



FOCUS ON: Food Import Safety

FOOD SAFETY MODERNIZATION ACT

Executive Summary

Americans' appetite for imported food has expanded dramatically over the past few decades. For each of the past seven years, food imports have grown by an average of 10 percent.¹ Currently, between 10 and 15 percent of all food consumed by U.S. households is imported.² According to the U.S. Food and Drug Administration (FDA), nearly two-thirds of the fruits and vegetables and 80 percent of seafood consumed domestically come from outside the United States.³

In this issue brief, the Pew Health Group and Center for Science in the Public Interest (CSPI) address the safety of imported seafood and raw produce, two of the largest categories of FDA-regulated food items produced and processed abroad and then sold in the United States.⁴ Our analysis of the rejections of these

items in border inspections over the past two years found that a substantial amount is arriving in the United States potentially adulterated, thereby highlighting the significant challenge that the increasing amount of food imports poses to FDA. We follow up on this assessment by reviewing the new system for import safety established in the recently enacted FDA food safety law, the FDA Food Safety Modernization Act (FSMA). We urge Congress to provide FDA with the resources necessary to fully implement this new and ambitious, but sorely needed, food import safety system. We also make recommendations regarding priorities FDA should focus on in creating this new regulatory scheme,⁵ and we conclude by recommending that FDA inspections of food imports—both in the countries of origin and at the U.S. border—be increased to keep up with the expanding globalization of our nation's food supply.

Methodology

Pew and CSPI assessed the safety of imported seafood and raw produce by analyzing instances in which these foods were rejected (or "refused")⁶ during border inspections by FDA in 2009 and 2010 on the grounds that they presented the potential of being dangerously adulterated. Using publically available data from the FDA's Operational and Administrative System for Import Support (OASIS) program,⁷ we identify the most frequent violations cited in over 4,000 refusals issued. We also list the five countries with the largest number of refused entries and describe the reasons for these refusals.

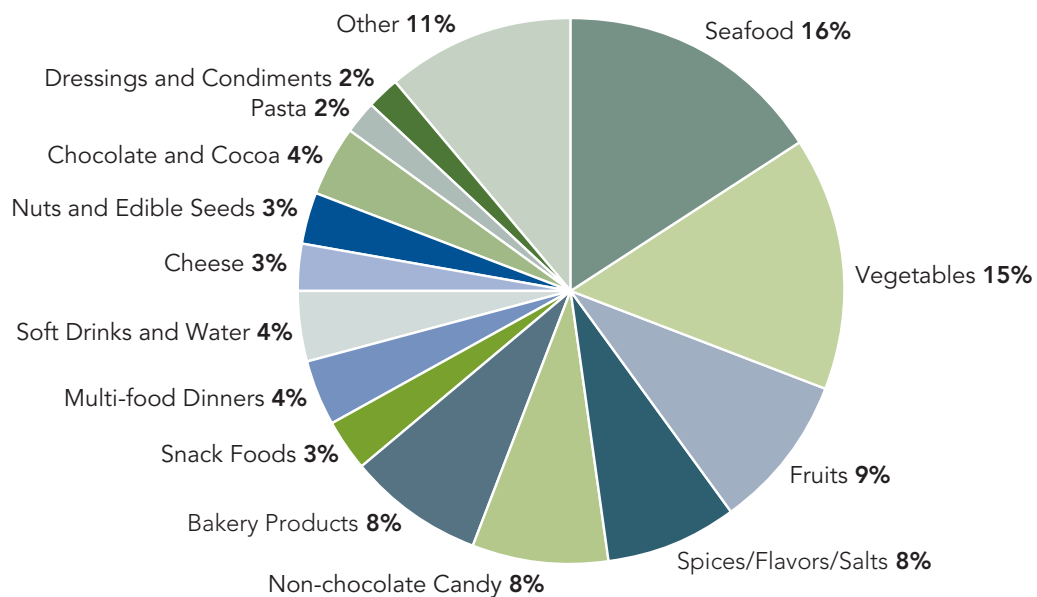
We analyzed 809 line items (i.e., any part of a shipment that is listed as a separate item on the entry document⁸) of raw produce and 3,453 line items of seafood that FDA refused because of the appearance of adulteration. This report looks at any fruit or vegetable item identified in its product code as raw, including raw produce that was refrigerated or frozen. All seafood was included in this analysis, regardless of whether it was shipped as a raw or processed product. Produce and seafood were examined because they are typically considered to be of high risk and, with 40 percent of refusals in 2010, are the most frequently rejected items in the FDA's OASIS database.

How Safe Are Our Food Imports?

In 2010, the United States imported more than 14 million metric tons of raw fruits and vegetables and 2.4 million metric tons of seafood.⁹ Ninety-six percent of all raw produce imports comes from just 10 countries.¹⁰ Similarly, almost 80 percent of imported seafood is sourced

by 10 countries.¹¹ Overall, more than 90 percent of the imported produce and seafood rejected in border inspections was cited for the appearance of potentially dangerous adulteration, including the presence of pathogens, illegal pesticides, chemicals and other sanitary violations.¹²

FDA Import Violations by Food Product, FY 2010*



*This chart includes all violations—not just those related to safety—that resulted in a line item being refused.

Examples of Outbreaks Linked to Imported Foods

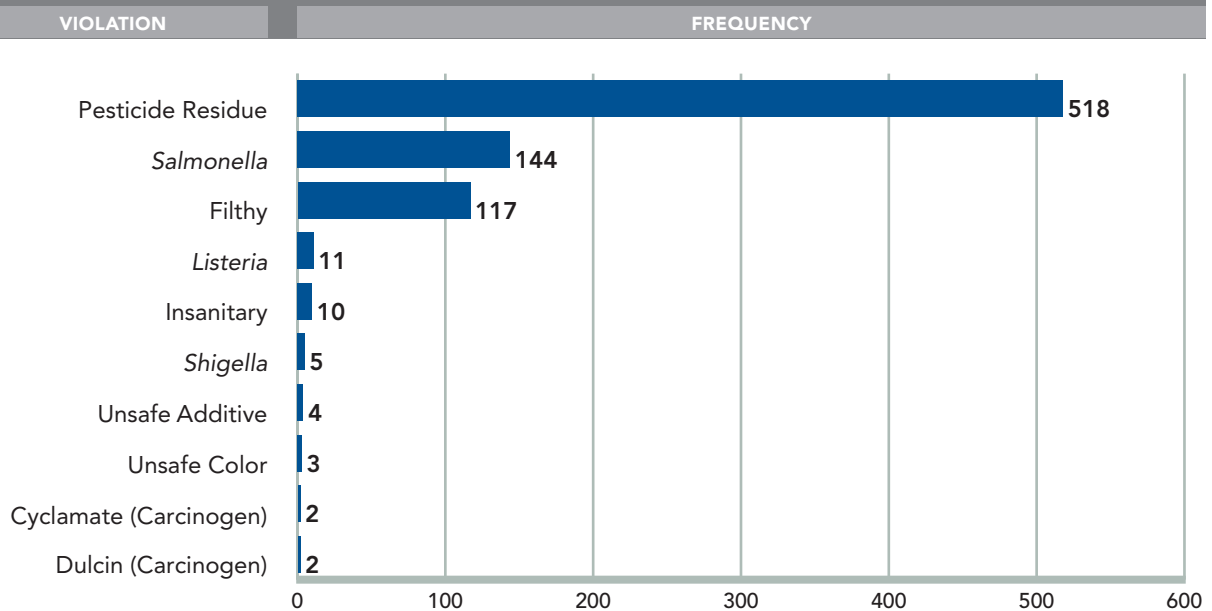
- Red and Black Pepper from Asia** – Fifty-two people were hospitalized and nearly 300 more were sickened across 44 states after they ate salami coated with black and red pepper contaminated with *Salmonella* Montevideo. The pepper was imported from three Asian countries in 2009 and 2010.
 (Source: *Salmonella* Montevideo Infections Associated with Salami Products Made with Contaminated Imported Black and Red Pepper—United States, July 2009–April 2010. www.cdc.gov/mmwr/preview/mmwrhtml/mm5950a3.htm?s_cid=mm5950a3_w)
- Serrano and Jalapeno Peppers from Mexico** – Two people died, nearly 300 were hospitalized and almost 1,500 were sickened across 43 states after they ate *Salmonella* Saintpaul–contaminated peppers (and maybe tomatoes). The food was imported from Mexico in 2008.
 (Source: Investigation of Outbreak of Infections Caused by *Salmonella* Saintpaul. www.cdc.gov/salmonella/saintpaul/jalapeno)
- Cantaloupe from Honduras** – Sixteen people were hospitalized and 51 were sickened across 16 states after they ate cantaloupe contaminated with *Salmonella* Litchfield. The melon was imported from Honduras in 2008.
 (Source: Investigation of Outbreak of Infections Caused by *Salmonella* Litchfield. www.cdc.gov/salmonella/litchfield)
- Pet Food from China** – In 2007, a Chinese ingredient supplier to pet food companies in North America used a dangerous substance in its product to save money. That substance, melamine, is an animal feed filler that, when combined with another chemical, cyanuric acid, causes kidney failure. Upon issuing a recall, which encompassed 100 brands of pet food, the FDA received 18,000 phone calls from consumers reporting a pet's illness.
 (Source: Recent Food Safety Incidents in FDA Regulated Products. dpc.senate.gov/dpcdoc-safetytimeline.cfm?doc_name=fs-111-2-58)

Raw Produce

For the raw produce refused over the two-year period, illegal pesticide residues are the most commonly cited type of adulteration.¹³ Contamination with the pathogen *Salmonella* was the second most commonly cited reason for a refusal and, along with the pathogens *Listeria* and *Shigella*, accounted for 20 percent of all refusals.¹⁴ Since FDA can also base refusals on appearance, “filth”—insects, pests or other debris¹⁵—is often cited as a reason for refusal.¹⁶

The five countries most frequently identified with refused raw produce shipments are Mexico, the Dominican Republic, Guatemala, Chile and Canada. Mexico is not only the largest foreign source of raw produce imported into the United States; the nation also leads the pack for refused products. While most of these were for illegal pesticide residues, one-quarter of Mexico’s refusals (114 of 464) were for *Salmonella* contamination.

10 Most Frequent Violations Cited For Produce, 2009-2010 (Adulteration)



Five Raw Produce Importing Countries Most Frequently Refused Entry, 2009-2010

Country/Area	Raw Produce Refusals 2009-10 (line items)	Quantity of Raw Produce Imports (metric tons)
Mexico	464	11,125,743
Dominican Republic	91	94,164
Guatemala	64	3,135,063
Chile	36	1,777,782
Canada	30	2,125,824

Sources: Refusals data from FDA OASIS. Quantity of imports from FAS GATS.

Seafood

While seafood can harbor a number of unique pathogens, such as ciguatera and scombroid toxins, seafood imports are not examined for these hazards at the border.¹⁷ *Salmonella* is the pathogen responsible for most of the rejections, with *Listeria* also appearing among the top 10 reasons for refusing seafood at the border.

The most common reason cited for rejection is filth, which appears in almost half of the refusals of imported seafood. In addition to filth, contaminants (microbial or chemical) and failure to comply with manufacturing requirements under the Low-Acid Canned Food (LACF) rule¹⁸

or the Seafood HACCP rule¹⁹ were other common safety-related reasons for refusals.

Unapproved drug and antibiotic residues are also a significant concern with imported seafood. Together, these were a factor in 380 refusals. Some of the drugs are particularly serious, such as chloramphenicol, a broad-spectrum antibiotic banned by FDA for use in seafood and food-producing animals.²⁰

Asia, which as a region accounts for 60 percent of the seafood shipped to the United States, dominates as the source of both seafood

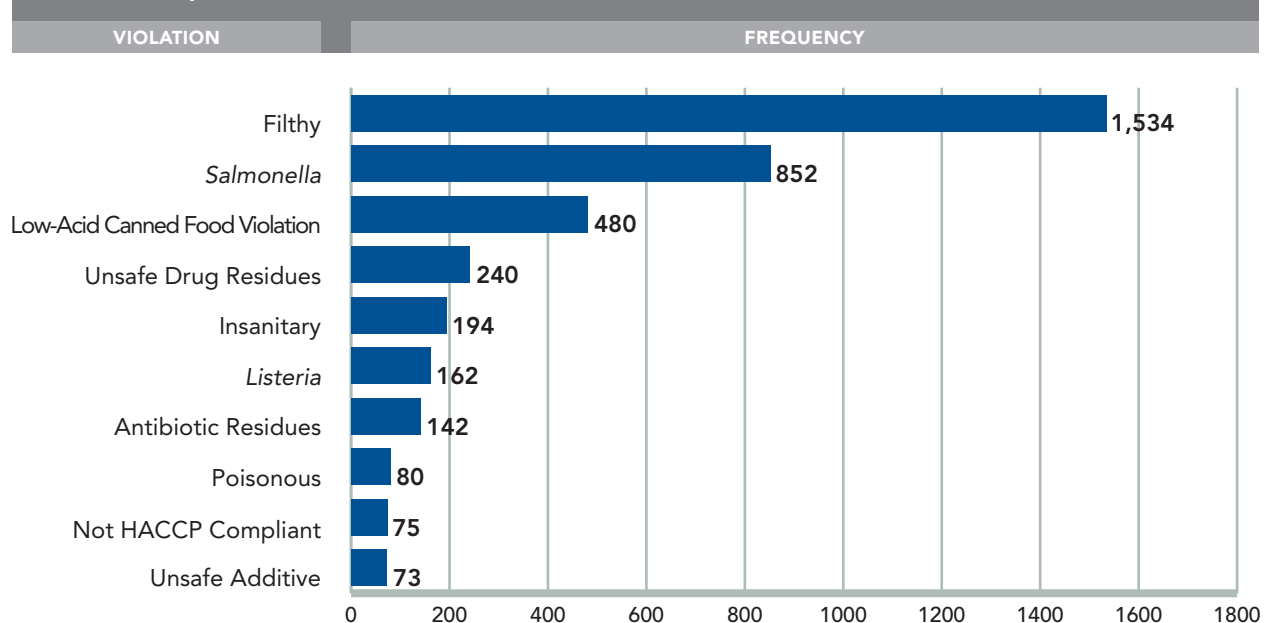
imports and refused-entry orders. The five countries most frequently identified with refused seafood are Vietnam, Indonesia, China, the Philippines and Thailand. A range of violations is cited for each country, with filth and pathogenic contamination accounting for a large percentage of refusals. Among the five countries, China has the greatest incidence of refusals for unsafe drug residues.

Five Seafood Importing Countries Most Frequently Refused Entry, 2009-2010

Country/Area	Seafood Refusals 2009-10 (line items)	Quantity of Seafood Imports (metric tons)
Vietnam	555	253,078
Indonesia	538	251,897
China	422	1,074,521
Philippines	224	99,924
Thailand	200	788,030

Sources: Refusals data from FDA OASIS. Quantity of imports from FAS GATS.

10 Most Frequent Violations Cited For Seafood, 2009-2010 (Adulteration)



Regulation of Food Imports Under FSMA

In the years leading up to enactment of FSMA, FDA relied on border inspections as its primary means of identifying problems with imported food, yet physically examined only 2 percent or less of the food products entering the country.²¹ Regarding FDA inspection of foreign facilities, the U.S. Government Accountability Office (GAO) found that, in 2008, FDA inspected only 153 of the roughly 189,000 registered foreign food facilities. That number was, in fact, an improvement from the 95 inspected in 2007.²² In a review of the FDA's oversight of imported seafood, GAO found the agency's performance lacking and urged it to enhance its import sampling program.²² Additionally, a recent report by the Office of the Inspector General at the Department of Health and Human Services found that the FDA guidance for recalls of imported food was "not adequate" and, in some instances, recall procedures were not followed.²⁴

Recognizing the inadequacy of the existing food import safety system for handling the growing globalization of the food supply, the drafters of FSMA included as one of the legislation's cornerstones a comprehensive system for better ensuring the safety of imported foods.²⁵ The first component of this system, which became effective in July 2011, strengthens the FDA's existing prior notice standards by requiring that importing companies inform FDA of the name of any country to which the food has been previously refused entry.²⁶

The new law places emphasis on safety programs in the originating countries before food is shipped to the United States. Specifically, the law:

- establishes a Foreign Supplier Verification Program that, for the first time, requires importers to ensure that their food meets current U.S. food safety standards²⁷
- creates a Voluntary Qualified Importer Program that gives companies an incentive to use enhanced food safety measures abroad by offering expedited review of shipments if the importer meets certain criteria²⁸
- authorizes the FDA to require that certain foods be certified regarding their safety by a government representative of the country of origin or other accredited entities²⁹
- creates an accreditation process for third-party auditors.³⁰

In order to address food safety issues at the point of origin, FSMA requires FDA to develop a plan to assist foreign governments and their food industries in expanding their food safety capacity.³¹ Furthermore, to provide better oversight abroad, the law directs FDA to establish offices in foreign countries³² and to inspect foreign facilities at a prescribed rate. Specifically, in the one-year period following the date of enactment of the new law, no fewer than 600 foreign facilities are to be inspected, with this number doubling for each of the next five years.³³ FSMA seeks to encourage compliance with the new system by barring entry to any food originating from a facility that refuses an inspection by American officials.³⁴

Recommendations for Improving Import Safety

In the face of the growing globalization of the U.S. food supply, FDA must ensure that our nation's food supply—including imported foods—is safe. A clear priority in this area is for Congress to provide FDA with the resources necessary to implement the comprehensive import safety system envisioned by FSMA.

In addition, Pew and CSPI urge FDA to focus on the following priorities in developing this system:

- FDA should build a robust inspection program to meet FSMA's requirement relating to inspection of foreign facilities.
- FDA must balance appropriately the resources directed to both foreign and domestic inspections.
- FDA should leverage the inspection resources of other federal agencies, such as the Food Safety and Inspection Service and the National Oceanic and Atmospheric Administration, in meeting its foreign facility inspection mandate.
- FDA should encourage more reliance on the inspections undertaken by trusted foreign governments when their food safety regimes meet U.S. standards.
- FDA should use its detention authority and other enforcement tools strategically to demonstrate that all importers must play by the rules and, when they don't, there will be consequences.
- Third-party auditors must be required to adhere to the same public health objectives, receive at least the same level of training and be held to the same standards as FDA employees. There must be stringent conflict-of-interest requirements and transparency in the auditing process.

Acknowledgments

The project team would like to thank the following individual for his careful and critical reading of this issue brief:

Mark Mansour, Partner, Akin Gump Strauss Hauer & Feld LLP

We thank our Pew colleagues—Gabrielle Cosel, Lisa Gonzales, Julia Moore, Alexis Matsui and Kodi Seaton—for their assistance in readying this report for publication. Our thanks also go to Penelope Malish of Malish & Pagonis Graphic Design and Bulletproof Proofreading.

Pew Health Group's Food Safety Campaign Team

Sandra Eskin
Project Director
Colin Finan
Project Manager
Ben Kessler

Pew Health Group

Shelley A. Hearne
Managing Director
Erik Olson
Director of Food Programs

Center for Science in the Public Interest

Caroline Smith DeWaal
Food Safety Director
David Plunkett
Senior Staff Attorney
Natalya Watson
Caitlin Catella
Cindy Roberts

For more information, see www.pewtrusts.org/foodsafety.

The analysis included in this report is solely that of The Pew Charitable Trusts and the Center for Science in the Public Interest and does not necessarily reflect the views of outside reviewers. This report is intended for educational and informative purposes.

Endnotes

1. FDA, Pathway to Global Product Safety and Quality, p. 1, (2011).
2. *Id.* at p.15.
3. *Id.* at p.1.
4. *Id.*
5. FDA Food Safety Modernization Act (FSMA), Public Law 111-353 (2011).
6. FDA uses the terms “refused” or “refusal” rather than “rejected” to describe when an imported product is not allowed into the United States. This issue brief uses the terms interchangeably.
7. OASIS is FDA’s automated system for processing and making admissibility determinations for shipments of foreign-origin, FDA-regulated products. OASIS refusals are publicly reported at www.accessdata.fda.gov/scripts/importrefusals.
8. Since a single shipment may contain multiple line items of food offered for import, if the entire shipment is refused, then each line item counts as a separate refusal.
9. Foreign Agricultural Service, Global Agricultural Trade System Online, query of imports for consumption of bananas and plantains, other fresh fruit, fresh vegetables and seafood for calendar year 2010.
10. The 10 largest importers of raw produce in order are: Mexico, Guatemala, Costa Rica, Ecuador, Canada, Chile, Honduras, Columbia, Peru and China (import totals for 2009 and 2010).
11. The 10 largest importers of seafood in order are: China, Thailand, Canada, Vietnam, Indonesia, Ecuador, Chile, Mexico, Philippines and Norway (import totals for 2009 and 2010).
12. The Federal Food Drug and Cosmetic Act (FFDCA) provides FDA with broad regulatory authority over food that is put into interstate commerce. Section 402(a)(1) (21 U.S.C. § 342(a)(1)) of the FFDCA provides that a food is deemed to be adulterated if it contains any poisonous or deleterious substances, such as chemical or microbial contaminants, which may, or ordinarily, render it harmful to health.
13. A finding of an illegal pesticide residue may or may not be a safety issue. For example, some pesticides that are authorized for use in the United States for certain crops may be used on other unapproved imported crops, resulting in a violation. This unapproved use may or may not pose a health threat.
14. Not all refusals for contaminants are the result of direct testing at the border. FDA may also base its refusal for illegal pesticides or pathogens on an import alert. FDA issues import alerts if the agency has sufficient information to refuse an item without physically examining it. If the importer does not introduce evidence—such as testing results from a private lab—to prove that the item is not adulterated, then the item is refused for the reason stated in the alert. For the raw produce items covered in this report, tests conducted by FDA were used in 274 refusals, while tests conducted by a private laboratory were used in 88 refusals.
15. The Office of Regulatory Affairs at FDA defines filth as “any type of matter that obviously does not belong in a food product,” for example, “rodent excreta, insects, parasites, and extraneous materials such as metal and glass shards.” ORA Laboratory Manual, Vol. IV (revised 2010).
16. The FFDCA defines “insanitary conditions” as, among other things, “contaminated with filth.” See 21 U.S.C. §§ 342(a)(3),381(a)(1).
17. Violation codes used in the import program do not include a specific code for Ciguatera and Scombroid toxins, and no violations reported for the generic code “BIO TOXIN” appear in the two years surveyed.
18. 21 C.F.R. Part 108 (2010).
19. 21 C.F.R. Part 123 (2010).
20. FDA Compliance Policy Guide Sec. 654.300 Chloramphenicol as an Unapproved New Animal Drug—Direct Reference Seizure Authority.
21. FDA Justification of Estimates for Appropriations Committee FY2012, p. 139 (reporting that in FY2010, FDA examined 2.06 percent of imported food line items, but will examine less than 2 percent in 2011).
22. GAO Testimony before the House Energy and Commerce Subcommittee on Oversight and Investigations, FDA Could Strengthen Oversight of Imported Food by Improving Enforcement and Seeking Additional Authorities (2010).
23. GAO, Seafood Safety: FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources (GAO-11-286) April 2011.
24. HHS Office of the Inspector General, Review of the Food and Drug Administration’s Monitoring of Imported Food Recalls, p. 1 (2011).
25. Title III, Improving the Safety of Imported Food, Food Safety Modernization Act.
26. Section 304 of FSMA.
27. Section 301 of FSMA.
28. Section 302 of FSMA. FSMA also addresses the treatment of food that is smuggled into the United States. See Section 309 of FSMA.
29. Section 303 of FSMA.
30. Section 307 of FSMA.
31. Section 305 of FSMA.
32. Section 308 of FSMA.
33. Section 201(a)(2)(D)(i) of FSMA.
34. Section 306 of FSMA.

