules: preventive controls for both human food and food for animals and FSVP for imported food. FDA says additional measures and data will be added to the dashboard in the future.[103]

Figure 8 and **Figure 9** show available data on the number of foreign Preventive Controls (PC) inspections and the number of FSVP inspections from FY2017 to FY2019. Data are for human food only (excluding animal food) and shown by outcome, measured in terms of no action indicated (NAIs), voluntary action indicated (VAIs), or official action indicated (OAIs). In FY2019, there were 1,139 foreign PC inspections and 869 FSVP inspections.[104] VAIs accounted for about one-fifth (273) of all foreign PC inspections and about two-thirds of all FSVP inspections of human food (**Figure 8** and **Figure 9**, respectively). Of total foreign inspections in FY2019, there were six OAIs within foreign PC inspections and seven OAIs within FSVP inspections of human food. In addition, there were 33 foreign PC inspections of animal food and another 28 FSVP inspections of animal food.

Reported recall data indicate that there were 81 recalls attributed to imported human foods in FY2019, of which 36 were Class I recalls and 45 recalls were Class II recalls.[105] Four recalls were attributed to imported animal foods—all Class I recall events.

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[100] During those years, FDA's report was compiled within the agency's *Annual Report on Food Facilities, Food Imports, and FDA Foreign Offices* and last reported in 2013 (https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-reports-studies). FDA's most recent report on the agency's foreign offices was published in 2012.

[101] FDA, "FDA-TRACK: Food Safety Dashboard," https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-food-safety-dashboard.

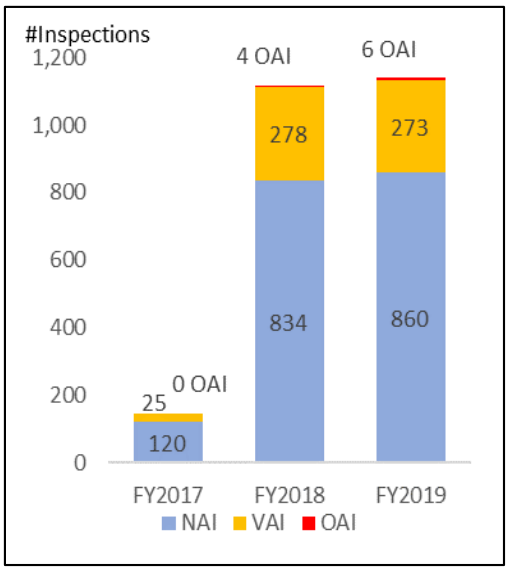
[102] FDA, "Imported Food Safety Measures," https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/imported-food-safety-measures.

[103] HHS, *FDA Justification if Estimates for Appropriations Committees*, FY2021, p. 278.

[104] Data may not reflect unique inspections (i.e., spanning human and animal food, and facility inspections across different inspection programs) and cumulative totals may not match data shown in **Table 5**

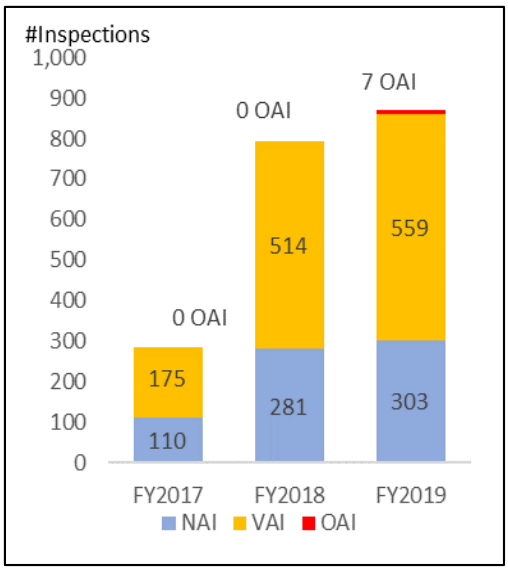
[105] Includes Class I recalls (where there is a reasonable probability that the use of or exposure to a violative product will

Figure 8. Foreign Preventive Controls Inspections (FY2017-FY2019)



Source: FDA-TRACK: Food Safety Dashboard. Human food (excluding animal food). Blue = NAI (no action indicated); yellow = VAI (voluntary action indicated); red = OAI (official action indicated).

Figure 9. Foreign Supplier Verification Program Inspections (FY2017-FY2019)



Source: FDA-TRACK: Food Safety Dashboard. Human food (excluding animal food). Blue = NAI (no action indicated); yellow = VAI (voluntary action indicated); red = OAI (official action indicated).

USDA, Food Safety and Inspection Service

FSIS regulates the safety and labeling of most domestic and imported meat, poultry, and egg products under the Federal Meat Inspection Act (FMIA) as amended (21 U.S.C. §601 et seq.), the Poultry Products Inspection Act (PPIA) as amended (21 U.S.C. §451 et seq.), and the Egg Products Inspection Act (EPIA, 21 U.S.C. §1031, et seq.).[106] FMIA, as amended, requires USDA to inspect all cattle, sheep, swine, goats, horses, mules, and other equines slaughtered and processed for human consumption. PPIA, as amended, gives USDA the authority to inspect poultry meat. The PPIA mandates USDA inspection of any domesticated birds (chickens, turkeys, ducks, geese, guineas, ratites,[107] and squab [pigeons up to one month old]) intended for use as human food. EPIA, as amended, provides USDA authority to inspect liquid, frozen, and dried egg products. Each of these laws also contains provisions governing USDA's authority to label food products under its jurisdiction.[108] In addition, under the authority of the Agricultural Marketing

cause serious adverse health consequences or death) and Class II recalls (where use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote).

[106] FSIS inspects the major red meat and poultry species and their products; catfish was added to FSIS's responsibilities by the 2008 farm bill (P.L. 110-246; §11016). FDA has jurisdiction over all meat and poultry not inspected by FSIS. The agencies share responsibility for egg safety, under , as amended. FSIS covers processed egg products; FDA covers most whole eggs.

[107] Ratites includes flightless birds such as emu, ostrich, and rhea.

[108] "A Guide to Federal Food Labeling Requirements for Meat, Poultry, and Egg Products," prepared for FSIS by Hogan and Hartson, August 2007, http://www.fsis.usda.gov/wps/wcm/connect/f4af7c74-2b9f-4484-bb16-fd8f9820012d/Labeling_Requirements_Guide.pdf?MOD=AJPERES.

Act of 1946, as amended, FSIS may provide voluntary inspection for buffalo, antelope, reindeer, elk, migratory waterfowl, game birds, and rabbits. These meat and poultry species are still within the purview of FDA under FFDCA, whether or not inspected under the voluntary FSIS program. The 2008 and 2014 farm bills further required that FSIS inspect and grade farmed catfish (Siluriformes) products.[109]

FSIS Foreign Facility Inspection

Under the laws governing FSIS, inspectors are to be present at all times in slaughter plants and for at least part of each day in establishments that further process meat and poultry products. FSIS inspects all meat and poultry animals to look for signs of disease, contamination, and other abnormal conditions, both before and after slaughter ("antemortem" and "postmortem," respectively), on a continuous basis—meaning that no animal may be slaughtered and dressed unless an inspector has examined it. One or more federal inspectors are on the line during all hours the plant is operating. Processing plants visited once every day by an FSIS inspector are considered to be under continuous inspection in keeping with the applicable laws. Inspectors monitor operations, check sanitary conditions, examine ingredient levels and packaging, review records, verify food safety plans,[110] and conduct statistical sampling and testing of products for pathogens and residues during their inspections.[111] They are to examine all animals destined for human food both before and after slaughter and ensure that plants are operating in a sanitary manner under an FSIS-approved safety plan.[112] FSIS is also responsible for determining the equivalence of other countries' safeguards, and a foreign plant cannot ship products to the United States unless the agency has determined that the country in which it is located has a meat and/or poultry program that provides a level of protection that is at least equivalent to the U.S. system.

FSIS Inspection System *Equivalency* Determination

For imported product, FSIS is responsible for certifying that foreign meat and poultry plants are operating under an inspection system that is equivalent to the U.S. system before they can export their product to the United States. As part of its responsibility for determining the *equivalence* of another country's inspection system, FSIS visits the exporting country to review its rules and regulations, meets with foreign officials, and accompanies them on visits to establishments. FSIS conducts a document review that focuses on sanitation controls, animal disease controls, slaughter and processing controls, residue controls, and enforcement controls.[113] FSIS also conducts an on-site audit that assesses these five risk areas and verifies other aspects of a country's inspection system, including plant facilities and equipment, laboratories, training programs, and in-plant

[109] FSIS was authorized to inspect farmed catfish products under a 2008 farm bill provision (P.L. 110-246, §11016). The 2014 farm bill (P.L. 113-79, §12106) reconfirmed this provision and also mandated USDA and FDA enter into an agreement to improve interagency cooperation and prevent duplication; see MOU 225-14-0009 (between FSIS and FDA), http://www.fda.gov/aboutfda/partnershipscollaborations/memorandaofunderstandingmous/domesticmous/ucm396294.htm. FSIS promulgated final regulations in December 2015 (80 *Federal Register* 75590-75630, December 2, 2015).

[110] In a Hazard Analysis and Critical Control Point (HACCP) plan, a facility must identify each point in its processes where contamination could occur ("critical control point") and have a plan to control it. It must also document and maintain records.

[111] For more information, see CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*.

[112] For more general information on U.S. meat inspection requirements, see CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*.

[113] FSIS, "FSIS Import Procedures for Meat, Poultry and Egg Products," https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/production-and-inspection/fsis-import-procedures-for-meat-poultry-and-egg-products/fsis-import-procedures.

inspection operations. If FSIS deems the inspection system to be equivalent to the U.S. system, USDA publishes its findings and intent in a proposed rule in the *Federal Register*. After consideration of public comments, FSIS issues a final decision on the country's eligibility. Once a foreign country's inspection system has been approved, FSIS relies on that government to certify the eligibility of individual exporting establishments, to inspect them, and to provide annual re-certification documentation. FSIS periodically reviews foreign government documents and conducts on-site audits at least annually to verify an eligible country's inspection system to ensure that it continues to be equivalent to the U.S. system. No foreign plant is authorized to ship meat or poultry to the United States unless the country where it is located has received such an FSIS determination.

FSIS Reinspection of Imported Food

At the U.S. port of entry, an FSIS import inspector is to reinspect all meat and poultry shipments before shipments are allowed entry to ensure that foreign countries have maintained equivalent inspection systems.[114] Meat and poultry imports are to be 100% visually inspected for appearance and condition and checked for certification and label compliance. Physical inspections of imports may be more random.

At the port of entry, once a product shipment of meat or poultry has cleared the CBP and APHIS requirements, all product shipments must be presented to FSIS for routine *reinspection* at an approved import inspection facility. FSIS first is to verify that the product is from an eligible country and certified establishment.[115] All imported product shipments presented for inspection receive a routine reinspection for general condition, labeling, proper certification, and accurate count. Reinspections may include a physical examination of the product for visible defects or a collection of samples for microbiological, food chemistry, drug, or chemical residue analysis. Product shipments are then randomly selected for an additional reinspection based on the volume imported from the country within each category. Products that pass reinspection are considered accepted for entry into the United States. Products that fail reinspection are to be refused entry and must be re-exported, converted to nonhuman food, or destroyed. This automatically results in an intensified rate of reinspection for future shipments of like product from the same establishment.

FSIS currently reinspects imported meat (including Siluriformes), poultry (including ratite), and egg products at about 1,300 *eligible foreign establishments* in nearly 40 countries.[116] Eligible countries include many of the countries of the European Union, as well as Argentina, Australia, Brazil, Canada, Chile, Costa Rica, Honduras, Iceland, Israel, Japan, Mexico, Namibia, New Zealand, Nicaragua, China, South Korea, San Marino, Thailand, Uruguay, and Vietnam. As part of this responsibility, importers of foreign food are responsible for verifying that the products obtained from foreign processors are in compliance with U.S. laws.

In FY2019, a reported 3,954 million pounds of imported meat and poultry products and a reported 7.5 million pounds of imported egg products were presented to USDA for reinspection (**Table 6**).

[114] FSIS, "FSIS Import Procedures for Meat, Poultry and Egg Products." About 65 FSIS inspectors carry out reinspection at approximately 150 official import establishments.

[115] If the foreign country or the foreign establishment that produced the product is not eligible to export to the United States, the shipment is to be refused entry.

[116] FSIS, "Eligible Foreign Establishments," https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/eligible-foreign-establishments.

Table 6. Imported Meat, Poultry, Egg Product Reinspection and Refusal, 2005-2019

	Meat and Poultry Products			Egg Products		
	Presented	Refused/Rejected	Rate	Presented	Refused/Rejected	Rate
Fiscal Year	(1,000 pounds)		(%)	(1,000 pounds)		(%)
FY2005	4,303,345	9,207	0.21%	N/A	N/A	N/A
FY2006	3,888,188	11,624	0.30%	N/A	N/A	N/A
FY2007	3,398,480	6,602	0.19%	N/A	N/A	N/A
FY2008	3,273,517	11,624	0.36%	21,758	48	0.22%
FY2009	3,398,480	6,602	0.19%	19,371	0	0.00%
FY2010	3,210,034	9,297	0.29%	22,435	0	0.00%
FY2011	2,900,139	5,536	0.19%	18,471	50	0.27%
FY2012	3,066,627	4,859	0.16%	16,128	0	0.00%
FY2013	3,141,960	4,744	0.15%	10,227	<1	0.00%
FY2014	3,575,728	3,881	0.11%	24,503	39	0.16%
FY2015	4,442,517	5,082	0.11%	14,593	86	0.59%
FY2016	4,148,379	6,572	0.16%	22,449	63	0.28%
FY2017	4,064,517	11,993	0.30%	12,490	23	0.18%
FY2018	4,366,648	5,689	0.13%	9,473	36	0.38%
FY2019	3,953,922	5,327	0.13%	7,518	5	0.07%

Source: CRS from various FSIS *Quarterly Enforcement Reports*, http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/regulatory-enforcement/quarterly-enforcement-reports. FY data (October 1 through September 30). N/A = not available.

Notes: Annual totals are in the quarterly report ending September. For more recent years, see meat and poultry products (Table 3a) and egg products (Table 3b). Rejected/Refused Entry reflect the difference between imported products refused entry excluding refused products that were subsequently rectified.

FSIS's Authority to Refuse Import Shipments

FMIA and PPIA authorize USDA to regulate labeling and packaging of meat, poultry, or processed parts to prevent false or misleading marks, labels, or containers (FMIA, 21 U.S.C. §607; PPIA, 21 U.S.C. §457).[117] Similar to FFDCA, both FMIA and PPIA disallow "prohibited" acts involving products that are "adulterated or misbranded at the time of such sale, transportation, offer for sale or transportation, or receipt for transportation" or products "required to be inspected … unless they have been so inspected and passed" (FMIA, 21 U.S.C. §10; PPIA, 21 U.S.C. §458).

FSIS is responsible for developing the labeling policy to determine that meat or poultry products are wholesome, not adulterated, and properly marked, labeled, and packaged. FMIA and PPIA both define "misbranded" foods as bearing a false or misleading label, or foods that are "offered

[117] FSIS regulations are at Title 9, Section 300, of the *Code of Federal Regulations*. For meat products, labeling regulations are at Title 9, Section 317; for poultry, regulations are at Title 9, Section 381. Regulations regarding weights are at Title 9, Section 442. Other information on FSIS labeling requirements is at http://www.aamp.com/regulations/fsis-labeling/.

for sale under the name of another food," or are "an imitation of another food, unless its label bears a statement to that effect, in type of uniform size and prominence," or if "its container is so made, formed, or filled as to be misleading, or is otherwise misrepresented" (21 U.S.C. §§453 and 601). An "adulterated" food is one that bears or contains any "poisonous or deleterious substance which may render it injurious to health" or otherwise poses a risk to consumer health.

Food Safety Concerns Involving Imports

A number of high profile food safety-related incidents and outbreaks involving imported foods have generated growing concerns about whether current federal programs sufficiently ensure the safety of U.S. food imports.[118] Several large multi-state outbreaks have been linked to foods regulated by both FDA and USDA.

Attention focused on the safety of food imports in 2007 when pet food ingredients imported from China, contaminated with the chemical melamine, sickened or killed an unknown number of dogs and cats and contaminated some livestock feeds. Then, in 2008, melamine contamination of infant formula in China sickened thousands of children and raised concerns about the safety of infant formula in the United States and elsewhere. Also in 2008, more than 1,400 persons were infected with an unusual strain of bacteria, *Salmonella* Saintpaul. Officials first suspected fresh tomatoes, but later tests found the pathogen in serrano peppers and irrigation water from a farm in Mexico. Other foodborne illness outbreaks have involved imported fish and seafood and fruits and vegetables, among other products. These incidents highlighted the limited reach of government oversight of U.S. food imports but have also highlighted the difficulty in tracing the many pathways taken by a common food ingredient as well as the frequent confluence of human and animal food ingredients. An Interagency Working Group submitted a report to the President in 2007 further highlighting the need to foster compliance with U.S. safety standards through enhanced certification; encourage improved importer practices, transparency, and information exchange; strengthen penalties for noncompliance; and increase U.S. presence overseas and training for foreign inspection agencies.[119] Additional recommendations include those in a 2010 report by the NASEM.[120] A series of Senate hearings in 1998 had earlier highlighted "weaknesses in federal agencies' control over shipments of imported foods that allow unsafe foods to enter domestic commerce."[121]

Public concerns about foodborne illness incidents contributed to Congress enacting FSMA in 2010. Despite the implementation of preventive controls and other standards involving both imported and domestically produced foods as part of FSMA, foodborne illness incidents involving imported foods have continued to be of particular concern. Import alerts targeting

[118] The Centers for Disease Control and Prevention (CDC) defines a "foodborne disease outbreak" as occurring when two or more people get the same illness from the same contaminated food or drink.

[119] White House Office of the Press Secretary, *Import Safety Action Plan: Increasing Protection of American Consumers*, November 6, 2007. A report to the President by the Interagency Working Group on Import Safety is available at https://2001-2009.state.gov/e/eeb/rls/fs/2007/94675.htm.

[120] NASEM, *Food Safety: The Role of the Food and Drug Administration*, Appendix E (The U.S. Food and Drug Administration and Imported Food Safety), 2010, pp. 483-488, https://doi.org/10.17226/12892. Recommendations included the following: establish a tiered food import monitoring system and base examination/sampling rates on risk and in-country information; establish an importer licensing program; give priority to negotiating agreements with countries that have comparable food safety systems; require fees for safety inspections; provide technical capacity assistance to foreign suppliers; provide recognition of third-party audits of firms (by accredited certifying bodies); require import certification for some food products; and provide additional training and inspection resources.

[121] Hearing on "The Safety of Food Imports" before the Permanent Subcommittee on Investigations of the Committee on Governmental Affairs, 115th Congress, 2nd Session (S. Hrg. 105-516), September 1998.

adulterated products, including pet food ingredients, farmed seafood, and other food products and ingredients from China have continued.[122]

While attention has tended to focus on the safety of imported foods, it is unclear whether imported foods pose any greater safety risk than domestically produced foods.[123] Available data regarding foodborne illness outbreak investigations do not readily identify whether a food is domestic or foreign sourced.[124] Although available data on FDA and USDA import refusals may reveal recurring problems in certain types of imported foods, these data do not indicate the actual level or distribution of food safety risk. In part, this is attributable to the process for selecting shipments for inspection and for other types of administrative actions. Namely, the selection process for deciding which imports to inspect is not random but instead uses a risk-based approach to set sample size. Consequently, analysis of U.S. import refusals due to food safety violations highlight food safety problems that appear to recur in trade and where FDA has focused monitoring efforts.[125] Furthermore, analysis of available foodborne outbreak and import refusal data does not take into account the quantitative increase in the volume of food imports.[126]

Higher relative numbers of refusals do not necessarily indicate that one country's products are less safe or that its food safety system is less rigorous than that of another country. The country simply might be a more important source of U.S. agricultural and/or seafood products. For example, Mexico is among the leading countries in terms of numbers of refused shipments, but it is also the single largest exporter of agricultural products to the United States. Given the diversity of traded products and the available data, however, it is difficult to compare foreign food suppliers on food safety in a meaningful way.

In some cases, import violations appear to be relatively more prevalent involving products originating from low- and middle-income countries. For example, one study showed that there were 605 violations per billion dollars of trade (1998-2004) involving products originating from low- and middle-income countries compared to 134 over the same period among products originating from high-income countries.[127]

Global sourcing and related supply chain complexities in the U.S. food system (**text box**) further complicate the efforts of federal and state authorities to effectively respond to food safety threats.

[122] For information on recent FDA import alerts, see FDA, Import Refusal Report data files, https://www.accessdata.fda.gov/scripts/importrefusals/.

[123] For example, comments by CDC and industry presenters at the Food Safety Research Consortium and the University of Florida Emerging Pathogens Institute's Workshop, *Assuring Safety of Imported Food: Public and Private Roles in a Risk-Based System*, February 1-2, 2010.

[124] For example, CDC, National Outbreak Reporting System (NORS), https://wwwn.cdc.gov/norsdashboard/; or FDA, "Outbreaks of Foodborne Illness," https://www.fda.gov/food/recalls-outbreaks-emergencies/.

[125] For additional discussion, see C. Buzby et al., *Food Safety and Imports: An Analysis of FDA Food-Related Import Refusal Reports* (EIB-39), ERS, September 2008, p. iii.

[126] D. Flynn, "More Imported Food Isn't More Dangerous, Attorneys Say," *Food Safety News*, March 28, 2017.

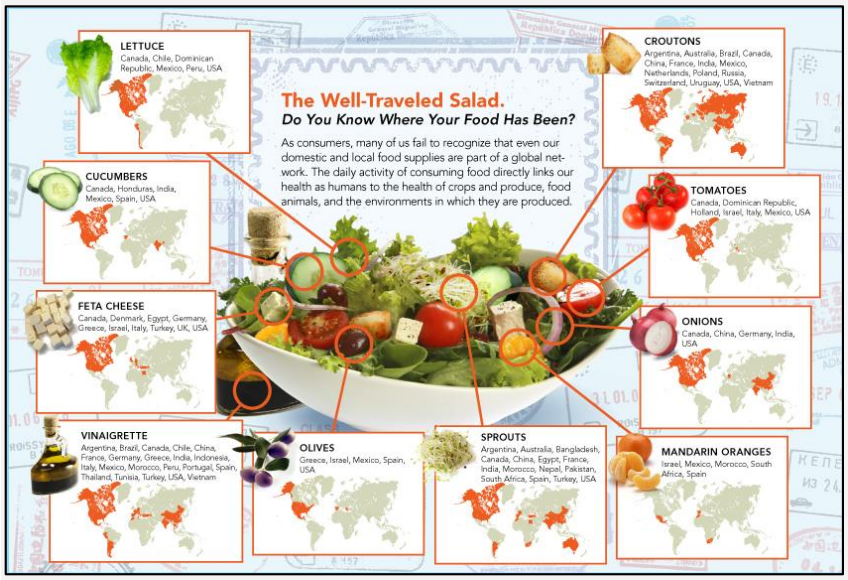
[127] See, for example, L. Unnevehr, "Information Needs for Creating Incentives in Global Supply Chains," presentation at *Assuring Safety of Imported Food*.

Global Sourcing and Supply Chain Complexity

A number of factors are shaping current competitive market and trade conditions worldwide and contributing to overall trends in global food trade. In general, these include:

- a relatively open U.S. import regime and lower average import tariffs, with products from most leading suppliers entering the U.S. duty-free or at preferential duty rates;
- relatively low U.S. non-tariff trade barriers—such as restrictive import and inspection requirements, technical product standards, and sanitary and phytosanitary (SPS) requirements—on imported foods;
- opportunities to import foods outside the U.S. production window (referred to as counter-seasonal trade), such as fruit and vegetable supplies from Southern Hemisphere countries during winter months in the United States, driven, in part, by increased domestic and year-round demand by U.S. consumers;
- consumer demand for specialty foods, such as European cheese and wine or Southeast Asian spices or other international specialty products, including tropical products not commonly grown in the United States;
- competition and supplies from relatively low-cost or subsidized production in some countries; and
- other market factors, such as exchange rate fluctuations and structural changes in the U.S. food industry and production efficiencies associated with global sourcing, as well as increased U.S. overseas investment and diversification in market sourcing by U.S. companies.

These trends have contributed to considerable supply chain complexities worldwide. A 2012 NASEM report highlights the so-called "Well Traveled Salad," illustrating a salad composed of 10 ingredients said to potentially originate in nearly 40 countries.



The report highlights how complexity in food sourcing has the potential to create "conditions favorable for emergence, reemergence, and spread of food-borne pathogens" compounded by the "challenge of anticipating, detecting, and effectively responding to food-borne threats to health."

Multiple ingredients and inputs are sourced from a wide range of countries, both individually sourced products and ingredients between individual food companies and importing countries as well as internally sourced products from foreign-owned entities within a larger multinational company (such as global sourcing between parent and subsidiary). The report asserts that such complexity, compounded by sourcing from many individual producers and various food business management systems (input suppliers, service providers, producers, processors, manufacturers, distributors, retailers, foodservice, etc.) makes it difficult to trace the source of contamination if and/or when it might occur. This is especially true regarding certain highly processed foods with multiple ingredients and inputs from multiple suppliers. Further complicating this process, according to the NASEM report, is often overlapping and/or inconsistent policies and goals among governments and private sector initiatives, as well as lack of clear guidance by international food safety and health organizations.

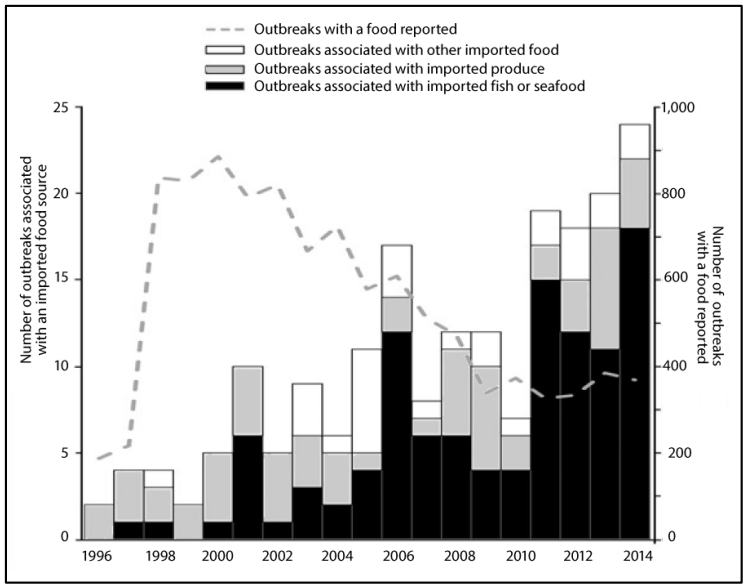
Among its conclusions, the report observes that as the volume of imports continues to steadily increase, in part given increased globalization and rising consumer demand for a wider variety of foods year-round, so do concerns about the safety of imported foods. The report contends that the sheer volume of imported foods annually strains the ability of federal resources to inspect incoming foods at the border.

For more information, see NASEM, *Improving Food Safety Through a One Health Approach: Workshop Summary*, 2012, http://iom.edu/Activities/PublicHealth/MicrobialThreats/2011-DEC-13.aspx. See also NASEM, *Stronger Food and Drug Regulatory Systems Abroad*, 2020, https://doi.org/10.17226/25651.

Foodborne Outbreaks Involving Imported Foods

Limited available data indicate that imported foods account for a small but growing share of U.S. foodborne illness outbreaks. A 2017 analysis by researchers at the Centers for Disease Control and Prevention (CDC) and FDA, using data for 1996-2014, found that "outbreaks associated with imported foods represented an increasing proportion of all foodborne disease outbreaks where a food was implicated and reported."[128] During 1996-2000, 1% of U.S. outbreaks were associated with imported foods, which compares to 5% during 2009-2014 (**Figure 10**). Outbreaks associated with an imported food increased from an average of three per year (1996-2000) to an average of 18 per year (2009-2014). From 1996 to 2014, a total of 195 outbreak investigations implicated an imported food, resulting in an estimated 10,685 illnesses, 1,017 hospitalizations, and 19 deaths.

Figure 10. Number of Outbreaks Caused by Imported Foods and Total Number of Outbreaks with a Food Reported, United States, 1996-2014



Source: L. H. Gould et al., "Outbreaks of Disease Associated with Food Imported into the United States, 1996-2014," *Emerging Infectious Diseases*, vol. 23, no. 3 (March 2017), pp. 525-528, https://wwwnc.cdc.gov/eid/article/23/3/16-1462 (doi:10.3201/eid2303.161462).

Notes: Based on a total of 195 outbreak investigations implicating an imported food, resulting in 10,685 illnesses, 1,017 hospitalizations, and 19 deaths (1996-2014).

Fish/seafood and produce were the imported foods most often linked to U.S. foodborne outbreaks, accounting for an estimated 55% and 33% of outbreaks, respectively. Of all outbreak-associated illnesses caused by imported foods, fish and seafood accounted for an estimated 11% of illnesses, while produce accounted for 84% of illnesses. Latin America and the Caribbean was the most common region of origin for imported foods most often linked to these outbreaks, followed by Asia. By country of origin, more than 30 countries were implicated during the 2009-2014 period, with foods from Mexico most frequently associated with U.S. foodborne outbreaks (42 outbreaks). Other countries associated with more than 10 U.S. outbreaks included Indonesia

[128] L. H. Gould et al., "Outbreaks of Disease Associated with Food Imported into the United States, 1996-2014," *Emerging Infectious Diseases*, vol. 23, no. 3 (March 2017), pp. 525-528 (doi:10.3201/eid2303.161462). Available at https://wwwnc.cdc.gov/eid/article/23/3/16-1462_article. The cited report updates previous CDC analysis of outbreaks caused by imported foods (2009-2010), https://www.cdc.gov/media/releases/2012/p0314_foodborne.html.

(17 outbreaks) and Canada (11 outbreaks). Outbreaks associated with imported fish and shellfish were most commonly imported from Asia (65% of outbreaks associated with fish or shellfish), while outbreaks associated with imported produce originated mostly from Latin America and the Caribbean (64% of outbreaks associated with produce).

FDA Import Violations and Shipment Refusals

As part of FDA's food safety inspection process, the agency inspects imports at the port of entry for signs of adulteration, misbranding, or other violations.[129] For some shipments, FDA may issue import alerts on food imported from foreign countries that could result in the imported product being detained and possibly refused entry into the United States. (For a more detailed discussion of this process, see "FDA's Authority to Refuse Import Shipments.")

Data compiled and verified by FDA and reported in a 2016 study by USDA's Economic Research Service indicate that adulteration accounted for 57% of all FDA import refusals during the 2005-2013 period (totaling 80,825 import refusals) (**Figure 11**). More recent FDA-verified data are not readily available.[130] Based on available FDA-verified data, about half of FDA import refusals due to adulteration were attributable to other sanitary adulteration, such as filthy or decomposed appearance or unregistered processes. About one-third of FDA import refusals due to adulteration were attributable to chemical adulteration (such as unregistered pesticides or other illegal additives), with the remainder due to pathogens and their toxins (such as Salmonella, Listeria, and aflatoxins). Misleading or missing labels accounted for another 41% of all FDA import refusals during the 2005-2013 period (totaling 58,764 import refusals). Another 2% of all FDA import refusals were attributable to other (not easily classifiable) reasons. Overall, countries with the most shipments refused over the period were Mexico, India, and China.[131]

Compared to a previous USDA study covering the 1998-2004 period, USDA's most recent study notes that the number of refused shipments declined relative to the volume of imports over the 2005-2013 period.[132] It is unclear whether this decrease reflects improvements by foreign producers, shippers, and importers in complying with U.S. laws or a lower incidence of FDA inspections and thus fewer detentions and refusals of imported foods, or a combination of both.

Data on FDA import refusals are based on the number of import lines refused, not the volume of products being rejected either as an absolute quantity or as a proportion of total imports. The number of import lines does not necessarily equal the number of shipments. In FY2018, FDA examined more than 16.9 million import lines of FDA-regulated foods.[133] The actual number of import refusals is not available. The rate of violations of FDA-regulated food imports reported by USDA from 2009 to 2013 of about 0.1% to 0.2% of all import lines examined is the most recent available (see data excerpted in **Table 4**). If this rate of refusals continued to be representative in FY2018, then import refusals that year may have numbered around 16,800.

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[129] FFDCA prohibits adulterated or misbranded foods in interstate commerce (21 U.S.C. §§331(a), (b), (c), (k)).

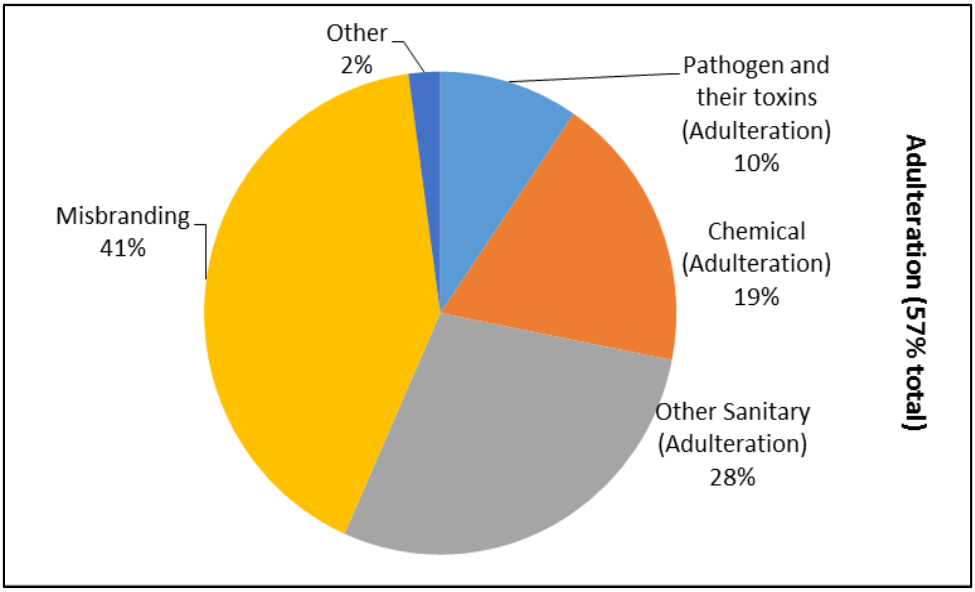
[130] Actual raw data are available from FDA for the years since 2014 as part of its Import Refusal Report data files (https://www.accessdata.fda.gov/scripts/importrefusals/). These data often require additional checks and verification from FDA to remove any duplicate and/or overlapping data. The data files also include other FDA-regulated products: drugs, medical devices, and vitamins.

[131] By 2018 total value, these countries accounted for nearly 40% of the total value of U.S. food imports: Mexico (27.2%), China (7.5%), and India (4.8%) (**Table 2**).

[132] J. Bovay, *FDA Refusals of Imported Food Products by Country and Category, 2005-2013*, Table 3, March 2016. Data for 1998-2004 are from C. Buzby et al., *Food Safety and Imports: An Analysis of FDA Food-Related Import Refusal Reports* (EIB-39), ERS, September 2008.

[133] FDA, *FDA Justification if Estimates for Appropriations Committees*, FY2021, p. 71.

Figure 11. FDA Import Refusals, by Violation Charges, 2005-2013



Source: CRS from data in J. Bovay, *FDA Refusals of Imported Food Products by Country and Category, 2005-2013*, March 2016, Table 3, https://www.ers.usda.gov/webdocs/publications/44066/57014_eib151.pdf. Also see J. Bovay, "Patterns in FDA Food Import Refusals Highlight Most Frequently Detected Problems," *Amber Waves*, 2016.

Notes: USDA/ERS using data from FDA's OASIS (Operational and Administrative System for Import Support) database. Based on a total of 142,679 shipment refusals (2005-2013). Data are calendar year. Percentages reflect share of the total number of FDA import refusals.

Table 7 shows the types of adulteration and mislabeling violations for selected years and totals for 2005-2013. Adulteration violations involving pathogens, toxins, and chemical contamination are of particular concern because of their links to foodborne illness in humans. Misbranding and mislabeling is also a concern given that failure to identify allergens or other undeclared ingredients may lead to illness and even fatalities in some cases.

Data on FDA import refusals by food group indicate that fish and seafood, vegetables and fruits, and spices accounted for more than half of all import refusals during 2005-2013 (**Figure 12**). Most produce refusals were due to violative residues (such as pesticides); filth, microbial pathogens, and bacterial contamination (mostly *Salmonella*); and improper documentation. Import violations involving produce were 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 a number of other Asian nations. Other analysis of U.S. import refusal data showed that more than half of product refusals from 2002 to 2012 (based on number of consignments) were from Brazil, Russia, India, Indonesia, China, and South Africa.[134] Among the leading products refused entry from these countries were fish and seafood products, spices, flavorings and salts, and vegetables and vegetable products. Other research suggests that food import refusals may result in rejected products being diverted to other export markets.[135]

[134] See, for example, M. Kallummal and H. M. Gurung, "Agriculture Products Imported by United States and SPS Measures Based Refusals: Impact of Refusals by the FDA of United States on BRIICS Countries," 2013.

[135] See, for example, K. Baylis et al., "Food Import Refusals: Evidence from the European Union," *American Journal*

Compared to USDA's previous analysis covering the 1998-2004 period, the share of total FDA refusals of imported vegetables and vegetable products has decreased—from 20.6% of all refusals (1998-2004) to 16.1% of refusals (2005-2013). The share of FDA refusals of imported spices increased from 3.8% to 7.7% of all FDA import refusals during the same period (**Figure 12**).[136] Over the 2005-2013 period, adulteration violations accounted for 57% of all violations (compared with 65% over the 1998-2004 period), while misbranding violations accounted for 41% of violations (compared with 33% over the previous study period).[137] **Figure 13** shows the number of shipment violations due to adulteration by the type of adulteration for selected product categories. Additional data and accompanying discussion about these violations is available in the report.

Table 7. Number of Violations, by Selected Charge Code for Selected Years

	2005	2010	2012	2013	Total (2005-2013)
Adulteration					
Filth/filthy	2,121	1,851	1,918	1,598	16,801
Salmonella	874	1,406	1,350	1,150	11,407
No information on scheduled process field	1,495	1,039	944	705	11,163
Unsafe color additive	961	1,555	923	1,097	10,784
Pesticides	1,117	830	1,678	1,920	10,090
Needs food canning establishment number	993	720	516	414	7,598
Manufactured under insanitary conditions	222	95	780	339	2,213
Insanitary	150	270	404	310	1,974
Unsafe food additive	80	215	153	235	1,718
Veterinary drug residue	74	199	135	123	1,466
Poisonous	109	120	226	184	1,319
Misbranding/Mislabeling					
Fails to bear nutrition label	1,035	1,889	1,299	1,401	14,684
No list of ingredients	851	1,088	818	786	8,589
Lacks numerical count label	557	870	640	700	8,123
No English	518	777	583	806	5,934
Labeling	381	386	463	428	3,641
Does not bear usual name	264	328	324	462	3,202
Lacks firm name	318	349	341	322	3,102
Fails to bear artificial color labeling	236	415	293	344	2,984
False or misleading label	119	250	126	176	1,512
Total (excluding "Other" violations)	**13,370**	**16,386**	**15,709**	**15,223**	**142,679**

Source: J. Bovay, *FDA Refusals of Imported Food Products by Country and Category, 2005-2013*, March 2016, Table 5. "Total" includes other shipment refusals not separately listed under each separate "Adulteration" and Misbranding/Mislabeling category (thus totals do not add).

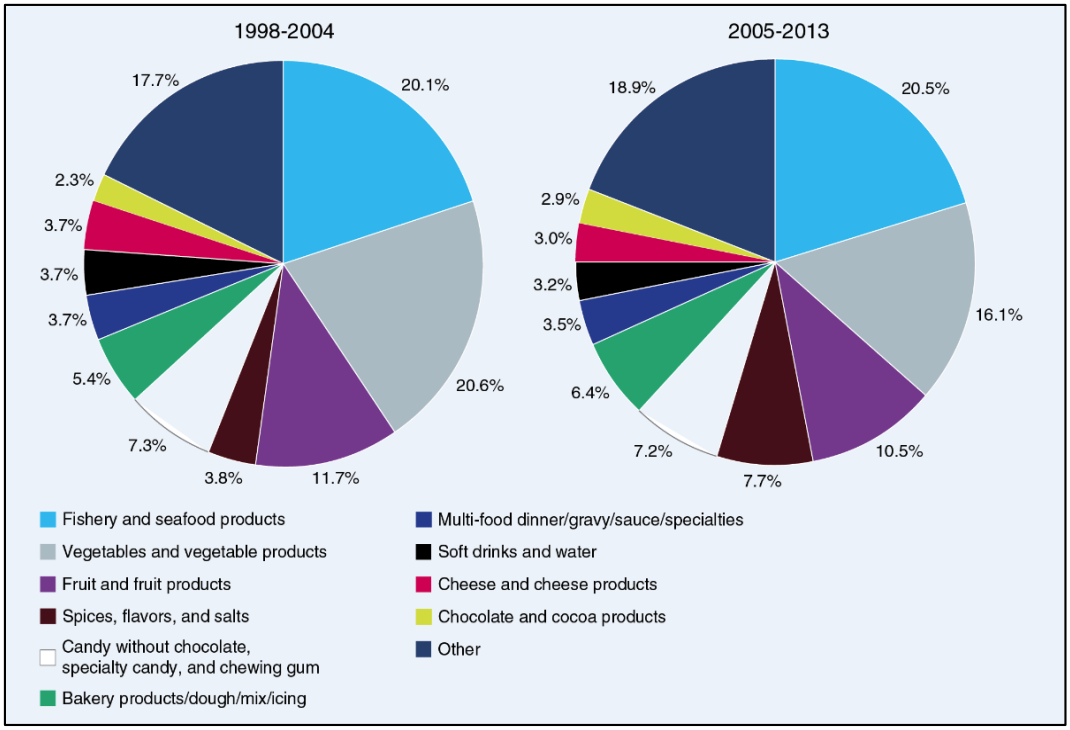
Notes: Data from FDA's OASIS (Operational and Administrative System for Import Support) database.

of Agricultural Economics, vol. 93, no. 2 (January 2011), https://doi.org/10.1093/ajae/aaq149.

[136] In 2013, FDA released its risk profile, *Pathogens and Filth in Spices*, detailing 14 spice-related outbreaks worldwide between 1973 and 2010. The report is available at https://www.fda.gov/food/cfsan-risk-safety-assessments/risk-profile-pathogen-and-filth-spices.

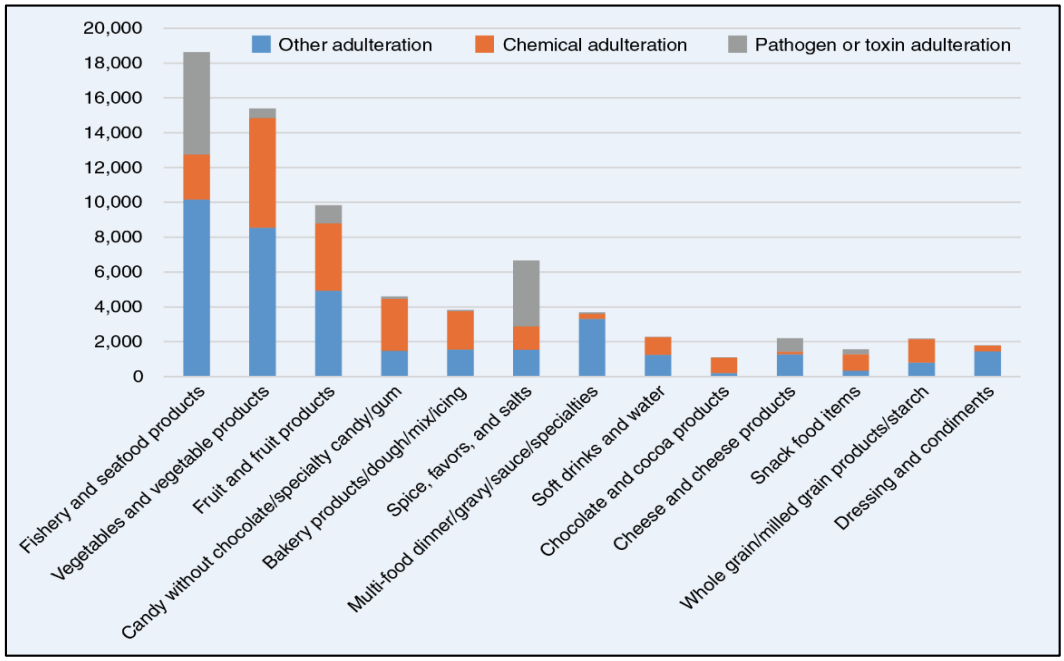
[137] J. Bovay, *FDA Refusals of Imported Food Products by Country and Category, 2005-2013*, March 2016.

Figure 12. FDA Imported Food Refusals, by Percentage Share



Source: J. Bovay, *FDA Refusals of Imported Food Products by Country and Category, 2005-2013*, March 2016.
Notes: Data from FDA's OASIS (Operational and Administrative System for Import Support) database.

Figure 13. Number of Adulteration Violations, 2005-2013



Source: J. Bovay, *FDA Refusals of Imported Food Products by Country and Category, 2005-2013*, March 2016.
Notes: Data from FDA's OASIS (Operational and Administrative System for Import Support) database.

USDA Import Violations and Shipment Refusals

As part of its food safety inspection process, FSIS conducts port-of-entry reinspection of imported meat, poultry, and egg products, as well as port-of-entry reinspection of imported Siluriformes fish or catfish. These products have already been inspected and passed by an equivalent foreign inspection system, but reinspection provides a means of verifying the equivalence of a foreign country's inspection system on an ongoing basis. (For a more detailed discussion of this process, see "FSIS's Authority to Refuse Import Shipments.")

Information on shipment refusals of USDA-regulated meat and poultry products comes from a different inspection regimen than FDA's, and the data collected on product refusals are not comparable to data for FDA-regulated food products. Within USDA, routine reinspection includes the Certification and Label Verification Types of Inspection as well as verification of product condition and identification of shipping damage. Products are refused reinspection (i.e., not allowed entry) if the foreign country is not eligible, the foreign establishment is not listed, USDA has placed animal disease restrictions on the country, the product presented for reinspection is not eligible, or duplicate shipping marks are identified. Products are also rejected for reinspection if they fail to meet U.S. import requirements. If a shipment is refused entry, the importer of record has options including destruction, re-export if allowed, conversion to animal food with FDA approval, or being allowed to rectify the situation.

Compared to data and analysis of FDA import refusals, information on USDA refusals is more limited. For meat and poultry imports, available data are from FSIS quarterly enforcement reports and are based on product reinspections.[138] Statistics on refused or rejected shipments are measured by volume of trade (i.e., number of pounds of product) and not by the number of import or entry lines refused or rejected. In addition, USDA does not make information available on the type of violations (e.g., whether a shipment was refused due to adulteration or mislabeling or other types of violations). Moreover, USDA does not make information available on the country of origin of refused/rejected shipments. FSIS does report the volume of shipments initially refused but then later rectified and accepted.

Table 6 summarizes available data from FSIS quarterly enforcement reports during the 2005-2018 period. Data are based on reports of the total volume of meat and poultry products presented to FSIS for import reinspection and the quantity that was refused entry into the United States (adjusted for product initially refused entry but then later rectified and accepted for entry).

In FY2019, a reported 3,954 million pounds of imported meat and poultry products were presented to USDA for reinspection. Of this total, about 5.3 million pounds were refused/rejected (excluding products subsequently rectified and allowed entry), resulting in a refusal/rejection rate of 0.13% of imported meat and poultry products for the year.[139] Over the 2005-2019 period, import refusals of USDA-regulated meat and poultry products ranged from 0.11% to 0.35% of annual reinspections (**Table 6**).

A reported 7.5 million pounds of imported egg products were presented to USDA for reinspection in FY2019. Of this total, 5,000 pounds were refused entry into the United States—a refusal rate of 0.07% (excluding refused product rectified).[140] Over the 2005-2019 period, import refusals of USDA-regulated egg products ranged from zero to 0.59% of annual reinspections (**Table 6**).

[138] FSIS *Quarterly Enforcement Reports*, http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/regulatory-enforcement/quarterly-enforcement-reports.

[139] CRS from FSIS data, "Quarterly Enforcement Report (July 1, 2018, through September 30, 2019), Table 3a.

[140] CRS from FSIS data, "Quarterly Enforcement Report (July 1, 2018, through September 30, 2019), Table 3b.

Congressional Considerations

A steady increase in food imports—a result of globalization and consumer desire for a wider variety of foods year-round—has generated growing concerns about whether current federal programs sufficiently ensure the safety of these imports. Despite changes enacted as part of FSMA, GAO has continued (since 2007) to regularly place federal oversight of U.S. food safety on its biennial *High Risk* list[141] and has recommended that the United States take steps to "improve the federal food safety oversight system and address ongoing fragmentation."[142] Congress may consider whether changes are needed to improve the safety of imported foods.

Following is a brief discussion of these and other selected topics related to the safety of imported food products and ingredients.

FDA Inspections of Foreign Facilities and Imported Foods

FSMA provided FDA with additional authorities regarding inspection and oversight; however, FDA continues to physically examine about 1% of the total number of food import lines each year—rates similar to that prior to FSMA. Certain mandates—including an increase in the number of facility inspections and an increase in the number of FDA inspectors—have not kept pace with targets set by Congress in FSMA. For example, in FY2019, FDA conducted 1,747 facility inspections of foreign establishments, compared to nearly 3,300 facility inspections that were expected under FSMA (**Table 5**, **Figure 7**). FSMA further required that FDA increase the number of food safety inspectors to 5,000 staff, but actual staffing levels remain below mandated levels, totaling 3,905 full-time equivalents in FY2019. FDA continues to issue import alerts on a range of imported foods, including pet food, farmed seafood, dairy products, and ingredients.

As part of its ongoing oversight, Congress may continue to monitor FDA's progress in implementing FSMA and examine the agency's ability to ensure the safety of imported foods. Congress may also consider whether the agency has an adequate inspection structure and the necessary resources to meet the targets mandated in FSMA. Although FSMA did not provide additional resources to FDA to implement some of the mandates enacted in FSMA, Congress has made funding for FDA's food safety activities and FSMA implementation a priority. Since FSMA became law in 2011, congressional appropriators have increased annual funding for the FDA Foods Program by $204.3 million—an increase of about 24% between FY2011 and FY2018—largely in an effort to support FDA's implementation of FSMA.[143] This funding is augmented by authorized user fees levied on imported foods.[144] Some groups, however, call for additional funding for FDA to implement FSMA and for enhanced cooperation with states, with a focus on produce safety, import safety, and training/education, among other priorities.[145]

[141] GAO, *High-Risk Series: Substantial Efforts Needed to Achieve Greater Progress on High-Risk Areas*, GAO-19-157SP, March 6, 2019, pp. 195-198.

[142] GAO, *A National Strategy Is Needed to Address Fragmentation in Federal Oversight*, GAO-17-74, January 13, 2017. For related background, see CRS Report RS22600, *The Federal Food Safety System: A Primer*.

[143] See CRS Report R45413, *FY2018 and FY2019 Agriculture Appropriations: Federal Food Safety Activities*.

[144] See FDA's website at https://www.fda.gov/food/food-safety-modernization-act-fsma/fees-under-fsma.

[145] Alliance for a Stronger FDA press release, March 21, 2020, https://strengthenfda.org/2020/03/20/alliance-for-a-stronger-fda-fy-21-ask-and-explanation/.

Safety of Imported Fish and Seafood

The safety of fish and seafood—most of which is imported—continues to be an active congressional issue. In particular, there has been long-standing concern about the safety of imported fish and seafood from China and some Southeast Asian countries,[146] and some Members of Congress have sought to require food safety assurances as part of international trade liberalization discussions.[147] GAO has continued to highlight a range of concerns involving imported fish and seafood safety broadly focused on FDA's oversight. GAO recommendations include the need to improve FDA's oversight of the food safety system of supplier countries for individual food products (such as seafood) and not just a country's food safety systems as a whole. Other recommendations include the need to monitor whether FDA is meeting its audit goals and expectations for sampling and inspections to support its removal decisions for seafood import alerts, and the need for drug residue testing methods and corresponding maximum residue levels for imported seafood.[148]

GAO recommends that catfish inspection be subject to FDA and not USDA inspection, citing concerns about the potential for overlap or inefficient use of resources, inconsistent oversight of imported seafood, and additional costs associated with FSIS's catfish inspection program.[149]

Congress may wish to continue monitoring the safety of imported fish and seafood and may consider whether additional requirements are needed to address such imports. For example, legislation reintroduced in the 116th Congress (Safe Food Act of 2019, S. 1995, H.R. 4755) would establish a single food safety agency to address potential overlap and inefficiencies in the U.S. food safety system, among other concerns. Legislation reintroduced in the 115th Congress (H.R. 6212, Imported Seafood Safety Standards Act) would have amended FDA food safety laws to require an annual inspection of each foreign facility that exports seafood to the United States to ensure compliance with U.S. standards for seafood manufacturing, processing, and holding.

Congress has also addressed concerns about the safety of seafood imports through the annual Agriculture appropriations process. For example, for both FY2019 and FY2020 Congress provided $15 million for FDA to conduct inspections of foreign seafood manufacturers and field examinations of imported seafood.[150] Congress also appropriated $20 million in FY2020 to remain available until expended "for necessary expenses of plans, construction, repair, improvement, extension, alteration, demolition and purchase of fixed equipment or facilities of or used by FDA for seafood safety."[151]

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[146] See testimony before the U.S.-China Economic and Security Review Commission, "Chinese Seafood: Safety and Trade Issues," April 24-25, 2008, https://www.uscc.gov/hearings/hearing-chinese-seafood-safety-and-trade-issues.

[147] For example, briefing hosted by Representative Rosa L. DeLauro, "Trans-Pacific Partnership and Its Impact on Seafood Import Safety," September 10, 2013; and Center for Food Safety, "Seafood Safety and the Trans-Pacific Partnership," December 5, 2014, http://www.centerforfoodsafety.org/files/tpp-and-seafood-fact-sheet_00590.pdf.

[148] GAO, *Imported Seafood Safety: Actions Needed to Improve FDA Oversight of Import Alert Removal Decisions* (GAO-20-62; November 6, 2019); *Imported Seafood Safety: FDA and USDA Could Strengthen Efforts to Prevent Unsafe Drug Residues* (GAO-17-443; September 2017); *FDA Can Better Oversee Food Imports by Assessing and Leveraging Other Countries' Oversight Resources* (GAO-12-933; October 31, 2012), and *Seafood Safety: FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources* (GAO-11-286; April 2011). Also see GAO, *Status of Issues Related to Catfish Inspection* (GAO-17-289T; December 7, 2016), and *Responsibility for Inspecting Catfish Should Not Be Assigned to USDA* (GAO-12-411, June 8, 2012).

[149] GAO, *Status of Issues Related to Catfish Inspection* (GAO-17-289T; December 7, 2016), and *Responsibility for Inspecting Catfish Should Not Be Assigned to USDA* (GAO-12-411, June 8, 2012).

[150] P.L. 116-6, H.Rept. 116-9 (Conference Report); and P.L. 116-94.

[151] P.L. 116-94, §780.

Safety of Meat Imports from China

Some in Congress have continued to question the safety of imported foods under USDA's jurisdiction and have scrutinized the agency's process for determining the eligibility of foreign establishments to export meat (including catfish) and poultry products to the United States. In particular, some Members of Congress have expressed concerns about USDA-regulated products originating from certain countries, such as China and some Southeast Asian countries.[152] These Members cite numerous past incidents of unsafe or tainted food, the perception of poor hygiene practices in production and manufacturing, alleged lack of adequate regulatory oversight from the Chinese government, and persistent evidence of economically incentivized food fraud with public health implications. In light of these ongoing concerns, Congress could consider whether additional requirements may be necessary to address imports under USDA's jurisdiction.

One such long-standing issue for some in Congress involves the importation of poultry products from China.[153] In November 2019, FSIS issued a final rule that determined that China's poultry slaughter system is equivalent to its U.S. counterpart, and therefore China could export domestically slaughtered poultry meat to the United States.[154] The final rule allows China to export only fully cooked but not shelf-stable products.[155] However, concerns persist in Congress regarding China's food safety regime for poultry products.[156] In response to concern about China's food safety record, Congress acted to restrict imports of poultry products from China in the FY2020 Agriculture appropriations process.[157] Congress may continue to monitor imported poultry products from China and could extend such restrictions. The United States did not record any imported poultry meat from China in 2018 and 2019.

Harmonization of Global Food Safety Standards

Despite requirements under FSMA for FDA to expand the technical, scientific, and regulatory capacity of foreign food suppliers, some suppliers in low- and middle-income countries may face challenges meeting enhanced food safety requirements and standards as well as additional FSMA-related user fees associated with imported foods. This could heighten trade tensions about potential non-tariff barriers to trade and result in international trade disputes.

As Congress exercises its legislative, oversight, and advisory role with respect to U.S. trade negotiations, it may consider how best to leverage future trade agreements and U.S. participation in international bodies, such as the WTO and the Codex Alimentarius Commission, to further its

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[152] For example, H.R. 3337 (115th Congress) and various appropriations provisions, as well as congressional hearings such as a 2013 House Foreign Affairs Committee hearing ("Threat of China's Unsafe Consumables," May 8, 2013) and a 2014 Congressional-Executive Commission hearing ("Pet Treats and Processed Chicken from China," June 17, 2014). For related background, see CRS In Focus IF10465, *China's Efforts to Address Ongoing Food Safety Concerns*.

[153] For more information, see CRS Report R46242, *Major Agricultural Trade Issues in 2020*; and CRS In Focus IF10148, *Chicken Imports from China*.

[154] 84 *Federal Register* 60318, November 8, 2019. The final rule requires China to comply with any APHIS animal health requirements, and all imports from China will be subject to reinspection. These actions were the culmination of a process that began in 2005, when China requested that USDA evaluate its poultry inspection system.

[155] Allowable products include those that undergo a full lethality heat process (cooking) and require freezing or refrigeration for food safety. China is not permitted to export raw poultry products due to animal disease risks.

[156] See, for example, testimony presented during a Congressional-Executive Commission on China, "Pet Treats and Processed Chicken from China," June 17, 2014," http://www.cecc.gov/events/hearings/pet-treats-and-processed-chicken-from-china-concerns-for-american-consumers-and-pets.

[157] Section 738 (Division B) of P.L. 116-94 prohibits USDA from using any appropriated funds to purchase Chinese raw or processed poultry products for feeding programs, including the school lunch and school breakfast programs.

objectives for enhancing the safety of imported foods. Differences between the United States and its trading partners in food safety regulations and standards may be addressed through further harmonization of standards on a multilateral level or through bilateral free trade agreements. Both the SPS and TBT agreements encourage the international harmonization of food standards through international standard setting organizations, including Codex.[158] The U.S. Codex Office, housed at USDA, manages the planning, policy development, support, and coordination for U.S. involvement in Codex.[159] This work is ongoing.

[158] See Codex's website at http://www.codexalimentarius.org/. Other recognized standard-setting organizations include the World Organisation for Animal Health (OIE, http://www.oie.int/index.php) and the International Plant Protection Convention (IPPC, http://www.ippc.int/).

[159] See https://www.usda.gov/codex.

Appendix. Role of Other Federal Agencies

Other federal agencies beyond FDA and FSIS have responsibilities for overseeing U.S. food imports. For example, USDA's Animal and Plant Health Inspection Service (APHIS) is responsible for protecting plant and animal resources from domestic and foreign pests and diseases. The Department of Homeland Security (DHS) is responsible for coordinating agencies' food security activities, including border inspections. The U.S. Environmental Protection Agency (EPA) is responsible for ensuring that the chemicals used on food crops do not endanger public health. Other federal agencies are involved in various food quality and inspection programs.

USDA, Animal and Plant Health Inspection Service

APHIS's authority over agricultural imports is largely provided by the Plant Protection Act, the Animal Health Protection Act, and the Agricultural Bioterrorism Act of 2002. These laws authorize APHIS to conduct agricultural import inspections and administer animal and plant health import permits.[160] These laws provide a legal basis for ensuring that imports are free of foreign diseases or pests that would threaten U.S. animal or plant resources.

Plant Protection Act

The Plant Protection Act (PPA, 7 U.S.C. §§7701 et seq.) is the primary federal law governing plant pests in foreign and interstate commerce, covering agricultural commodities, plants, biological control organisms, articles that might be infested, means of transportation, and other pathways for moving pests. The law consolidates several plant quarantine authorities, some dating back to the 1880s.[161] It authorizes APHIS to inspect foreign plant imports; quarantine any state or premise infested with a new pest or noxious weed; and cooperate with states, localities, and others to prevent the spread of, or eradicate, invasive pests and diseases. It also authorizes APHIS to prohibit or restrict the importation, exportation, and interstate movement of plants, plant products, certain biological control organisms, noxious weeds, and plant pests. PPA further requires phytosanitary certificates for many plants and plant product imports and mandates more detailed import permits for most foreign fruits and vegetables. APHIS administers these authorities in collaboration with state departments of agriculture and their plant protection boards.

PPA gives USDA authority to use a wide range of measures to prevent entry of plants carrying alien pests and prevent the spread of new pests that are not already widespread in the United States. Preventive measures include inspections, surveillance, quarantines, treatments, or destruction. USDA can develop lists of organisms that can or cannot enter the United States and goods that can be imported from specific countries, and it has the authority to certify that U.S. agricultural exports meet the phytosanitary standards of other countries. USDA can require

[160] For more information on APHIS import certificates, see CRS Report R45457, *Animal and Plant Health Import Permits in U.S. Agricultural Trade*.

[161] PPA became law in June 2000 as part of the Agricultural Risk Protection Act (P.L. 106-224, Title IV). The law consolidated and superseded several U.S. plant health laws, including (1) the Act of August 20, 1912 (known as the Plant Quarantine Act, 7 U.S.C. §§151-164a, 167); (2) the Federal Plant Pest Act (7 U.S.C. §§150aa et seq. and 7 U.S.C. §147a); (3) Section 102 (a)-(e) of the Department of Agriculture Organic Act of 1944 (7 U.S.C. §147a); (4) the Federal Noxious Weed Act of 1974 (7 U.S.C. §§2801 et seq.), except Sections 1-15 of that act (7 U.S.C. §2801 note and 7 U.S.C. §2814); (5) the Joint Resolution of April 6, 1937 (commonly known as the Insect Control Act, 7 U.S.C. §§148 et seq.); (6) the Halogeton Glomeratus Act (7 U.S.C. §§1651 et seq.); (7) the Golden Nematode Act (7 U.S.C. §§150 et seq.); and (8) Section 1773 of the Food Security Act of 1985 (P.L. 99-198; 7 U.S.C. §148f). See also USDA's website at http://www.aphis.usda.gov/plant_health/plant_pest_info/ and information arranged by major pest.

private parties to take remedial actions without cost to the government but must select the least costly effective measure. The law also clarifies the extent of USDA's authority to regulate biological control agents and encourages the USDA, other federal agencies, and the states to facilitate biological control of pests and other invasive species whenever feasible. Violations may be subject to civil and criminal penalties.

According to APHIS, in 2019 the agency issued more than 23,000 import permits for plants and plant products and responded to over 19,400 inquiries about imports and plant health permits.[162] It inspected and cleared 2.5 billion pounds of fresh fruits and vegetables and 1.15 billion plants from 25 countries before they were shipped to the United States. Among its other responsibilities, in 2019 APHIS cleared 20,917 imported shipments containing nearly 1.7 billion plant units (cuttings, rooted plants, tissue culture) and nearly 422 tons of seeds and prevented entry of 1,119 quarantine-significant pests at U.S. plant inspection stations. Also in 2019, APHIS intercepted 79,388 pests found during CBP inspections of 30,227 ships and more than 1.2 million cargo, mail, and express carrier shipments.

In addition, PPA authorizes USDA to transfer funds from the Commodity Credit Corporation (CCC)[163] or other USDA program to implement an emergency program to control specific plant pests of concern, subject to Office of Management of Budget (OMB) review.[164] Under some circumstances, USDA may declare an extraordinary emergency and take action to control outbreaks of new pests and may compensate growers for losses caused by the control program.[165] States may also petition USDA for a "special need" exception to federal rules to request permission to impose restrictions beyond what is required by APHIS.[166] In addition, "any person" (or state) may petition USDA to add or remove plant pests from federal regulation.[167]

Animal Health Protection Act

The Animal Health Protection Act (AHPA, 7 U.S.C. §§8301 et seq.) is the primary federal law governing the protection of animal health and gives USDA's APHIS broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The law consolidates existing animal quarantine and related laws (some dating back to the late 1800s) into a single statutory framework.[168] The law authorizes USDA to prohibit or restrict the import or export of any animal or related material if necessary to prevent the spread of any livestock or poultry pest or disease, including the quarantine of animals. USDA has the authority to hold, seize, treat, or destroy any

[162] APHIS, *2019 Impact Report*, https://www.aphis.usda.gov/publications/aphis_general/rpt-aphis-impact-2019.pdf.

[163] USDA's CCC is a government-owned corporation that is authorized to borrow up to $30 billion at any one time from the U.S. Treasury. The CCC is mainly a financing mechanism for farm bill programs such as commodity price and income supports, agricultural conservation, export assistance, and other mandated authorizations. For more information, see CRS Report R44606, *The Commodity Credit Corporation: In Brief*.

[164] 7 U.S.C. §§7751 and 7772. Such cases often occur in response to larger-scale plant and animal pest and disease outbreaks where the costs are too large to cover within existing appropriations or to respond to new and emerging agricultural issues that warrant a federal role.

[165] 7 U.S.C. §7715.

[166] 7 U.S.C. §7756. Procedures on how to process a special needs request are at APHIS, "USDA Establishes Process for States to Impose Additional Restrictions," http://www.aphis.usda.gov/plant_health/special_needs_request/index.shtml.

[167] 7 U.S.C. §7711.

[168] AHPA became law in May 2002 as part of the Farm Security and Rural Investment Act of 2002 (P.L. 107-171, Title X, §10401) and consolidated and superseded several U.S. animal quarantine laws across several previous statutes (including 21 U.S.C. §§101-135b and 19 U.S.C. §1306, among others).

animal and to limit movement of invasive animal species. Under AHPA, most meat and poultry imports must be accompanied by a veterinary permit.

According to APHIS, in 2019 the agency issued 17,933 import permits for live animals, animal products, organisms, and vectors.[169] It conducted 1,701 foreign animal disease investigations, with 79% targeting vesicular disease, mainly due to the ongoing Senecavirus A in pigs in the United States and Canada. Among its other responsibilities, in 2019 APHIS monitored U.S. livestock for disease, including 630,000 tests for brucellosis; 209,608 animal inspections or treatments for cattle fever tick; 815,000 tests for cattle tuberculosis; 10,000 tests for classical swine fever (with 1,550 targeted tests for African Swine Fever); 80,000 tests for swine pseudorabies; and 34,000 tests for scrapie.

Similar to PPA, AHPA provides authority for USDA to make emergency fund transfers and to make determinations of extraordinary emergencies so that it can, under some circumstances, take actions within a state. The law also gives USDA the authority to enter into agreements with foreign governments, state governments, or other organizations to protect animal health. AHPA requires that compensation be provided to farm owners based on the fair market value of destroyed animals and related material. The law authorizes USDA to transfer funds from the CCC or other USDA programs to implement an emergency control program, subject to OMB review.[170]

Agricultural Bioterrorism Act of 2002

Enacted as part of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. §262a), the Agricultural Bioterrorism Act of 2002 (7 U.S.C. §8401) provides for the regulation of certain biological agents and toxins by USDA and HHS and provides for interagency coordination between the two departments regarding certain biological agents and toxins.[171] Both APHIS and the CDC have primary responsibility for implementing the law's provisions. The law authorizes APHIS to regulate a list of biological agents and toxins that have the potential to pose a severe threat to animal health and safety, plant health and safety, or the safety of animal or plant products.[172]

DHS, Customs and Border Protection

After the 2001 terrorist attacks, Congress created DHS, whose agents now play a major role in inspections of imports, including food and agricultural products. Most of APHIS's border inspection functions and personnel were transferred to DHS by the Homeland Security Act of 2002 (P.L. 107-296). CBP was created in 2003 through a merger of the former U.S. Customs Service and the agricultural inspection portion of USDA's APHIS.[173]

CBP enforces FDA and USDA regulations at ports of entry. Import security measures, in conjunction with existing CBP border inspections, are intended to address concerns about possible contaminated food imports. CBP is responsible for monitoring goods and materials in cargo shipments arriving at all U.S. ports of entry and is a regular participant in inspection

[169] APHIS, *2019 Impact Report*, https://www.aphis.usda.gov/publications/aphis_general/rpt-aphis-impact-2019.pdf.

[170] AHPA (7 U.S.C. §§8310 and 8316).

[171] P.L. 107-188, Title II, §§201-231, "Enhancing Controls on Dangerous Biological Agents and Toxins."

[172] The list of select agents and toxins is available at https://www.selectagents.gov/SelectAgentsandToxins.html.

[173] Memorandum of Agreement, DHS Agreement# BTS-03-0001 and USDA-APHIS Agreement# 03-1001-0382-MU, March 2003, http://www.aphis.usda.gov/plant_health/moa_dhs/downloads/article1.pdf.

procedures carried out at every port of entry nationwide.[174] CBP's border inspections help prevent the entry of harmful plant and animal pests and diseases; interdict potential agro- and bioterrorism threats; and ensure that the required permits, sanitary certificates (for animal products), and phytosanitary certificates (for plant products) accompany each product shipment.[175] CBP inspections do not specifically address intentional contamination of food and food ingredients. As part of its role in enforcing plant and animal regulations, CBP has the authority to detain, where necessary, imported or exported products pending their clearance by agency inspectors.

Imported products must meet the same standards as domestic goods and must contain informative and truthful labeling in English. Existing U.S. trade laws, such as general requirements under the Tariff Act of 1930 (19 U.S.C. §1304), require all imported articles to be marked with the English name of the country of origin.[176] Other labeling requirements also apply under other laws that govern both FDA and USDA's authority over food. For example, FDA requirements under FFDCA require that a food label must contain specific information. However, as noted by FDA, "The law does not specifically require that the country of origin statement be placed on the [principal display panel, or the label panel], but requires that it be conspicuous."[177] Certain labeling requirements for meat and poultry products are also required under laws administered by FSIS. The country of origin must appear in English on containers of all meat and poultry products entering the United States.[178] Additional country-of-origin requirements may apply for some foods under other USDA-administered programs.[179]

Environmental Protection Agency

EPA has the statutory responsibility for ensuring that the chemicals used on food crops do not endanger public health. Among its responsibilities, EPA's Office of Pesticide Programs is the part of the agency that registers new pesticides and regulates the amount of pesticide chemical residues that can remain on or in food or animal feed. Specifically, EPA sets *tolerances*—the maximum amount of a pesticide residue that is allowed to remain on or in a food or animal feed.[180] Most countries refer to tolerances as maximum residue limits (MRLs). By law, residue of pesticides for which EPA has not set a tolerance or an exemption from a tolerance is considered unsafe and therefore prohibited in foods. The Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. §§136 et seq.), and FFDCA, as amended (21 U.S.C. §§301 et seq.), are the primary authorities for EPA's activities in this area.

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[174] The authority to search, inspect, and examine merchandise entering the United States is in Title 19, Section 1467, of the *United States Code*; regulations are at Title 19, Section 162.6, of the *Code of Federal Regulations*. Other search authorities include Title 19, Sections 482, 1496, 1581, and 1582, of the *U.S. Code*. These authorities rest with the U.S. Treasury, which typically delegates its authority via DHS to CBP.

[175] USDA, "Importing Food and Agricultural Products into the United States," August 2012.

[176] 19 C.F.R. §134. See CBP's *Compliance Policy Guide*, "CPG Sec. 560.200 Country of Origin Labeling," https://www.fda.gov/media/71994/download.

[177] 21 C.F.R. §101. See FDA, *Guidance for Industry: A Food Labeling Guide*, January 2013, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide.

[178] Regulations are at Title 9, Sections 327.14 and 381.205, of the *Code of Federal Regulations*.

[179] This includes Country of Origin Labeling requirements (P.L. 107-171, §10816, 7 U.S.C. §1638a et seq.), the Perishable Agricultural Commodities Act of 1930 (7 U.S.C. §499a et seq.), and the Produce Agency Act of 1937 (7 U.S.C. §1622). See CRS Report R42771, *Fruits, Vegetables, and Other Specialty Crops: Selected Farm Bill and Federal Programs*.

[180] See EPA's website at https://www.epa.gov/pesticide-tolerances.

EPA does not have the authority to enforce the tolerances it sets; rather, it coordinates with USDA and FDA, which have enforcement authority, on which pesticides to include in their monitoring and enforcement programs. FSIS monitors meat, poultry, and processed egg products for residues that exceed allowable levels,[181] while FDA monitors residues in the foods it inspects.[182] FSIS and FDA have jurisdiction over both domestic and imported foods.[183]

MRLs often vary among countries given different food safety regulations and perceived risks, which can result in differences in import requirements across countries, complicating international trade.[184] USDA maintains a database of MRL standards on imported food products to help ensure that the imports are free from contaminants.[185] USDA's database specifies maximum acceptable levels of pesticides and veterinary drugs in food and agricultural products in the United States and many of its trading partners. It includes MRLs for fruit, vegetable, and nut commodities and pesticides approved for use on those commodities by EPA. It also includes pesticide and veterinary drug residue tolerances in major export markets for hay, feed, grains, oilseeds, poultry, eggs, meat, and dairy. The database does not include processed food products. The Codex Alimentarius Commission, an international standard setting organization, also maintains a series of searchable online databases of numerical Codex standards for food additives, veterinary drug maximum residue levels, and pesticide maximum residue levels.[186]

Other Agency Authorities and Activities

Other federal agencies are involved in various food quality and inspection programs. Examples include USDA's voluntary product quality, grading, and standards for selected foods and voluntary seafood and fisheries inspections conducted by agencies within NOAA, a scientific agency within the U.S. Department of Commerce. Although these programs are not regulatory in nature and are not intended to address potential food safety or food fraud concerns, food quality, and grading standards, they provide for product oversight as part of USDA's product quality and marketing grades and standards, thus providing an added control layer. Food quality and grading standards also provide a product benchmark for certain foods or food ingredients.[187]

In addition, certain *standards of identity* for some products—mostly value-added or processed foods—establish a common name and set of content requirements for a food product and refer to

[181] See FSIS's National Residue Program at https://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/chemistry. AMS also implements the Pesticide Data Program, which surveys pesticide residues in fruits, vegetables, and other foods (https://www.ams.usda.gov/datasets/pdp).

[182] See FDA's website at https://www.fda.gov/food/pesticides/pesticide-residue-monitoring-program-reports-and-data.

[183] In 2014, GAO conducted a review of the reliability and sampling methods of pesticide residues in food and recommended that FDA and USDA make certain changes to the agencies' monitoring and data collection efforts. See GAO, *FDA and USDA Should Strengthen Pesticide Residue Monitoring Programs and Further Disclose Monitoring Limitations*, GAO-15-38, October 2014.

[184] See, for example, D. J. Miller, "North American International Harmonization Efforts for Pesticides: An Update on Current Status and Activities," 48th Codex Committee on Pesticide Residues, April 2016; and J. C. Buzby and L. Mitchell, "Food Safety and Trade: Regulations, Risks, and Reconciliation," *Amber Waves*, November 1, 2003. See also GAO, *U.S. and Mexican Fruit and Vegetable Pesticide Programs Differ*, T-RCED-93-9, February 1993.

[185] USDA's MRL database is available at https://www.fas.usda.gov/maximum-residue-limits-mrl-database.

[186] Codex's databases are at http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/en/.

[187] At the federal level, three agencies have the authority to set requirements for foods entering interstate commerce: FDA (covering 300 identity standards in 20 categories of food, not including meat and poultry products [21 C.F.R. Parts 130-169]); FSIS (covering most meat [9 C.F.R. Part 319] and poultry [9 C.F.R. Parts 381.155-381.174] products); and the Alcohol and Tobacco Tax and Trade Bureau (TTB) (covering malt beverages and distilled spirits, such as vodka, whiskeys, gin, brandy, and flavored liqueurs [27 C.F.R. Parts 5.22, 5.27, and 5.35]).

requirements that define the composition of food, prescribing both mandatory and optional ingredients in a product. Standards of identity cover a wide range of products and ingredients for both FDA- and USDA-regulated food products and apply equally to domestically produced and foreign-origin products. FDA and USDA standards of identity are not addressed in this report.

USDA, Agricultural Marketing Service

Among its responsibilities, AMS oversees product quality and marketing grades and standards for a range of crops and agricultural products, including imported products in certain circumstances. AMS also certifies and verifies quality programs and conducts quality-grading services, which are generally user-fee-funded and voluntary in nature and in most cases do not directly address adulteration of food and food ingredients.[188] USDA programs establishing quality grade standards to encourage uniformity and consistency in commercial practices are provided for in the Agricultural Marketing Act of 1946.[189] AMS develops quality grade standards for commodities as needed by the agriculture and food industry for a range of products, including cotton, dairy products, fresh and processed fruits and vegetables (and fruits and vegetables for processing), nuts and other specialty crops, livestock (including wool and mohair), poultry shell eggs,[190] rabbits, seafood, and tobacco.[191] AMS also surveys pesticide residues in fruits, vegetables, and other foods under its Pesticide Data Program.

Under federal-state agreements, AMS-licensed state employees work where needed: in fields during harvest; at land, air, and sea ports of entry; and at packing houses, processing plants, warehouses, and federal and federal-state terminal markets. Grading is paid for by user fees and is voluntary unless the commodity is regulated for quality under a marketing order or agreement, subject to export requirements, or purchased by USDA or another federal agency for distribution (e.g., through the school lunch program or the military). Shipments of any imported commodity whose domestic production is under a marketing order or agreement must receive AMS grading to assure that the product is comparable to U.S. grade, size, quality, and maturity requirements.

In addition, USDA marketing orders and agreements for selected crops and agricultural products regulate certain marketing aspects, including quality standards and volume controls for the marketing order commodities. Regulations may include quality standards, grading and inspection requirements, packaging standards, and research and development projects, as authorized by the Agricultural Marketing Agreement Act of 1937 (AMAA).[192] Imported products of commodities covered by a marketing order or agreement are similarly covered. AMAA Section 8e applies to specific fruit, vegetable, and specialty crop imports into the United States, requiring that imported products meet the same or comparable grade, size, quality, and maturity standards as domestic products covered by a federal marketing order. The law requires that the importer of record have each lot (shipment) imported inspected for grade and quality by AMS.[193] Imports of a commodity

[188] USDA, "Grades and Standards," http://www.ams.usda.gov/standards/. See also USDA, "Understanding Food Quality Labels," https://www.ams.usda.gov/sites/default/files/media/AMSProductLabelFactsheet.pdf.

[189] 7 U.S.C. §1621 et seq.

[190] AMS also administers the egg surveillance program requiring quarterly inspections of egg facilities (21 U.S.C. §§1031-1056; 7 C.F.R. Part 57). Additional information is at https://www.ams.usda.gov/rules-regulations/eggs.

[191] USDA, "Grades and Standards," http://www.ams.usda.gov/standards/. See also USDA, "Understanding Food Quality Labels," https://www.ams.usda.gov/sites/default/files/media/AMSProductLabelFactsheet.pdf.

[192] 7 U.S.C. §§601, 602, 608a-608e, 610, 612, 614, 624, 627, 671-674. Regulations are at 7 C.F.R. Subchapter C. In addition to fluid milk sales, a list of fruit and vegetable commodities covered by a marketing order or agreement is available at https://www.ams.usda.gov/rules-regulations/moa/commodities.

[193] The importer is defined as the party responsible for clearing the goods through customs and could be the shipper, the

are regulated by AMAA Section 8e only during the period of time that the domestic commodity is also being shipped and regulated and not during the period when imports complement U.S. production (i.e., not during the U.S. winter production window).[194]

NOAA, National Marine Fisheries Service (NMFS)

NMFS administers a number of seafood and fisheries safety and sanitation programs. Its voluntary fee-for-service seafood and fisheries inspection program focuses on marketing and product quality under the authority of the Agricultural Marketing Act of 1946 (7 U.S.C. §1621 et seq.).[195] The program offers additional levels and types of inspection that exceed FDA requirements, which program participants must also meet. Examples include onsite NOAA inspections during production hours, certification that plants or vessels meet specified sanitation requirements, quality inspections of individual product lots, and laboratory testing of products, among other services. NMFS works with FDA, which helps provide training and other technical assistance to NMFS. As part of its guidance, NOAA identifies common seafood fraud consisting of the addition of water or ice to add weight to the product, use of masking agents (such as carbon monoxide in tuna) that may give the fish added color or make it seem much fresher than it actually is, and seafood substitution or intentional mislabeling and selling a less expensive fish product as a more expensive product.[196]

Under the program, NMFS inspects about 20% of the seafood consumed in the United States, including imported seafood.[197] Industry generally contracts with NMFS to provide the service, and NMFS personnel may inspect fishing vessels and processing plants to ensure that sanitary practices are in keeping with FDA standards. These services are provided on a fee-for-service basis and entitle participants to use various official grading and labeling marks, which are viewed as making their products more attractive to buyers. NMFS may also periodically evaluate products at processing facilities for general condition, wholesomeness, and proper grading and labeling, and they may sample products for chemical and microbiological contamination, decomposition, and species identification.[198]

In addition, NOAA works with FDA and other federal agencies, as well as various state agencies, under the National Shellfish Sanitation Program, a federal/state cooperative program recognized by FDA, and the Interstate Shellfish Sanitation Conference (ISSC) to promote and improve the sanitation of shellfish—oysters, clams, mussels, and scallops—moving in interstate commerce through federal-state cooperation, as well as to promote uniformity of state shellfish programs.[199] Participants include agencies from states, several federal agencies, the shellfish industry, and foreign governments.

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receiver, or a third party such as a broker or attorney of record.

[194] Section 8e applies to avocados, dates (other than dates for processing), hazelnuts (filberts), grapefruit, table grapes, kiwifruit, olives (other than Spanish-style), onions, oranges, Irish potatoes, pistachios, raisins, tomatoes, and walnuts.

[195] 7 U.S.C. §1621 et seq. For more information, see NOAA Seafood Inspection Program, https://www.fisheries.noaa.gov/insight/noaas-seafood-inspection-program; and *Seafood Inspection Manual*, U.S. Grading Standards and Procedures for Grading (Part 5), https://www.fisheries.noaa.gov/webdam/download/64649290. See also CRS Report RS22797, *Seafood Safety: Background and Issues*.

[196] See, for example, NOAA's seafood fraud FAQ, https://www.iuufishing.noaa.gov/FAQs/SeafoodFraudFAQs.aspx.

[197] Ryan, J.M., *Food Fraud*, Chapter 2, p. 12, 2016 (Academic Press).

[198] See, for example, FDA, *2012 Annual Report on Food Facilities, Food Imports, and FDA Foreign Offices*, August 2012, https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-reports-studies.

[199] Information is at FDA, http://www.fda.gov/food/guidanceregulation/federalstatefoodprograms/ucm2006754.htm. As part of a 1984 Memorandum of Understanding, ISSC was recognized as the primary voluntary national organization of state shellfish regulatory officials, providing guidance and counsel on matters for the sanitary control of shellfish.

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