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Examining Pathogen-Based Import Refusals: Trends and Analysis From 2002 to 2019

Jae-Wan Ahn and M. Taylor Rhodes

Abstract

Identifying adulterants in imported foods and refusing contaminated shipments help minimize the risk of foodborne illness from foreign products and are essential to keep U.S. consumers safe. This report uses import refusal data from the Food and Drug Administration (FDA) from 2002 to 2019 to explore import refusals based on contamination with pathogens and toxins. The report examines trends in total, annually, by industry, and by country. The analysis helps identify which pathogen/toxin is the most common in refused imports, which industries are the most frequently refused in total and by pathogen/toxin type, which countries are the most frequently refused in total and by pathogen/toxin type, and what changes occurred over time. From 2002 to 2019, *Salmonella* violations accounted for nearly 79.8 percent of all pathogen/toxin violations, followed by *Listeria* at 11 percent. By food industry group, most pathogen/toxin violations occurred in fishery and seafood products (44.1 percent), followed by spices, flavors, and salts (26.3 percent). Shipments from India, Mexico, and Vietnam accounted for 22.9 percent, 14.9 percent, and 8.6 percent of import refusals due to pathogen/toxin violations, respectively. This report has a limited understanding of which factors affect the refusals because the dataset does not have the volume of shipments inspected, and the FDA inspected only a small percent of the shipment, not randomly, based on the previous history.

Keywords:

Import refusals, pathogen, toxin, foreign food inspection, food imports, *Salmonella*, *Listeria*, vibrio, shigella, OASIS, PREDICT, food safety oversight

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Errata

On December 23, the title of figure 4 on page 9 was revised to say, “Total number of pathogen/toxin violations by industry, 2002-19.” In addition, the titles of figures 11b, 11c, and 11d on pages 17 and 18 were revised to show the correct country.

On January 18, the first row of appendix 2 was revised to correct number of pathogen/toxin violations by histamine and aflatoxin to match those shown in figure 5. No other text or figures were affected.

Examining Pathogen-Based Import Refusals: Trends and Analysis From 2002 to 2019

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What Is the Issue?

In the interest of public health, it is important to understand and minimize possible foodborne illness risks to U.S. consumers from foreign food products. One possible risk is that food may be contaminated with pathogens (bacteria, viruses, or other disease-causing microorganisms) or toxins (mostly produced by microorganisms). While data capable of estimating the risk of foodborne illness from foreign producers is limited, U.S. import refusal data list the most common reasons why foreign shipments were refused. Previous ERS reports presented 7 to 9 years of records of import refusals, which was a relatively short period to reveal trends. The most recent previous report examined data up to 2013. Previous USDA, ERS reports showed adulteration and misbranding violations in aggregate, but possible foodborne illness risks more likely resulted from pathogen violations.

This report examines changes in imported shipments that were refused due to pathogen/toxin violations using FDA data from the Operational and Administrative System for Import Support (OASIS) database from 2002 to 2019.



What Did the Study Find?

Overall pathogen/toxin prevalence in refusals

- From 2002 to 2019, *Salmonella* violations accounted for 79.8 percent of pathogen/toxin violations, followed by *Listeria* at 11 percent, histamine at 3.6 percent, aflatoxin at 3 percent, and other bacteria at 2 percent. All remaining pathogen types accounted for 0.6 percent of pathogen/toxin violations.
- Annually, the number of violations for *Salmonella* peaked in 2011, then declined. The number of violations for *Listeria* declined from 2003 until 2008 but was volatile with a slight downward trend since 2010.
- Compared to the previous ERS report, the share of *Salmonella* violations increased from 63 percent from 1998–2004 to 79.8 percent over 2002–19. *Listeria* violations decreased from 24.8 percent to 11 percent.

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Refusals by food industry group

- From 2002 to 2019, most pathogen/toxin violations occurred in fishery and seafood products (44.1 percent); followed by spices, flavors, and salts (26.3 percent); cheese and cheese products (7.1 percent); fruit and fruit products (6.2 percent); and nuts and edible seeds (5.1 percent). *Salmonella* was the most common type of pathogen/toxin violation for fishery and seafood products; spices, flavors, and salts; fruit and fruit products; and nuts and edible seeds. *Listeria* was the most common type of pathogen/toxin violation for cheese and cheese products.
- Annually, the number of violations for fishery and seafood products increased until 2004, decreased until 2008, increased and peaked in 2011, and decreased thereafter.
- Compared to 1998–2004, violations shifted from fishery and seafood to other products; however, fishery and seafood products continue to account for the largest share.

Refusals by country of origin

- From 2002 to 2019, India, Mexico, Vietnam, Indonesia, and France accounted for 22.9 percent, 14.9 percent, 8.6 percent, 7.8 percent, and 4.3 percent of import refusals due to pathogen/toxin violations, respectively. *Salmonella* was the most common pathogen/toxin violation for shipments from India, Mexico, Vietnam, and Indonesia. *Listeria* was the most common violation for shipments from France.
- Annually, the number of pathogen/toxin violations from India slightly increased. Those from Mexico spiked in 2003, 2008, and 2010 but remained low and stable since 2012.

However, FDA's import refusal dataset does not have detailed records for the volume of shipments inspected. Only a small percentage of shipments were examined, not randomly, based on previous history. It is also difficult to assess how screening authorities' standards changed over time. For these reasons, this report has limited understanding of which factors affected the refusals by pathogen/toxin, industry, or country.

How Was the Study Conducted?

Import refusal data is publicly available for download from 2002 to the present. Authors focused on the number of import refusals in total and annually by pathogen/toxin type, food industry group, country, and select groupings such as leading violations within industry groups. For a given year, the sum of the notable pathogens, viruses, and toxins in the OASIS database define the annual number of violations. The number of pathogen/toxin violations is defined as the sum of an annual number of violations across all years of available data. The authors further examined violations by pathogen type, industry type, and country of origin. From 2002 to 2019, 10 types of pathogen/toxin violations were reported: *Salmonella*, *Listeria*, aflatoxin, histamine, *E. coli* O157, *Shigella*, patulin, *Vibrio*, Hepatitis A, and other bacteria. These occurred in 32 food industry groups, including bakery products, dairy products, fruit and vegetables, and seafood products. The data covered in this report reflect pathogen/toxin violations in shipments from 110 countries for which at least one violation was found from 2002–19.

Introduction

In the interest of public health, it is important to understand and minimize the possible foodborne illness risks to U.S. consumers from foreign food products. One possible risk is that food may be contaminated with pathogens (bacteria, viruses, or other disease-causing microorganisms) or toxins (mostly produced by microorganisms). The severity of illness can range from nausea, vomiting, and diarrhea to renal failure, paralysis, and death. According to the World Health Organization (WHO), global estimates of foodborne diseases showed that almost 10 percent of the world population became ill from consuming contaminated food, resulting in 420,000 deaths in 2010. The threat of foodborne disease for children under 5 years of age is particularly high. WHO estimates that 125,000 children under 5 years of age die from foodborne disease each year, about 30 percent of all deaths from foodborne disease (WHO, 2015). The U.S. Department of Agriculture's Economic Research Service (USDA, ERS) estimated that 15 major foodborne agents cost more than \$17.5 billion (in 2018 dollars) each year, including medical costs, productivity loss, and deaths in the United States (Hoffmann and Ahn, 2021).

Numerous recommendations, standards, oversight, and regulatory mechanisms exist in an effort to improve food safety. Examples include meal preparation guidelines (Dietary Guidelines for Americans), food safety education (Medeiros et al., 2001), national retail food standards and practices (2013 U.S. Food and Drug Administration Food Code), regulated use of pesticides (U.S. Environmental Protection Agency), and agricultural border inspection (U.S. Customs and Border Protection).

Both the USDA, Food Safety and Inspection Service (FSIS) and the U.S. Food and Drug Administration (FDA) provide food safety oversight for domestic and imported food (see box, "Federal Food Safety Oversight"). FSIS regulates domestic and imported meat, poultry, and processed egg products and inspects animal and carcass slaughtering plants as well as meat and poultry processing plants. For these reasons, this report does not include imported meat, poultry, and processed egg products regulated by USDA, FSIS. FDA oversees domestic and imported food (including shelled eggs but excluding meat and poultry), bottled water, and wine beverages with less than 7 percent alcohol.¹

The import share based on the volume of food and beverage consumption in the United States climbed from 11 percent in 1990 to 19 percent in 2013 (Johnson, 2020). U.S. residents annually consume approximately 32 percent of fresh vegetables, 55 percent of fresh fruit, and 94 percent of seafood imported from other countries by volume (FDA, 2019). Data from the USDA's Global Agricultural Trade System (GATS) indicates that the volume of imported food continued to increase from 36 million tons in 2002 to over 65 million tons in 2019, or 79.8 percent. This is equivalent to an annual increase of 3.5 percent. As more food is imported, it would not be surprising that consumers are increasingly concerned about food safety and risks of foodborne disease from pathogen-contaminated foods (Brewer and Rojas, 2008).

While data capable of estimating the risk of foodborne illness to U.S. consumers from foreign producers is limited, U.S. import refusal data list the most common reasons foreign shipments were refused. The FDA physically examines approximately 1 to 2 percent of imports. All imports are electronically screened using an automated system called Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PRE-DICT) (Bovay, 2016; Johnson, 2016). FDA inspects imports for signs of adulteration or misbranding. Import refusals are recorded in the Operational and Administrative System for Import Support (OASIS) database where each entry contains a violation code, industry group, and country of origin.

¹For a discussion on the inspection roles of FDA and FSIS and the Federal food safety legislation from 1862 to 2011, see Johnson (2016). For discussions on the food safety functions of specific Federal agencies, see Chapter 2 of *Enhancing Food Safety* (2010), Johnson (2016), and Bovay (2016). For discussions on Federal oversight on food and agricultural imports, see Buzby et al., (2008) and Becker (2010).

Federal Food Safety Oversight

In the United States, food safety inspections are divided among three regulatory agencies. Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture is responsible for the safety of all domestic and imported meat, poultry, and egg products. The Food and Drug Administration (FDA) supervises the safety of most other domestic and imported food consumed in the United States. Both FSIS and FDA require that producing facilities register with their respective agencies in order to supply meat, poultry, or egg products for interstate shipment. The U.S. Environmental Protection Agency (EPA) assesses pesticide residues on food, with a special emphasis on the unique vulnerability of children.

Many municipal governments, including State, Tribal, and local, cooperate with the food safety efforts of these agencies. FDA is responsible for all imported shipments except for meat, poultry, and egg products, which are controlled by FSIS jurisdiction. Agencies often share responsibility for particular food groups, such as fresh produce, where EPA and FDA have pesticide residue enforcement responsibilities, while FDA handles import inspections. In 2011, U.S. Congress enacted the Food Safety Modernization Act to ensure food in the United States is safe by shifting the focus from responding to foodborne illness to preventing it. This granted FDA the authority to mandate additional preventive regulations that aim to ensure food safety. In addition to inspecting domestic and imported food, FDA requires foreign and domestic producers to implement minimum standards for the safe growing, harvesting, packing, and holding of produce (FDA, 2019).

Even though OASIS is a rich data set for import refusal, it has limitations. First, the total volume or value of each shipment is not revealed, so it is hard to identify which product had the largest threat to food safety for the U.S. market. Second, FDA does not randomly choose a sample to inspect. The inspectors choose a sample based on informed choice from their previous experiences. This implies that OASIS data do not have randomness that would allow researchers to make inferences about the relative risk of food products or countries. Despite these limitations, OASIS data continuously recorded shipment refusal over decades, which makes them useful for analyzing trends and patterns of imported food both inspected and refused by FDA.

This report examines the number of import refusals for various bacteria (*E. coli* O157, *Listeria*, *Salmonella*, *Shigella*, and *Vibrio*), a virus (Hepatitis A), and some toxins (aflatoxin, histamine, and patulin) from 2002 to 2019. These types of refusals are referred to as pathogen/toxin violations. Although toxins are chemicals, not pathogenic microorganisms, they tend to be found in food products typically associated with risks of foodborne illnesses (Buzby et al., 2008). Many toxins are produced by microorganisms (Centers for Disease Control and Prevention, 2017). Thus, the authors aggregate pathogens and toxins. This report focuses on patterns in FDA import refusals by pathogen/toxin and by industry, also noting variation by country. The report delivers the latest refusal trends to help understand pathogen-country pairs that consistently threaten U.S. food safety. Unlike previous ERS reports, this study focuses on pathogen/toxin refusals instead of all types of import violations. First, most violations are adulteration. In previous studies, adulteration ranged from 57 percent to 65 percent (Buzby et al., 2008; Bovay, 2016). Second, outbreaks associated with imported foods increased in the United States. Most outbreaks were caused by pathogens. Furthermore, outbreaks linked to imported foods represented an increasing proportion of all foodborne disease outbreaks from 1 percent during 1996–2000 to 5 percent during 2009–14 (Gould et al., 2017).

The research explores four broad pathogen/toxin questions:

- What pathogen/toxin type accounts for the largest portion of the total number of violations from 2002 to 2019, and how did this composition change over time, if at all?
- What food industry group accounts for most of the violations and by which specific pathogen/toxin type? For industry groups with the highest violations, did notable changes occur over time?
- What country accounts for most of the violations and by which specific pathogen/toxin type? For countries with the highest total violations, did notable changes occur over time?
- What industry group and pathogen/toxin type comprise the highest share of a country's violations? Did important industry and country changes occur over time?

Previous research using FDA import refusal data examined trends and changes by violation type (Buzby et al., 2008 and Bovay, 2016), industry group (Buzby et al., 2008 and Bovay, 2016), and country of origin (Brooks et al., 2009, Buzby and Regmi, 2009, Buzby and Roberts, 2011, and Bovay, 2016). Research focusing on country, industry group pairings covered refusals from 1998 to 2004 and segmented countries not by name but by low, middle, or high incomes (Brooks et al., 2009, Buzby and Regmi, 2009). Gale and Buzby (2009) focused on industry import refusals, particularly for China. The most recent examination of broad trends in refusals was Bovay (2016), who examined import refusals by type, by industry group, and for some top country violators from 2005 to 2013. This report is the third analysis conducted by ERS following Buzby et al., (2008) and Bovay (2016). This study contributes by providing an in-depth analysis of pathogen/toxin violations.

Data

The FDA physically examines approximately 1 to 2 percent of imported foods. All import entries are electronically screened using an automated FDA system called PREDICT (Bovay, 2016; Johnson, 2016). PREDICT assesses the risks associated with imports based on intrinsic product risk, history of field examinations, results of facility inspection, and data anomalies. Import refusals by FDA are recorded in the OASIS database with violation codes, industry code (i.e., broad product categories), and country of origin. Notable pathogen/toxin violations (each charge code shown in parentheses) in the OASIS database include various bacteria (*Salmonella* (9), *Shigella* (293), *Vibrio* (3460), *E. coli* O157 (3480), and *Listeria* (295)) and a virus (Hepatitis A (3040)). Additionally, it includes some toxins such as aflatoxin (297), histamine (2360), and patulin (3180).

Import refusal data is available for download from 2002 to the present. This report focuses on the number of pathogen/toxin violations in total and annually by pathogen/toxin type, industry group, and country from 2002 to 2019. It also describes annual trends in selected groupings, like industry groups for top pathogens and leading pathogen/toxin violations within countries. For a given year, the sum of the notable pathogens, viruses, and toxins in the OASIS database define the annual number of violations. The total number of pathogen/toxin violations is the sum of an annual number of violations across all years of available data. There are 32 food industry groups, including bakery, dairy, fruit and vegetables, and seafood products.² The dataset includes shipment refusals from 110 countries. There are nine pathogen/toxin violations: *Salmonella*, *Listeria*, aflatoxin, histamine, *E. coli* O157, *Shigella*, patulin, *Vibrio*, Hepatitis A, and other bacteria.

The dataset recorded all shipments refused into U.S. ports. It includes the date of refusal, country of origin, name of the manufacturer, product code with description, FDA district where entry was made, and one or more violation codes with charge statement. The charge statement includes the specific reasons for the apparent shipment violations. These data recorded in detail allow tracking and examination of the frequencies of pathogen/toxin violations from imported foods in the United States for nearly two decades.

A total of 156,408 import refusal entries occurred during the study period, of which 22,460 were associated with pathogen/toxin. FDA can physically inspect only a small percentage of shipments due to the volume, limited personnel, and financial resources. Thus, the OASIS data do not represent a sample of all food imports in violation of FDA regulations. Despite these limitations, OASIS data documented import refusals since 1998, which makes them useful for analyzing trends and patterns of imported foods inspected and refused by FDA.

FDA recorded more than one charge code for each refusal entry if the shipment had more than one violation. The charge code documented the reason the shipment was refused. Of the total refused shipments, 30 percent have more than one charge code. Among the entries with multiple charge codes, the authors examined each item for a pathogen-related violation. When shipments are detected with chemical adulteration or misbranding, those violations have non-pathogen charge codes. If an item has more than one pathogen/toxin charge code, they are treated as a separate record. For example, if a certain imported food is recorded for violations of *Salmonella* and *Shigella* on a specific date, two records were created in one shipment. They are not treated as a separate record when calculating refusals by food industry group or country to avoid double counting.³ As a result, more than 22,000 pathogen/toxin violations were identified over the past 18 years.

² See appendix 3 for the full list of 32 productive industry types.

³For example, if a cheese product has a *Salmonella* and *Listeria* violation, it would be overestimated in the data to say that two cheese products were refused. Thus, we counted one cheese product that was refused. The same logic applies to the case of country of origin.

The data have some limitations. First, the total mass or value of each shipment was not recorded, so it is hard to identify which product had the largest potential threat for the U.S. market. Second, FDA does not randomly select a sample to inspect. This indicates that OASIS data do not have randomness that would allow making inferences about the relative risk of industry groups or countries. It cannot be determined which foods or countries pose the higher risk through cross-product and cross-country comparisons because the total volume/values of refused imports is unknown. FDA uses a risk-based prediction algorithm to inspect shipments, which is also affected by import alerts issued by FDA (Bovay, 2016). Thus, inspectors could decide what to investigate based on informed choices from previous experiences. This inherent selection bias may lead to distorted results. This is because the probabilities of violations in inspected shipments and the share of violated shipments in the total shipments are different and not proportional. When FDA issues import alerts, the shipments remain in detention and get refused unless manufacturers provide proof that shipments are safe. Last, the import refusal report does not record the country where products were manufactured. The data only includes the countries of manufacturers. Therefore, if a manufacturer produces foods in several countries but is registered in one country, the data shows only the registered country. It limits the identification of potential risks from countries where food is directly processed. Nevertheless, OASIS contains the most appropriate data to track changes over time of import refusals, as FDA consistently recorded all import refusals for many years. To complement the limitations of OASIS data, the authors used GATS data to determine changes in the volume of imported food for each food industry.

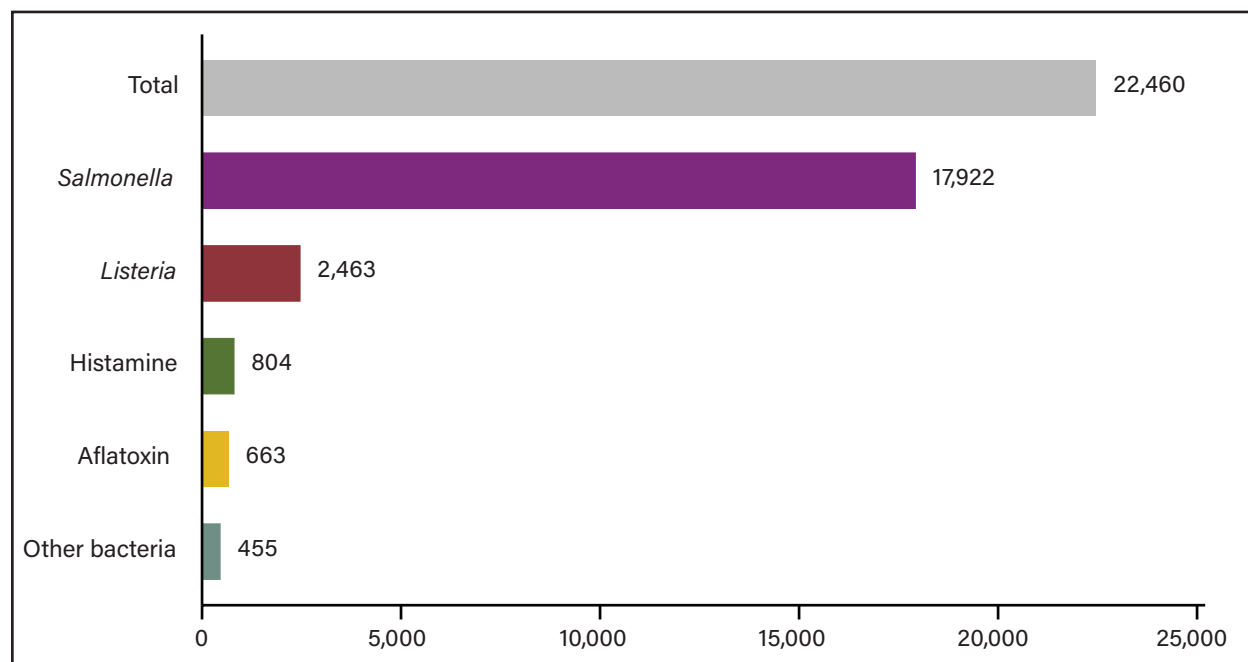
Findings

Overall import refusals by pathogen/toxin

From 2002 to 2019, 22,459 pathogen/toxin violations were detected. The majority of them—17,922—had the presence of *Salmonella*, which accounts for 79.8 percent of the total pathogen/toxin violations. Figure 1 shows *Listeria* next with 2,463 cases (11 percent), followed by histamine, aflatoxin, and other bacteria with 804 (3.6 percent), 663 (3 percent), and 455 violations (2 percent), respectively. The rest of the refused shipments due to other pathogens numbered just 153 cases (0.7 percent).

Compared to the previous ERS report (Buzby et al., 2008), the share of *Salmonella* violations increased from 63 percent over 1998–2004 to 79.8 percent over 2002–19. *Listeria* violations decreased from 24.8 percent over 1998–2004 to 11 percent over 2002–19. Since this study overlaps with Bovay (2016) over 2005–13, the authors calculated the share of each type of pathogen/toxin after 2013. *Salmonella* accounted for 81 percent (down from 83.7 percent over 2005–13); *Listeria* accounted for 8.7 percent (up from 8.5 percent); aflatoxin accounted for 3.6 percent (up from 2.8 percent); and histamine accounted for 4.3 percent (up from 2.6 percent) over 2013–19.

Figure 1
Total number of pathogen/toxin violations and by type, 2002–19



Note: Violations for the remaining pathogens were 153.

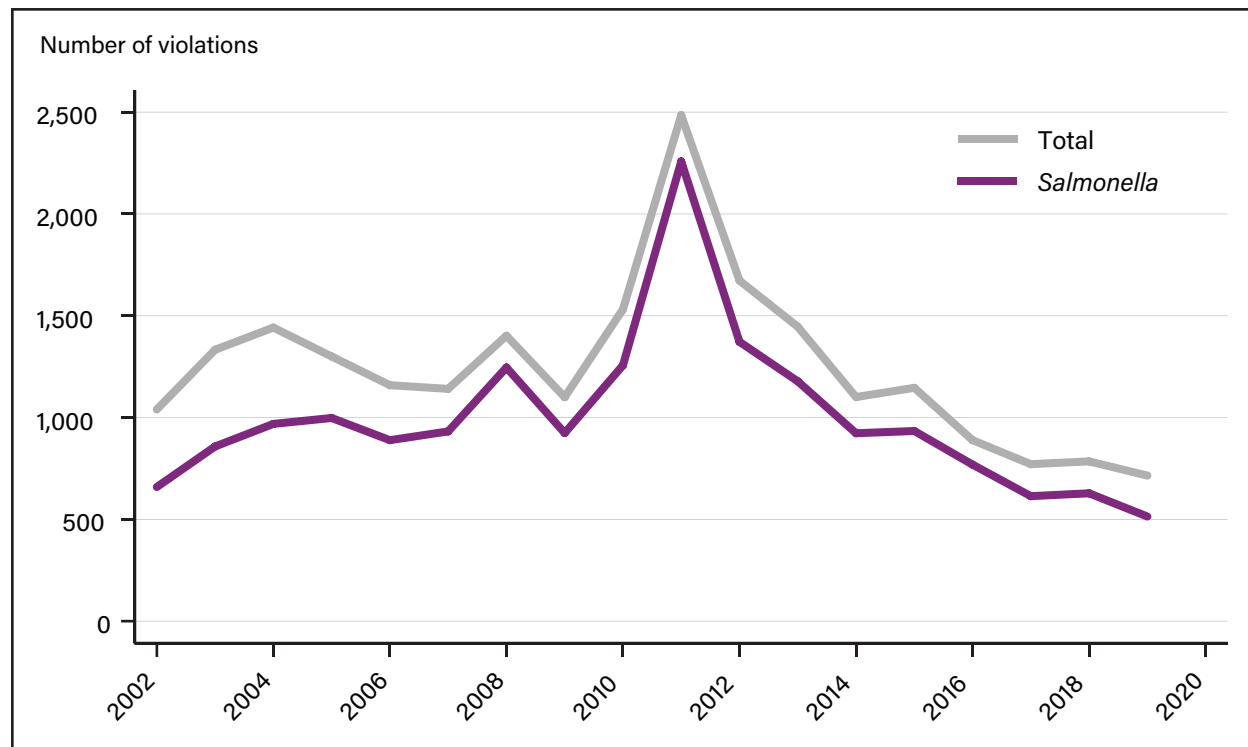
Source: USDA, Economic Research Service using data from OASIS (Operational and Administrative System for Import Support) database, U.S. Food and Drug Administration.

Annual trends in pathogen/toxin violations by leading pathogen/toxin

Figure 2 displays the trend of annual pathogen/toxin violations from imported foods between the total violations and *Salmonella* for 2002–19. Over time, *Salmonella* accounted for more violations. As a result, the *Salmonella* graph is similar to the shape of the total graph. One notable point is that refusals because of *Salmonella* increased from 924 violations in 2009 to 2,258 violations in 2011. These spikes were largely driven by fishery and seafood products, and fruits and fruit products. These results are consistent with the previous ERS

report (Bovay, 2016). After this spike, *Salmonella* violations continuously declined over time. One possible explanation for the continuous decrease in import refusals is the FDA Food Safety Modernization Act (FSMA), enacted in 2011. FSMA substantially expanded and modified the previous authority of FDA to enhance the agency’s oversight of imported food. As a result, FSMA could provide PREDICT with more data on imported food (GAO, 2016).

Figure 2
Annual number of pathogen/toxin violations in total and due to *Salmonella*, 2002–19



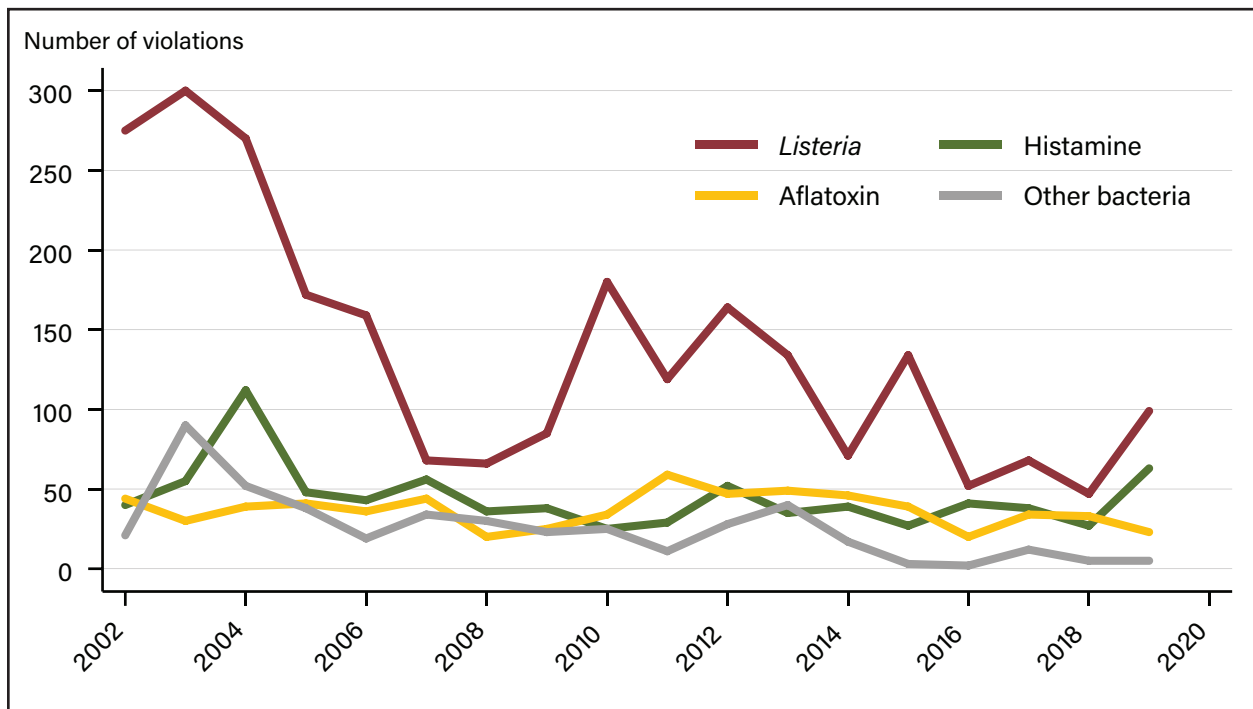
Source: USDA, Economic Research Service using data from OASIS (Operational and Administrative System for Import Support) database, U.S. Food and Drug Administration.

Figure 3 depicts trends of the remaining four leading pathogen/toxins. *Listeria*, histamine, aflatoxin, and other bacteria have either trended downward or remained relatively stable. The notable exception is the decline in *Listeria* violations from 300 cases in 2003 to 68 cases in 2007. This plunge mainly came from a large *Listeria* decrease in cheese and cheese products. *Listeria* violations, like *Salmonella*, increased during 2010–12, but the others—histamine, aflatoxin, and other bacteria—did not.

See Appendix 1 table for the total number of pathogen/toxin violations and annual variation.

Figure 3

Annual number of pathogen/toxin violations due to other major pathogens, 2002-19



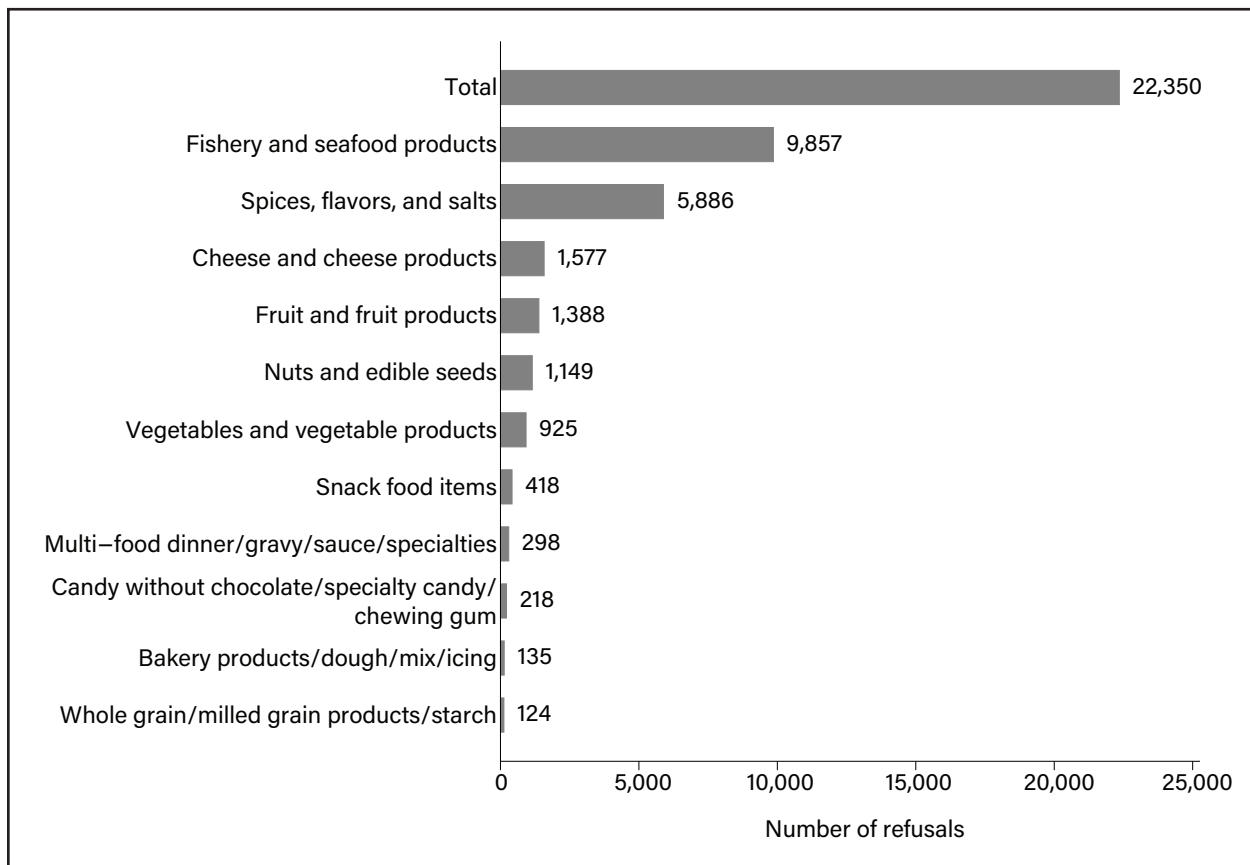
Source: USDA, Economic Research Service using data from OASIS (Operational and Administrative System for Import Support) database, U.S. Food and Drug Administration.

Pathogen/toxin violation by industry group

Fishery and seafood products had the most pathogen/toxin violations over 2002–19, accounting for 44.1 percent of violations. It was followed by the spices, flavors, and salts industry, which accounted for 26.3 percent of pathogen/toxin violations over the period. These two industry groups accounted for more than 70 percent of the total refusals. Compared to two previous ERS reports, fishery and seafood products accounted for from 53.1 percent (Buzby et al., 2008) to 42 percent (Bovay, 2016) to 44.1 percent in this report. Pathogen/toxin violations decreased by 9 percentage points from 1998–2004 data. The spices, flavors, and salts industry accounted for 10.5 percent to 33.2 percent to 26.3 percent. Figure 4 shows the number of pathogen/toxin violations by industry group over the study period. Following the two most frequent industries, cheese and cheese products, fruits and fruit products, nuts and edible seeds, and vegetables and vegetable products each accounted for more than 4 percent of the total violations. Each of the remaining industries accounted for less than 2 percent of violations. In total, the top six industry groups comprised 93 percent of the total pathogen/toxin violations over the period, even though this does not account for volume (physical mass or sales volume).

Figure 4

Total number of pathogen/toxin violations by industry, 2002–19

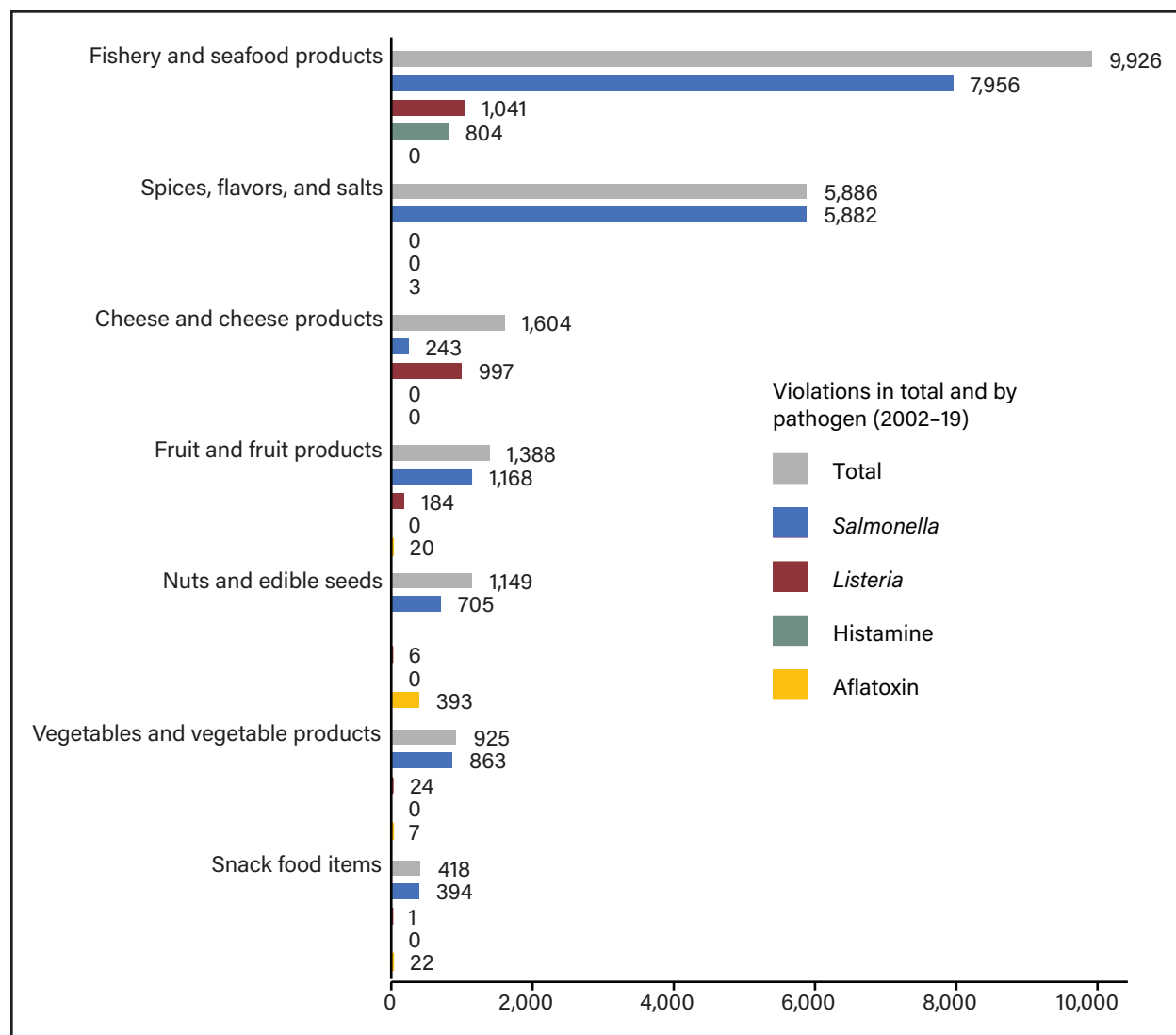


Source: USDA, Economic Research Service using data from OASIS (Operational and Administrative System for Import Support) database, U.S. Food and Drug Administration.

Figure 5 shows pathogen/toxin violations for the total and for the four most common violations in the top seven industry groups. Overall, *Salmonella* was the most common violation in each industry except cheese and cheese products, in which *Listeria* had the most violations. The Centers for Disease Control and Prevention notes that soft cheeses with unpasteurized milk are more likely to be contaminated by *Listeria* than other pathogens like *Salmonella*. *Salmonella*, however, accounted for almost all pathogen/toxin violations in spices, flavors, and salts.

Figure 5

Total number of pathogen/toxin violations—*Salmonella*, *Listeria*, histamine, aflatoxin—by industry

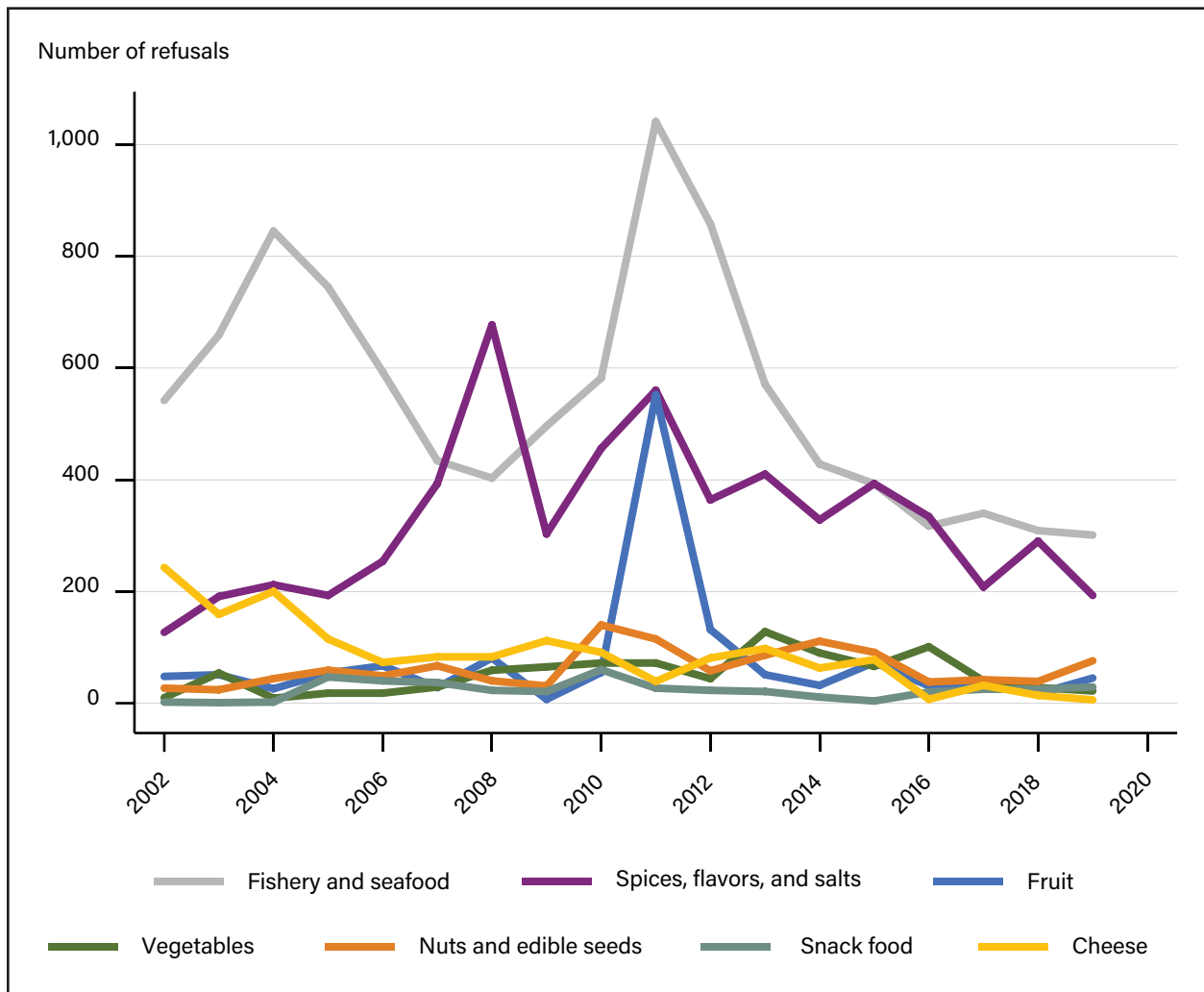


Notes: Pathogen violations in total and by common pathogens for the seven industries with the highest total number of pathogen violations. Total violations may include multiple pathogen violations per single entry.

Source: USDA, Economic Research Service using data from OASIS (Operational and Administrative System for Import Support) database, U.S. Food and Drug Administration.

Annual changes in pathogen/toxin violations focus on seven key industry groups—fishery and seafood products; spices, flavors, and salts; fruit and fruit products; vegetables and vegetable products; nuts and edible seeds; snack food; and cheese and cheese products. Figure 6 shows that overall annual changes in pathogen/toxin violations declined since 2012 in aggregate. Even though some products show little to no change, three industries show notable changes. The fruit industry showed a sharp spike in 2011 compared to other years, mainly resulting from a surge in *Salmonella* violations. Except for 2011, overall pathogen/toxin violations in the fruit industry were low during the study period. The fishery and seafood industry also declined in the number of pathogen/toxin violations, except for surges in 2004 and 2011, similar to the fruit industry. Those two spikes were also driven by sharp increases in *Salmonella* violations. The spices, flavors, and salts industry demonstrated an interesting trend, a gradual decline after a sharp increase during 2007–08 and 2011. *Salmonella* violations also accounted for the peak in spice refusals in 2008. The rest of the industries maintained relatively low detection numbers without noticeable changes during the study period. For a detailed breakdown by industry group, see Appendix 3.

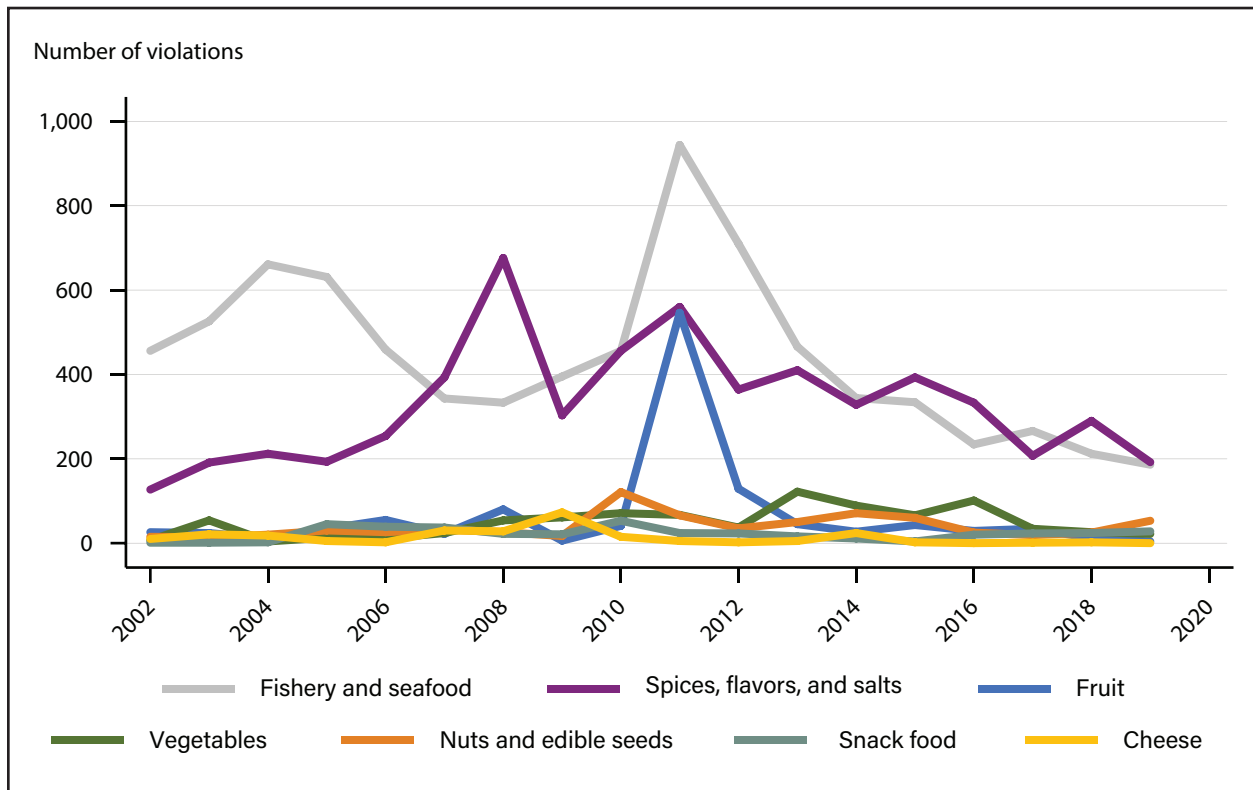
Figure 6
Annual trends of pathogen/toxin violation by industry, 2002-19



Source: USDA, Economic Research Service using data from OASIS (Operational and Administrative System for Import Support) database, U.S. Food and Drug Administration.

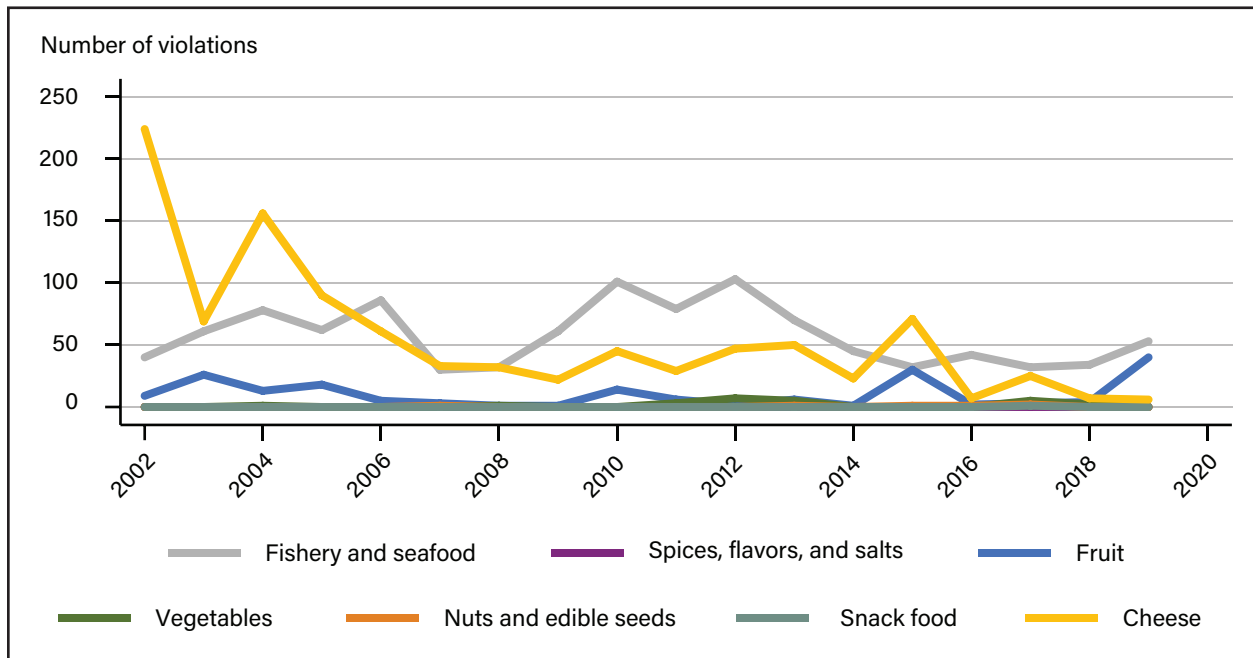
Salmonella and *Listeria* are the main drivers for the seven industry groups most frequently noted for pathogen/toxin violations. Figure 7 shows annual trends for both *Salmonella* and *Listeria*. In figure 7a, *Salmonella* violations are similar to figure 6, which depicts the violations from total pathogens. This indicates that *Salmonella* was a critical pathogen to threaten U.S. public health from imported products. Figure 7b shows the annual trends for refusals because of *Listeria*, which is relatively small compared to *Salmonella*. The cheese industry accounted for the largest portion of pathogen/toxin violations because of *Listeria* in the early 2000s. Average *Listeria* violations of cheese products fell from 150 in the early 2000s to 12 in the late 2010s. The fishery and seafood industry also accounted for many shipments with *Listeria* through the study period. A few intermittent rises of pathogen/toxin violations in the fruit industry were noted.

Figure 7a
Annual Salmonella violations by industry, 2002-19



Source: USDA, Economic Research Service using data from OASIS (Operational and Administrative System for Import Support) database, U.S. Food and Drug Administration.

Figure 7b
Annual Listeria violations by industry, 2002-19



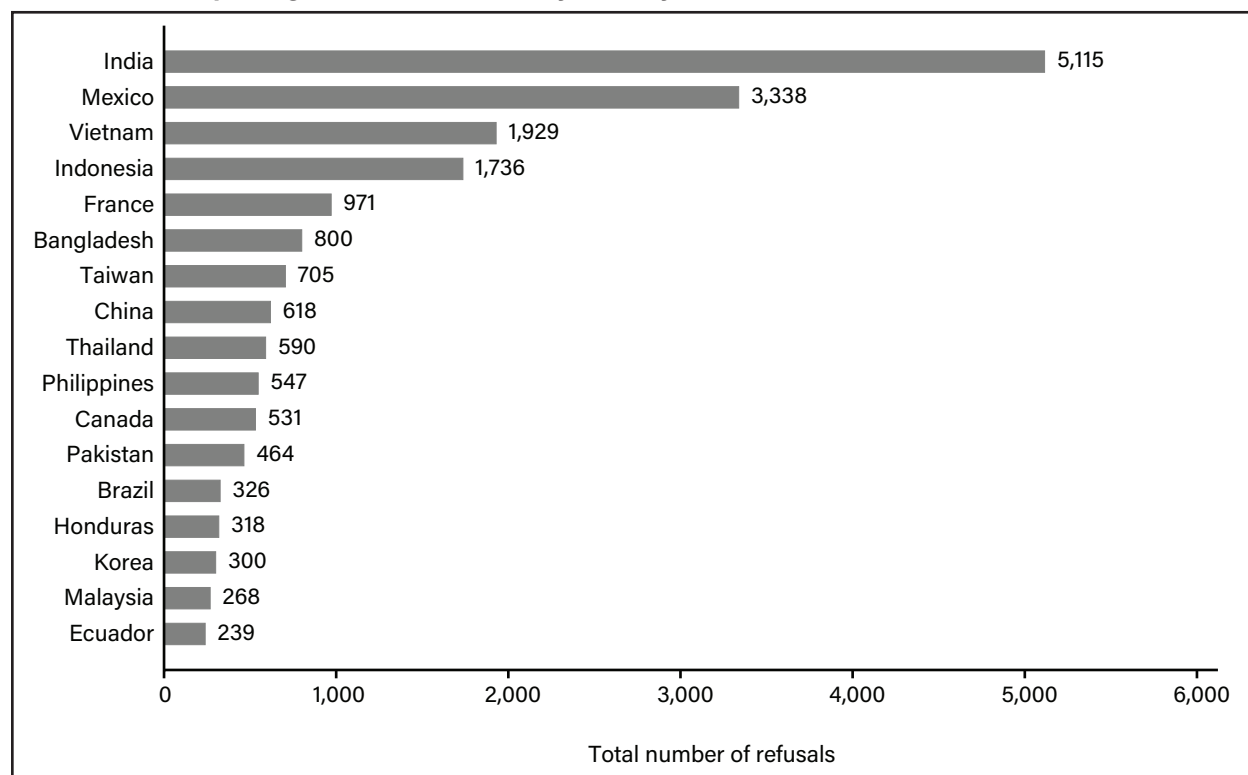
Source: USDA, Economic Research Service using data from OASIS (Operational and Administrative System for Import Support) database, U.S. Food and Drug Administration.

Pathogen/toxin violation by exporting country

Over the study period, 110 countries had at least 1 pathogen/toxin violation, and 29 countries had more than 100 shipment refusals. Figure 8 depicts the number of refusals for 17 countries, which account for 1 percent or more import refusals of the total number of violations. India had the most pathogen-related violations with 5,115 refusals, followed by Mexico with 3,338 violations. Next, Vietnam and Indonesia followed with more than 1,700 refusals over the study period. The remaining countries represent less than 1,000 refusals for each country.

Figure 8

Total number of pathogen/toxin violations by country, 2002-19



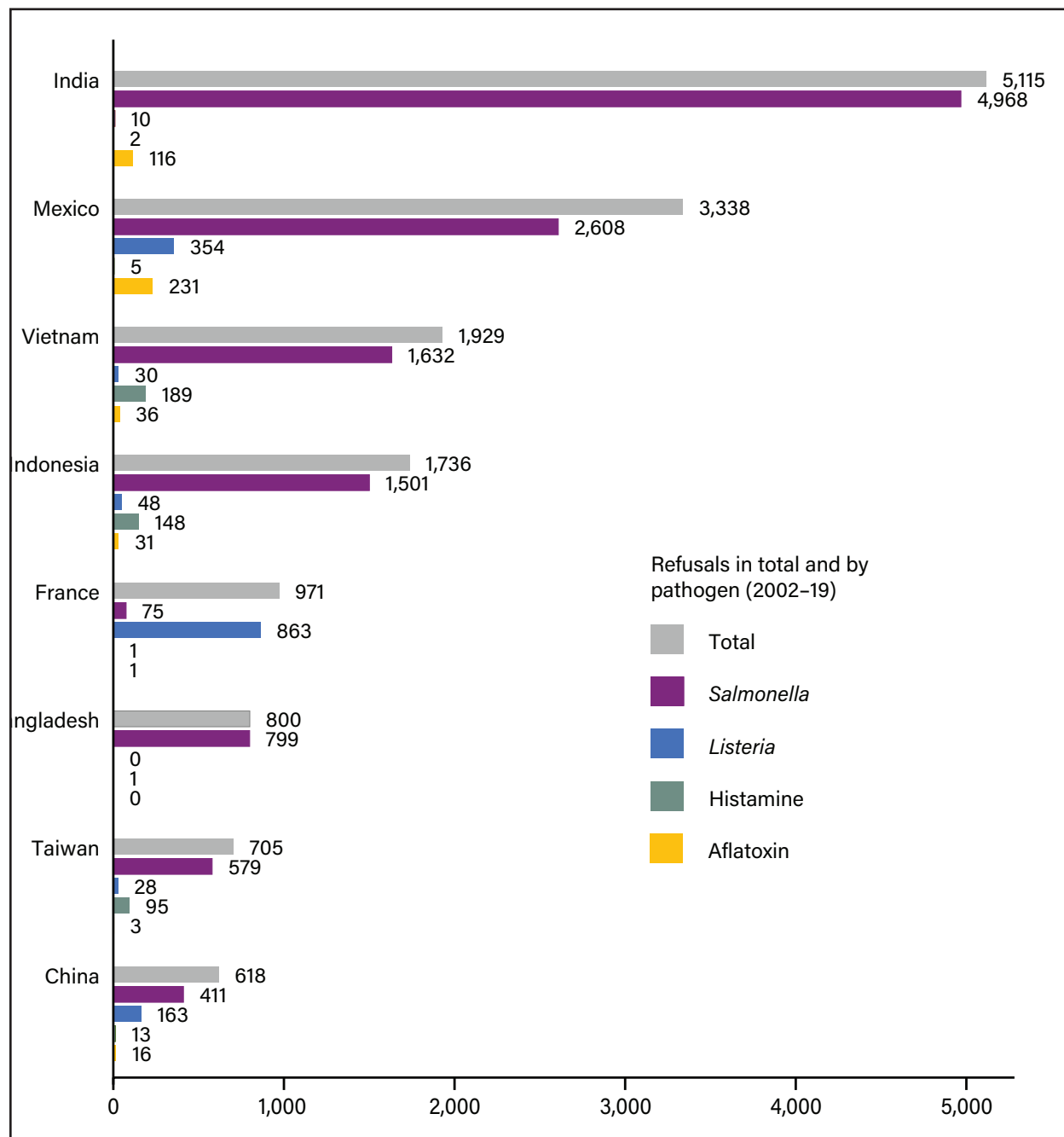
Note: The countries shown accounted for over 84 percent of the pathogen refusals from 2002 to 2019.

Source: USDA, Economic Research Service using data from OASIS (Operational and Administrative System for Import Support) database, U.S. Food and Drug Administration.

Figure 9 shows the total and four most common violations caused by pathogen/toxin in the eight countries with the highest violations. Except for France, *Salmonella* caused the majority of refusals in the rest of the countries. Most shipments from France were denied due to *Listeria* because France exports many cheese and cheese products to the United States. Of the 971 pathogen/toxin violations found from France, *Listeria* accounted for 863 violations or 88.9 percent. One possible explanation why many cheese products from France were refused is due to close monitoring of *Listeria* by the FDA. The largest number of cheese products made from unpasteurized milk came from France (FDA, 2016). *Salmonella* was the cause of most shipment refusals from India and Bangladesh from 2002 to 2019. Noticeable refusals due to histamine came from Southeast Asian countries such as Vietnam, Indonesia, and Taiwan. Gao et al., (2020) reported that histamine violations from Southeast Asia might have come from seafood products. Imports of seafood products from Vietnam, Indonesia, and Taiwan continuously increased. Together, their volume accounted for over 17 percent of imported seafood, based on GATS data. India and Mexico accounted for a large portion of refusals by aflatoxin over the study period. This may be because aflatoxin is mainly detected in rice samples from India and Mexico (Ali, 2019). See appendix 4 for pathogen/toxin violations by type and by selected countries.

Figure 9

Most common pathogen/toxin violations by country, 2002-19—total, *Salmonella*, *Listeria*, histamine, aflatoxin



Note: Pathogen refusals in total and by common pathogens for the top 8 countries with the highest total number of pathogen refusals, accounting for over 68 percent of the pathogen refusals from 2002 to 2019.

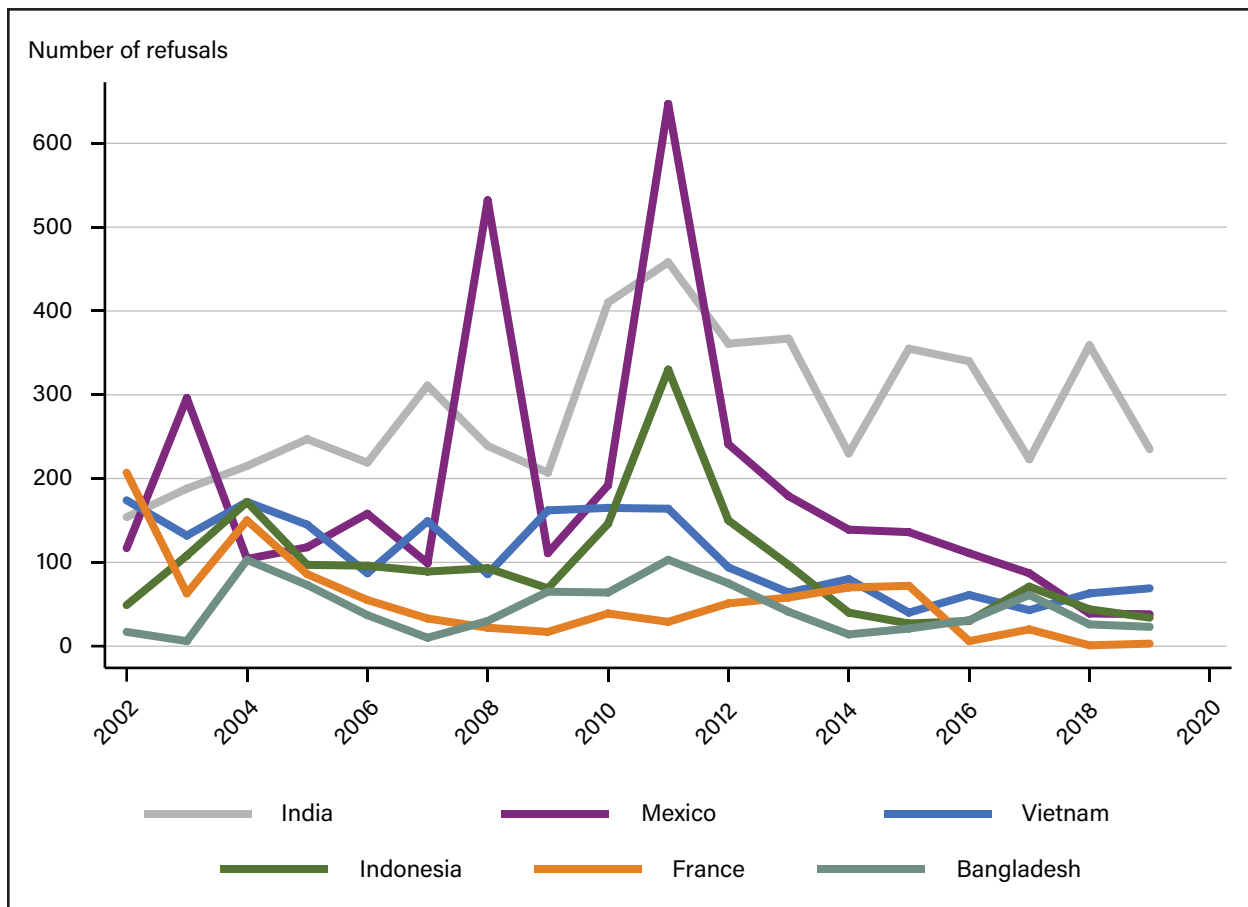
Source: USDA, Economic Research Service using data from OASIS (Operational and Administrative System for Import Support) database, U.S. Food and Drug Administration.

The authors focused on the six countries with the highest import refusals over the study period, tracing annual trends to identify how countries responded to pathogen/toxin violations over time. Figure 10 demonstrates annual pathogen/toxin violations from 2002 to 2019.⁴ Overall, the number of refusals due to pathogen/toxin declined after 2011. Shipments from Mexico, followed by India and Indonesia, surged in violations in 2011. Increases from Mexico and Indonesia were mainly from *Salmonella* violations. Specifically, a large number

⁴See Appendix 5 for exact numbers.

of papayas imported from Mexico were refused due to *Salmonella* contaminations in 2011 (Mba-Jonas et al., 2018). That outbreak led FDA to initiate a broader import alert that all papayas from Mexico should be detained. Shipments from Mexico showed a decline in import refusals by pathogen/toxin after 2011. Based on GATS data, the total volume of imported foods from Mexico increased from 10.5 million tons in 2012 to 15.3 million tons in 2019, a 45-percent increase. The number of pathogen/toxin violations continued to sharply drop from 241 in 2012 to 38 in 2019, an 85-percent decrease. Given these two different trends, we could infer that Mexico responded to the high number of refusals from the United States by reinforcing its food safety standards. Unlike other countries, India's shipments continued to face high levels of refusals since 2010, given the caveat that this report is unable to control for the total volume of imported foods FDA inspected. However, GATS data reports the volume of foods imported from India. Imported foods from India increased from about 1 million tons in 2011 to 1.8 million tons in 2019. During the same period, the number of violations nearly halved from 458 to 235. However, the rate of decline in the number of violations is lower than that of other leading countries, which fell by more than 80 percent.

Figure 10
Annual number of pathogen/toxin violations from most frequently detected countries, 2002-19

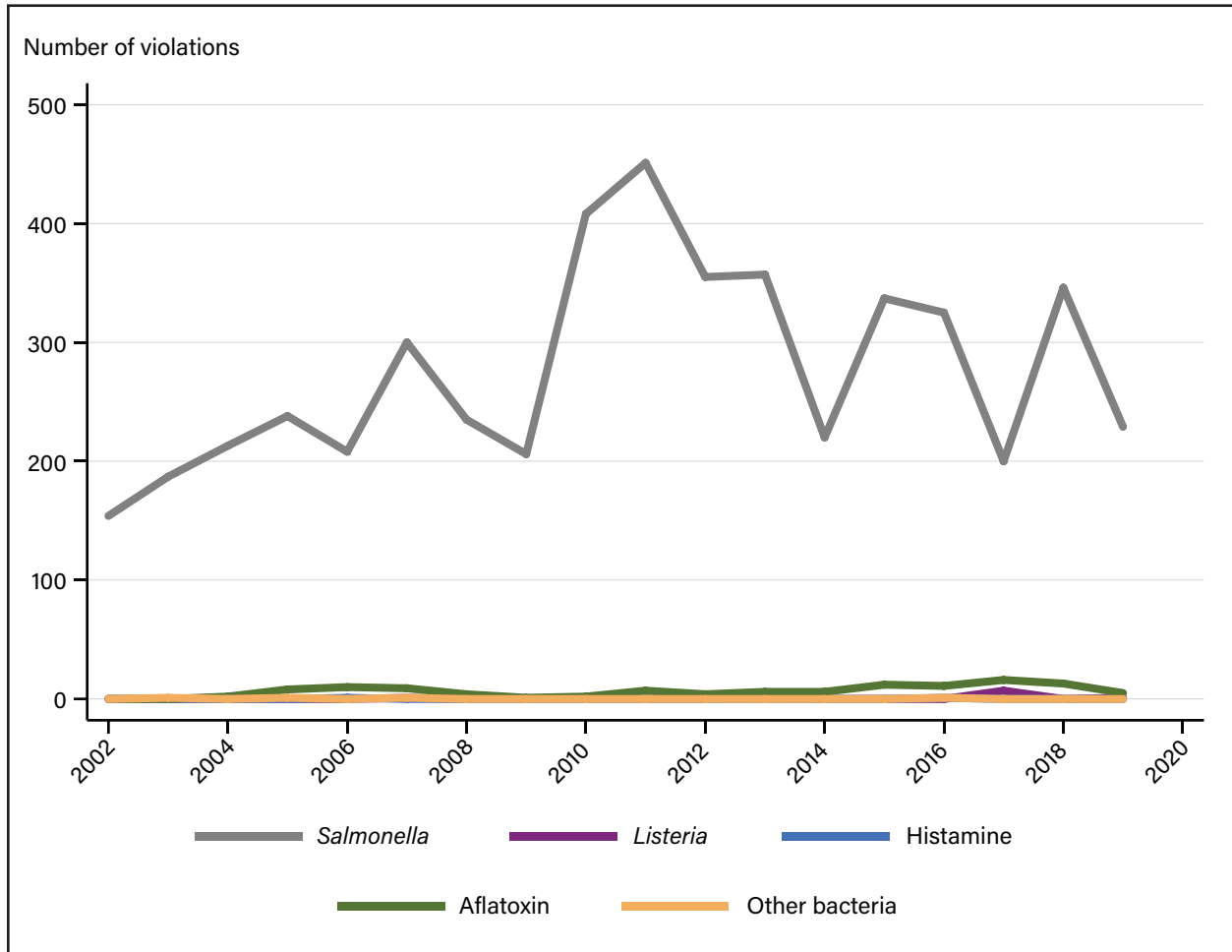


Source: USDA, Economic Research Service using data from OASIS (Operational and Administrative System for Import Support) database, U.S. Food and Drug Administration.

Finally, the authors analyzed which pathogen/toxin largely contributed to violations from India, Mexico, Vietnam, and Indonesia and how they changed during the study period. These countries were selected because Indonesia showed a sharp rise in 2011, and the other countries had the highest number of pathogen/toxin violations. Figure 11a depicts the number of refusals by the four most frequently detected pathogen/toxins in shipments from India. Almost all refused shipments were due to *Salmonella* contamination. This trend is also reflected in the number of refusals for Mexico in Figure 11b. Compared with other pathogens, *Salmonella*

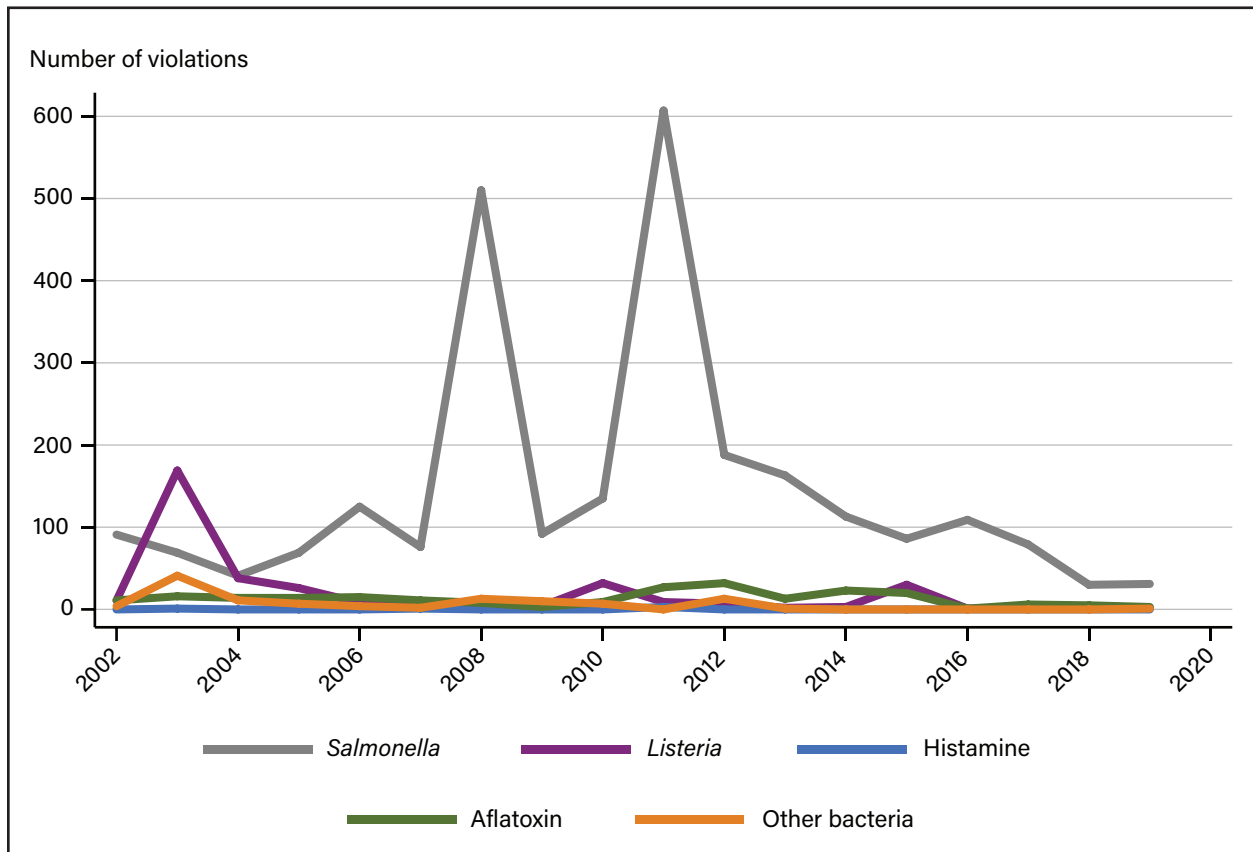
accounted for the majority of import refusals. Pathogen/toxin violations from Vietnam showed a different pattern compared to India and Mexico. Figure 11c shows that *Salmonella* violations accounted for most of the pathogen/toxin violations in Vietnamese shipments by 2017. However, *Salmonella* violations declined from 153 cases in 2011 to 18 cases in 2018. However, histamine violations climbed since then, bordering on the *Salmonella* violations. In Indonesia, *Salmonella* was also the primary cause of import refusals over time, but some cases were from histamine, shown in Figure 11d. The common trend in the four countries is that a large number of import refusals from pathogens were because of *Salmonella*. See Appendix 5 for a table showing the exact number of annual violations for four countries.

Figure 11a
Annual number of pathogen/toxin violations from India, 2002–19



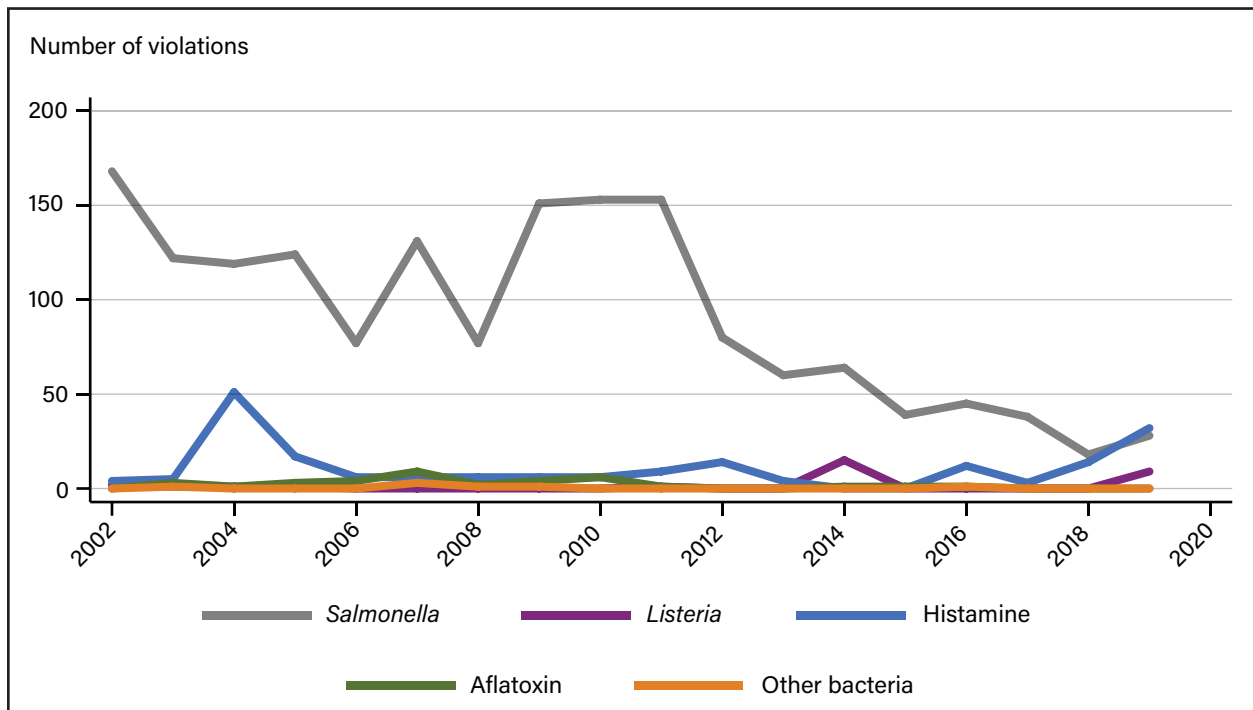
Source: USDA, Economic Research Service using data from OASIS (Operational and Administrative System for Import Support) database, U.S. Food and Drug Administration.

Figure 11b
Annual number of pathogen/toxin violations from Mexico, 2002-19



Source: USDA, Economic Research Service using data from OASIS (Operational and Administrative System for Import Support) database, U.S. Food and Drug Administration.

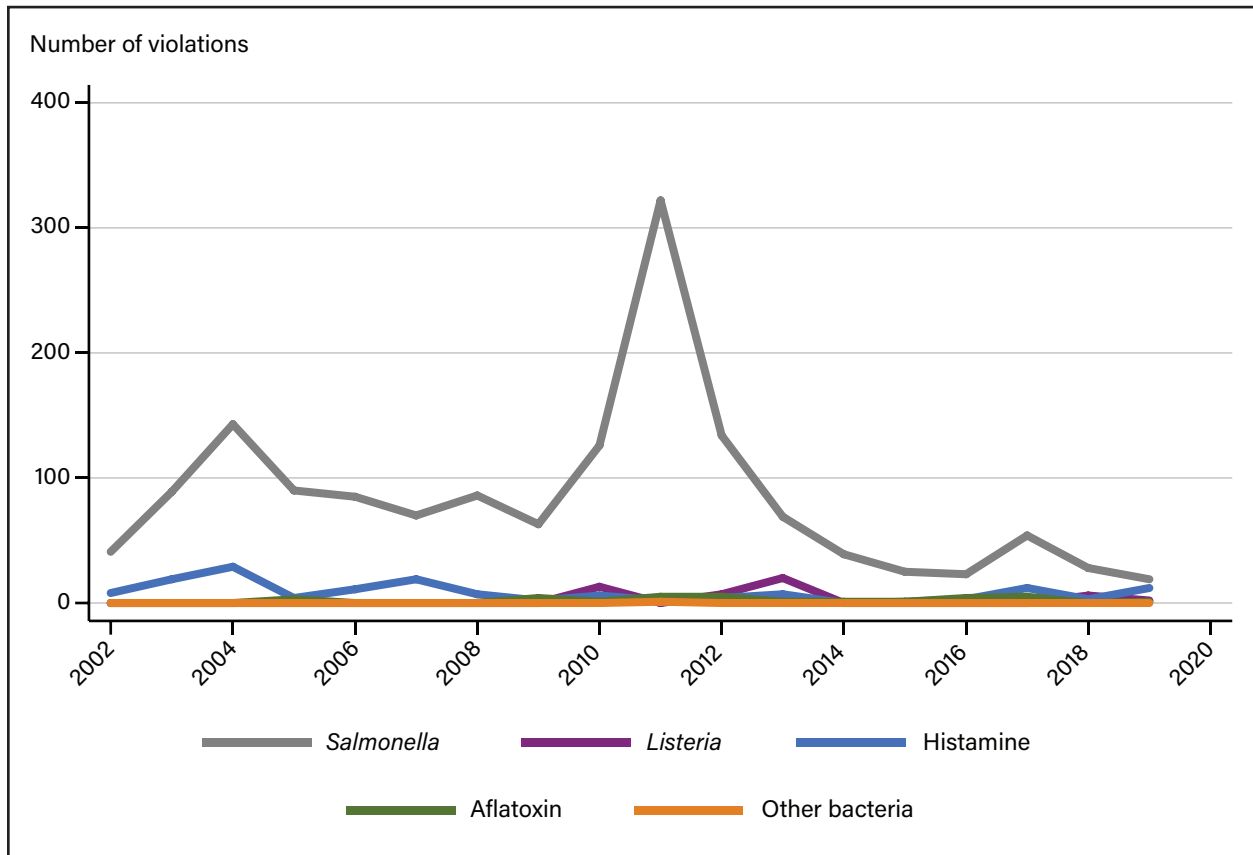
Figure 11c
Annual number of pathogen/toxin violations from Vietnam, 2002-19



Source: USDA, Economic Research Service using data from OASIS (Operational and Administrative System for Import Support) database, U.S. Food and Drug Administration.

Figure 11d

Annual number of pathogen/toxin violations from Indonesia, 2002-19



Source: USDA, Economic Research Service using data from OASIS (Operational and Administrative System for Import Support) database, U.S. Food and Drug Administration.

Conclusion

This report focuses on FDA import refusals because of pathogen/toxin violations from 2002 to 2019. Researchers report total violations by pathogen/toxin types, industry groups, and countries. This report provides annual trends to identify how food safety violations were distributed across different categories and how countries responded to import refusals over time.

Across the total number of refusals, *Salmonella* and *Listeria* account for the most violated shipments due to pathogen/toxin over the period. The industries with the most frequently detected pathogen/toxin violations included fishery and seafood products; spices, flavors, and salts; cheese and cheese products; and fruit and fruit products. The most pathogen/toxin violations came from India, Mexico, Vietnam, Indonesia, France, Bangladesh, Taiwan, and China. This report includes changes in annual refusal trends by categories. Though a sharp increase occurred in 2011, the number of refusals from *Salmonella* declined during the study period. This trend occurred for other frequently detected pathogen/toxins—*Listeria*, histamine, and aflatoxin. When annual pathogen/toxin violations patterns were graphed by industry, both fishery and seafood products and fruit and fruit products spiked in 2011. This resulted in a rapid increase in food imports refused by FDA because of *Salmonella*. Nonetheless, the overall trend went down after 2011 across industries.

This report provides trends over the last two decades for pathogen/toxin violations in imported foods for study by FDA officials and inspection agencies. Screening agencies can identify the most frequent pathogen/toxin violations, pathogen/toxin violations by industry, and countries with the greatest risk for their exported foods. The 18-year timeframe covered in the analysis provides insight into recurring problems of adulteration by pathogen/toxin in shipments. Rather than just showing the time trend of overall pathogen/toxin violations from imported foods, the report shows changes over time by each pathogen/toxin, food product, and country. The annual number of pathogen/toxin violations declined after 2011. This trend remained the same for pathogen/toxin violations by food products and country. Overall, pathogen/toxin violations from imported foods decreased over the past 18 years given the caveat that the data do not include the total amount of food imported.

However, FDA's import refusal dataset does not have detailed records for the volume of shipment and value. This dataset inspected only a small percentage of shipments, not randomly, based on previous history. It is also difficult to study how screening authorities' standards changed over time, especially during the Great Recession, 2007–09. For these reasons, the researchers have a limited understanding of which factors affect the refusals by pathogen/toxin, industry, or country. More research is needed when data are available to better understand what factors persistently threaten food safety in the United States.

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Appendix

Appendix 1

Annual total number of pathogen/toxin violations by type, 2002-19

Pathogen\year	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total
<i>Salmonella</i>	659	858	969	998	889	932	1,246	924	1,257	2,258	1,372	1,178	923	934	769	614	628	514	17,922
<i>Listeria</i>	275	300	270	172	159	68	66	85	180	119	164	134	71	134	52	68	47	99	2,463
Aflatoxin	44	30	39	41	36	44	20	25	34	59	47	49	46	39	20	34	33	23	663
Histamine	40	55	112	48	43	56	36	38	25	29	52	35	39	27	41	38	27	63	804
Other Bacteria	21	90	52	38	19	34	30	23	25	11	28	40	17	3	2	12	5	5	455
<i>E. coli O157</i>	0	0	0	0	0	0	0	1	10	4	7	7	0	3	0	0	3	0	35
<i>Shigella</i>	1	0	0	2	1	5	4	4	1	3	0	0	0	0	0	0	0	0	21
<i>Patulin</i>	0	0	0	1	6	2	0	0	0	0	1	0	1	0	0	1	0	0	12
<i>Vibrio</i>	0	0	0	0	0	0	0	0	0	1	2	3	4	6	5	2	4	9	36
Hepatitis A	0	0	0	0	6	0	0	0	0	0	0	0	0	0	0	2	38	2	48
Total	1,040	1,333	1,442	1,300	1,159	1,141	1,402	1,100	1,532	2,485	1,673	1,446	1,101	1,146	889	771	785	715	22,459

Source: USDA, Economic Research Service using data from OASIS (Operational and Administrative System for Import Support) database, U.S. Food and Drug Administration.

Appendix 2

Total violations by most common pathogen/toxin in the leading seven industry groups, 2002-19

Industry/pathogen	<i>Salmonella</i>	<i>Listeria</i>	Histamine	Aflatoxin	Total
Fishery and seafood products	7,956	1,041	804	0	9,926
Spices, flavors, and salts	5,882	0	3	0	5,886
Cheese and cheese products	243	997	0	0	1,604
Fruit and fruit products	1,168	184	20	0	1,388
Nuts and edible seeds	705	6	393	0	1,149
Vegetables and vegetable products	863	24	7	0	925
Snack food items	394	1	22	0	418

Source: USDA, Economic Research Service using data from OASIS (Operational and Administrative System for Import Support) database, U.S. Food and Drug Administration.

Annual total number of pathogen/toxin violations by industry groups, 2002-19

Industry\Year	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total
Fishery and seafood products	542	659	845	745	593	434	403	496	582	1,041	858	571	428	393	317	340	309	301	9,857
Spices, flavors, and salts	127	191	212	193	254	393	677	303	456	560	364	410	328	393	334	208	290	193	5,886
Cheese and cheese products	243	159	200	115	73	83	83	112	91	39	81	98	63	78	7	32	14	6	1,577
Fruit and fruit products	48	51	26	54	67	28	81	7	55	552	132	51	32	73	31	38	17	45	1,388
Nuts and edible seeds	27	24	44	59	49	67	40	31	140	115	58	86	111	91	38	42	39	76	1,137
Vegetables and vegetable products	10	54	9	18	18	29	59	65	72	72	44	128	90	66	101	40	28	22	925
Snack food items	2	1	2	47	40	37	23	21	60	27	23	21	11	4	20	25	25	29	418
Multi-food dinner/gravy/sauce/specialties	1	144	22	5	13	9	1	6	24	8	13	9	6	2	12	11	11	1	298
Candy without chocolate/specialty candy/chewing gum	12	14	12	30	21	10	2	9	20	4	23	17	10	6	2	5	9	12	218
Bakery products/dough/mix/icing	8	10	7	4	2	7	10	6	5	13	13	10	7	13	1	5	7	7	135
Whole grain/milled grain products/starch	2	3	2	3	4	5	2	4	2	3	15	3	7	13	16	15	21	4	124
Meat, meat products, and poultry*	3	8	19	3	8	2	1	3	7	13	13	22	3	1	0	3	1	11	121
Coffee and tea	0	0	2	3	5	1	4	6	3	6	5	7	3	4	4	5	0	2	60
Macaroni and noodle products	1	3	0	0	4	2	3	8	3	2	5	0	0	2	0	0	4	1	38
Chocolate and cocoa products	2	3	1	0	0	9	1	4	1	0	4	0	1	3	3	0	1	0	33
Cereal preparations/breakfast food	1	0	0	1	1	1	2	3	2	2	2	1	1	1	0	1	4	0	23
Egg and egg products	0	1	10	5	0	0	0	0	1	0	0	0	0	0	0	0	0	0	17
Milk/butter/dried milk products	1	1	0	3	0	1	1	3	2	1	0	0	0	0	1	0	0	0	14
Soup	1	0	1	1	2	0	1	3	1	2	1	0	0	0	0	1	0	0	14
Dressings and condiments	1	0	0	3	1	0	0	2	0	0	2	4	0	0	0	0	0	0	13
Dietary conventional foods/meat replacements	1	0	0	1	0	1	1	2	1	2	1	0	0	1	1	0	0	1	13
Food sweeteners (nutritive)	0	0	1	0	0	9	2	0	0	0	0	0	0	0	0	0	0	0	12
Vegetable protein products	1	0	0	0	0	1	1	0	0	1	6	0	0	0	0	0	0	0	10
Beverage bases, concentrate, nectar	0	2	1	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	5
Gelatin/pudding mix/pie filling	0	0	0	1	0	2	0	1	0	0	0	0	0	0	0	0	0	0	4
Soft drinks and water	0	0	0	1	0	1	0	1	0	0	0	1	0	0	0	0	0	0	4
Ice cream products	0	1	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	3
Vegetable oils	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	3
Prepared salad products	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Filled milk/imitation milk products	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Baby food products	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Alcoholic beverages	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Total	1,036	1,329	1,416	1,295	1,156	1,135	1,398	1,096	1,528	2,463	1,663	1,439	1,101	1,144	888	771	780	712	22,350

*Food and Drug Administration (FDA) does not inspect meat or poultry products, so only very few observations of meat or poultry appear in the import refusal data. The data only include FDA-regulated meat and poultry products, presumably due to the pre-certification of the exporting country's inspection systems conducted by USDA, Food Safety and Inspection Service (Buzby et al., 2008). Note: When each shipment has multiple pathogen/toxin violations, the industry group corresponding to each shipment is included only once to avoid double counting.

Source: USDA, Economic Research Service using data from OASIS (Operational and Administrative System for Import Support) database, U.S. Food and Drug Administration.

Total number of pathogen/toxin violations by country and type, 2002-19

Country/Pathogen	Salmonella	Listeria	Aflatoxin	Histamine	Bacteria	E. coli O157	Shigella	Patulin	Vibrio	Hepatitis A	Total
India	4,968	10	116	2	4	0	0	0	15	0	5,115
Mexico	2,608	354	231	5	114	8	9	1	1	7	3,338
Vietnam	1,632	30	36	189	7	0	0	0	2	33	1,929
Indonesia	1,501	48	31	148	1	0	0	0	0	7	1,736
France	75	863	1	1	22	9	0	0	0	0	971
Bangladesh	799	0	0	1	0	0	0	0	0	0	800
Taiwan	579	28	3	95	0	0	0	0	0	0	705
China	411	163	16	13	14	1	0	0	0	0	618
Thailand	491	9	7	83	0	0	0	0	0	0	590
Philippines	402	3	21	75	31	1	0	0	14	0	547
Canada	300	176	34	0	11	0	7	3	0	0	531
Pakistan	460	0	4	0	0	0	0	0	0	0	464
Brazil	315	0	3	8	0	0	0	0	0	0	326
Honduras	269	2	1	0	46	0	0	0	0	0	318
Korea	192	90	0	11	7	0	0	0	0	0	300
Malaysia	256	0	0	12	0	0	0	0	0	0	268
Ecuador	140	2	0	97	0	0	0	0	0	0	239

Source: USDA, Economic Research Service using data from OASIS (Operational and Administrative System for Import Support) database, U.S. Food and Drug Administration.

Annual number of pathogen/toxin violations for the four most common pathogen/toxins of top countries, 2002-19

Country/year	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
India	154	188	215	247	219	311	239	207	410	458	361	365	230	355	339	223	359	235
Mexico	117	295	104	118	157	98	530	111	192	646	241	179	139	136	111	87	39	38
Vietnam	174	132	169	141	87	149	86	161	165	152	93	64	80	40	61	43	63	69
Indonesia	49	108	172	97	95	89	92	69	143	329	150	97	40	27	30	71	44	34
France	207	63	150	86	55	32	22	17	39	21	51	57	70	71	6	20	1	3
Bangladesh	17	6	103	73	37	10	30	65	64	103	75	41	14	21	31	61	26	23

Note: When each shipment has multiple pathogen/toxin violations, the country corresponding to each shipment is included only once to avoid double counting.

Source: USDA, Economic Research Service using data from OASIS (Operational and Administrative System for Import Support) database, U.S. Food and Drug Administration.

Appendix 6

Annual pathogen/toxin violations from five most detected pathogens for India, Mexico, Vietnam, and Indonesia, 2002-19

Country	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	
India	Salmonella	154	187	213	238	208	206	206	408	451	355	357	220	337	325	200	346	229	
	Listeria	0	0	0	0	0	1	0	0	0	0	1	0	0	0	7	0	1	
	Aflatoxin	0	0	2	8	10	9	4	1	2	7	4	6	6	12	11	16	13	5
	Histamine	0	0	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0	0
Bacteria	0	1	0	1	0	1	0	0	0	0	0	0	0	0	1	0	0	0	0
Mexico	Salmonella	91	69	41	69	125	76	510	135	607	188	163	113	86	109	79	30	31	
	Listeria	11	169	38	26	8	5	1	4	32	9	7	2	3	30	1	2	4	2
	Aflatoxin	11	16	14	14	15	11	8	3	9	27	32	13	23	20	1	6	5	3
	Histamine	0	1	0	0	0	1	0	0	0	3	0	0	0	0	0	0	0	0
Bacteria	4	41	11	7	4	2	13	10	7	0	13	1	0	0	0	0	0	1	1
Vietnam	Salmonella	168	122	119	124	77	131	77	151	153	80	60	64	39	45	38	18	28	
	Listeria	2	1	1	1	0	0	0	0	0	1	0	0	15	0	0	0	9	
	Aflatoxin	0	3	1	3	4	9	2	4	6	1	0	0	1	1	1	0	0	0
	Histamine	4	5	51	17	6	6	6	6	6	9	14	4	0	0	12	3	14	32
Bacteria	0	1	0	0	0	3	1	1	0	0	0	0	0	0	1	0	0	0	0
Indonesia	Salmonella	41	89	143	90	85	70	86	126	322	134	69	39	25	23	54	28	19	
	Listeria	0	0	0	0	0	0	0	13	0	7	20	0	0	0	0	6	2	
	Aflatoxin	0	0	0	3	0	0	0	4	1	5	1	1	1	4	5	0	1	
	Histamine	8	19	29	4	11	19	7	2	6	2	4	7	0	1	3	12	3	12
Bacteria	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0

Note: India, Mexico, Vietnam, and Indonesia are selected because those countries had highest pathogen/toxin violations during the study period and, each showed more than 1,000 violations in total.

Source: USDA, Economic Research Service using data from OASIS (Operational and Administrative System for Import Support) database, U.S. Food and Drug Administration.