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Trends in Food Recalls: 2004-13

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Abstract

This report identifies trends, patterns, and outliers of food product recalls in the United States from 2004 through 2013. The analysis considers four factors: the types of foods being recalled, the reasons for initiating the recalls, the severity of the risks posed by the recalled products, and the geographic distribution. The results reveal that recall events increased across several major aggregate food categories (grain products, animal products, and prepared foods and meals), increased across all three risk severity classes, and occurred more frequently in highly populated States. Additionally, undeclared allergens were a leading cause of food product recalls, with the number of undeclared allergen recalls nearly doubling over the decade. Last, ingredient-driven recall events were the source of several extreme time trend outliers.

Keywords: food safety, food recalls, Food and Drug Administration, Food Safety and Inspection Service

Acknowledgments

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What Is the Issue?

The USDA Food Safety and Inspection Service (FSIS) and the U.S. Food and Drug Administration (FDA) are the primary Federal agencies responsible for overseeing the safety of food sold in the United States. Both agencies engage in preventive actions to protect consumers from unsafe foods, including overseeing food product recalls—the removal of risky food products from the U.S. marketplace. The number of food product recalls has increased significantly over the past couple of decades. This report examines the products and risks that may have contributed to this increase.

What Did the Study Find?

Between 2004 and 2008, food recalls averaged 304 a year; between 2009 and 2013, the annual average rose to 676. While an increase in the volume of food sold in the United States during this decade partially explains this statistically significant increase, other factors are also likely at play. For example, pathogen and risk detection technology substantially improved, regulatory oversight and enforcement increased, and Congress passed two major food policy laws: the Food Allergen Labeling and Consumer Protection Act (FALCPA) and the FDA Food Safety Modernization Act (FSMA).

The following six food categories accounted for the majority of food recalls in 2004-13: prepared foods and meals (excluding soups), 11.9 percent of all food recalls; nuts, seeds, and nut products, 10.9 percent; baked goods (including packaged baked goods), 9.0 percent; grains and grain products (excluding baked goods), 8.4 percent; candy products, 7.9 percent; and sauces, condiments, and dressings, 5.0 percent. For each of these foods, with the exception of nut products, the most common reason for initiating the recall was failure to declare major allergens. The most common reason for recalls of nut products was possible *Salmonella* contamination. While the number of food product recalls increased across every food category, the increase was statistically significant only for grain products, animal products, and prepared foods and meals.

Analyzing recalls by type of risk, 41.0 percent were the result of pathogen contamination (Shiga toxin-producing *Escherichia coli, Salmonella,* etc.) and 27.4 percent were the result of undeclared allergens. While the number of recalls due to pathogen contamination did not increase significantly during this decade, the number of allergen recalls nearly doubled. The passage of FALCPA likely played a major role in the growing number of undeclared allergen recalls.

Last, food product recalls of common ingredients may have significant and exponential impacts on manufacturers and users of recalled ingredients. From 2004 through 2013, 22.4 percent of all recalls were the result of an upstream ingredient being recalled first.

How Was the Study Conducted?

Researchers from USDA's Economic Research Service analyzed a unique dataset of food product recalls from January 1, 2004, through December 31, 2013. The dataset was constructed by extracting publicly available information from FSIS and FDA press releases, FSIS Recall Notification Reports, and FDA Enforcement Reports. Researchers charted and tabulated food product recall events by the types of food being recalled, reasons for the recall, risk severity, and geographic distribution. To identify statistically significant changes, averages from the first 5 years were compared with those from the last 5 years, and any differences were tested for significance. The study gives special attention to recalls of fresh produce and meat, poultry, and seafood because these foods are considered to pose the greatest potential health risk in terms of food safety.

Trends in Food Recalls: 2004-13

Introduction

Unsafe foods lead to significant losses of life and productivity. The Centers for Disease Control and Prevention (CDC) estimates that foodborne disease is the cause of approximately 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths annually in the United States (Scallan et al., 2011a and 2011b). Put another way, one in six Americans becomes ill from consuming contaminated food products each year. To protect public health and prevent foodborne illness, the Federal Government takes measures to ensure that the Nation's food supply is safe, wholesome, and accurately labeled. These measures include overseeing the removal of risky food products from the market through recalls.

While removal of risky and potentially contaminated goods from commerce is beneficial for public health, the direct and indirect costs to manufacturers and regulators can be substantial. According to a recent survey conducted by the Grocery Manufacturers Association (GMA), 29 percent of companies that had faced a recall within the prior 5 years estimated that the direct cost of the recall was between $10 million and $29 million (GMA, 2011). These direct costs include notification (i.e., to regulatory bodies, the downstream supply chain, and consumers); customer reimbursement; product retrieval, storage, and destruction; business interruption; and loss of sales.

The total cost can be even greater when accounting for indirect costs, including the cost of any subsequent litigation (Buzby and Frenzen, 1999) and the impact on the manufacturer's market value and brand reputation (Pozo and Schroeder, 2016). These costs can spill over and affect other manufacturers within the same industry, particularly for products that are marketed collectively. When a product is marketed collectively and has little to no brand differentiation, consumers may react by avoiding the commodity as a whole, and the reputation of the entire industry may be tarnished. In fact, several recent analyses have demonstrated that this is particularly true when recalls are linked to a major foodborne disease outbreak (see Arnade et al., 2009; Arnade et al., 2011; Bakhtavoryan et al., 2014; and Kuchler, 2015).

Food product recalls also pose a great concern for consumers. Many consumers deem recalls to be negative signals that convey information about the relative safety of a food product, and concerns over unsafe food products and foodborne disease have the strong potential to influence consumer purchases and demand. However, the burden falls on the consumer to remain informed of current product recalls and to monitor home inventories. A 2008 national survey of consumers revealed that 84 percent of 1,100 respondents had heard of at least 1 of 3 recent recall events, but less than half (45 percent) knew that there is always at least 1 food product recall in effect at any given time. The majority of respondents (59 percent) also reported having searched for a recalled product at some point in their own home (Hallman et al., 2009).

This report analyzes trends, patterns, and outliers of food product recalls over the course of a decade—2004 through 2013. During this time, the total number of food recall events increased considerably. Given the substantial direct and indirect costs of recalls on manufacturers, consumers, and regulators, there is a need to understand why the total number of food product recalls has

increased. Trends are identified by the types of food products recalled, the reasons for initiating recalls, the severity of the health risk posed by the recalled products, and the geographic distribution of the recalled products. Identification of trends and patterns may provide targets for both manufacturer food safety practices and regulatory oversight, which may ultimately aid in reducing the total number of recalls. This could reduce recall costs, improve the overall quality and safety of the food supply, and result in fewer foodborne illness outbreaks.

The period chosen for analysis, 2004 to 2013, was critical for food safety in the United States. The decade saw several major, highly publicized foodborne illness outbreaks linked to contaminated products, notably spinach (2006), peanut butter (2009), eggs (2010), and cantaloupe (2011). Additionally, Congress enacted two major pieces of food safety legislation: the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004, which requires all food labels to list major allergens; and the FDA Food Safety Modernization Act (FSMA), signed in 2011, which gives the U.S. Food and Drug Administration (FDA) the authority to impose mandatory recalls and, if necessary, shut down operations at food production facilities.

Background

Within the United States, the two primary Federal authorities responsible for food safety are the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) and the U.S. Food and Drug Administration (FDA), an agency of the U.S. Department of Health and Human Services (HHS). FSIS inspects and regulates meat, poultry, and processed egg products, and, as a result of the 2008 and 2014 Farm Bills, also inspects fish of the order *Siluriformes* (e.g., catfish) (USDA, FSIS, 2015).[1] FDA inspects and regulates all other food products, including sandwiches (made in central facilities for offsite consumption), certain products that contain a small amount of meat and poultry (by volume), and game/exotic meats.[2] This division of responsibilities dates back to 1906, when Congress passed two separate acts: the Federal Meat Inspection Act, which charged a branch of USDA with inspecting meat, and the Pure Food and Drug Act, which charged the predecessor of FDA with ensuring the safety of all other foods. The former addressed the unsafe and unsanitary conditions in meatpacking plants, and the latter addressed the widespread marketing of intentionally adulterated foods (Johnson, 2014).

FSIS and FDA currently coordinate and oversee the recalls of food products that may cause increased health risks. Examples of possible health risks include pathogen contamination, foreign object contamination, undeclared allergens, and undeclared sulfites. Health risks are usually discovered one of several ways: the manufacturer or distributer, USDA or FDA, or another Federal or State agency discovers the presence of a health risk through testing or inspection; a consumer inquires about or files a complaint against a specific product; or a consumer illness prompts an investigation and the source of illness is traced back to a specific product and manufacturer.

Once a health risk is discovered, the manufacturer or distributor may decide to recall the contaminated or risky product. This decision is, in general, a voluntary action. For products that fall under the authority of FDA, manufacturers initiate almost all of the recalls at their own behest or at the request of FDA. As of 2011, if a manufacturer does not comply with a voluntary recall request, FDA has the legal authority to mandate food product recalls and shut down operations at food production facilities (FDA, 2013). For products that fall under FSIS' authority, FSIS will coordinate with the manufacturer or distributor to determine whether there is a need for a recall. In doing so, FSIS convenes a committee of experts to evaluate all available information and make a recommendation to the firm. If a recall is recommended and the recommendation is ignored, FSIS may detain any product found in commerce that would have been subject to the recall (USDA, FSIS, 2013).

As soon as the manufacturer decides (or is mandated) to recall the risky product, FSIS or FDA determines the severity of the threat posed by the marketed product and classifies it as a Class I, II, or III. Class I represents a health hazard situation in which there is reasonable probability that consuming the product will cause health problems or death (e.g., pathogen contamination of a ready-to-eat food product); Class II represents a potential health hazard situation in which there is a remote probability of adverse health consequences from the consumption of the product (e.g., foreign object contamination); and Class III represents a situation in which consuming the product

[1] FSIS inspection of *Siluriformes* became effective March 1, 2016.

[2] FDA also ensures the safety of drugs, dietary supplements, medical devices, animal feed and pet food, tobacco, and cosmetics; for the purposes of this report, only food products are considered.

will not cause adverse health consequences (e.g., lack of an English language label on a retail food product). The same classification system is used by both FDA and FSIS.

Depending on the severity and the distribution of the recalled product, FSIS, FDA, and/or the manufacturer may issue a press release to vendors and media outlets in the areas where the recalled product was distributed. Vendors of the recalled product are instructed to remove the product from the market so that it is no longer available for purchase or consumption. Likewise, consumers are instructed to check any products they may have purchased before the recall announcement and determine whether products in their pantry or refrigerator match the description of the recalled product.

Data on Food Recalls

This report analyzes a unique dataset of food product recall events that occurred from January 1, 2004, through December 31, 2013, in the United States (excluding Puerto Rico and other island territories).[3] This dataset was constructed by USDA, Economic Research Service (ERS) researchers by extracting information from FSIS and FDA press releases, FSIS Recall Notification Reports, and FDA Enforcement Reports. Both FSIS and FDA issue a press release for a recall event when they determine that the situation warrants widespread public awareness—for example, the nationwide retail distribution of a Class I or II recalled product.[4] For recalls under the authority of FSIS, when a recall is not publicized with a press release, FSIS posts a Recall Notification Report on the FSIS website. For recalls under the authority of FDA, all recalls are logged in the weekly FDA Enforcement Reports, regardless of whether a press release has been issued. Together, the FDA and FSIS press releases, the FSIS Recall Notification Reports, and the FDA Enforcement Reports, archived and available to the public online, provide the most exhaustive and complete picture of food products recalled in the United States.[5]

Data collected from the press releases and the FSIS Recall Notification Reports include the date of the FDA or FSIS recall announcement, a description of the food product(s) recalled, the reason for the recall and the health risk involved (if any), the distribution of the contaminated product(s), and, for FSIS recalls, the severity classification. In addition, the press releases and reports sometimes include information on how the health risk was discovered and whether the contaminated product was available for retail purchase or distributed to restaurants and institutional facilities (schools, prisons, nursing homes, etc.). FDA Enforcement Reports were used to verify the information contained within the FDA press releases (if a press release exists), to identify events without press releases, and to collect data on the severity classification of recalled products.[6] Appendix A provides a complete list of variables collected. (For an example of an FSIS press release, see figure 1.[7] For examples of an FDA press release and corresponding entry in the FDA Enforcement Report, see figures 2 and 3, respectively.)

[3] Recalled food products include imported products intended for U.S. distribution.

[4] Press releases for recalls under the authority of FSIS are composed by FSIS, whereas press releases for recalls under the authority of FDA are composed by the manufacturer or distributor of the recalled product.

[5] Though there is significant overlap, these data differ from the Reportable Food Registry (RFR), which is an electronic portal for industry to report food products when there is reasonable probability that the product will cause serious adverse health consequences or death. The RFR is maintained by FDA and applies only to FDA-regulated categories of food and feed, except dietary supplements and infant formula.

[6] While great efforts were made to match each FDA press release to an FDA Enforcement Report entry, a match with certainty was not possible for 19.9 percent of FDA food recalls with press releases. Note that 44.4 percent of these unmatched recall events were from 2009, an exceptional year with a total of 888 FDA food product recalls.

[7] FSIS Recall Notification Reports and FSIS press releases are very similar in structure and content.

Figure 1

Example of an FSIS press release, February 28, 2011

News Releases

California Firm Recalls Chicken and Mushroom Pie Products due to Mislabeling and Undeclared Allergen

Recall Release
FSIS-RC-015-2011

CLASS I RECALL
HEALTH RISK: HIGH

Congressional and Public Affairs
[redacted]

WASHINGTON, February 28, 2011 - Piccadilly Fine Foods, a Santa Clara, Calif., establishment, is recalling approximately 775 pounds of chicken and mushroom pie products because they may contain an undeclared allergen, egg, the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) announced today. Egg is a known allergen, which may have not been declared on the label.

The following products are subject to recall: [Label]

- 12-lb. cases of "Piccadilly Fine Foods Chicken and Mushroom Pastie," with each case containing 24 individual packages.

The individual packages weigh 8 ounces each and say "Keep Frozen" on the label. The label also bears the establishment number "P-9216" inside the mark of inspection. Listed on the cases and individual packages are lot codes 213-10 through 365-10 and 001-11 through 056-11.

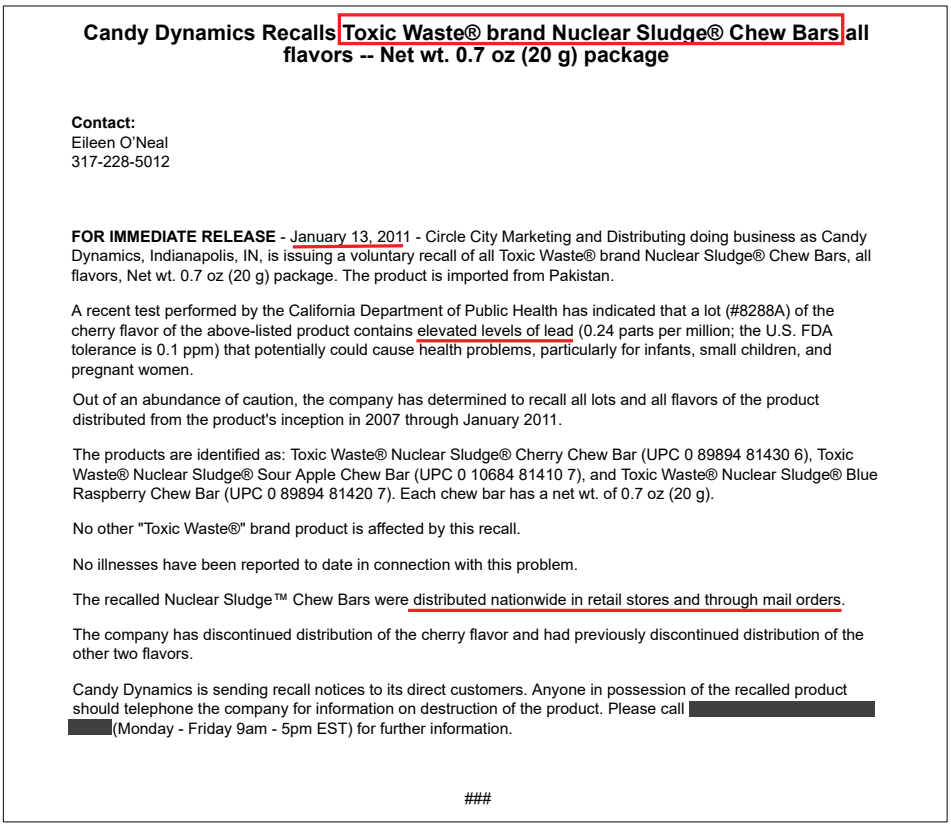
The chicken and mushroom pies were produced on various dates between Aug. 1, 2010, and Feb. 25, 2011. Note that some products subject to recall during this time frame are correctly labeled in that they do include "egg" in the ingredient statement. The "Chicken and Mushroom Pasties" that do not list "egg" are subject to recall. The products were shipped to distributors in California, Colorado, Florida and Texas for further distribution to retail outlets.

The problem was discovered by FSIS personnel during a routine label review. It was determined that while the label was approved with "egg" in the ingredients statement, some of the final product labels did not have it listed. FSIS and the company have received no reports of adverse reactions due to consumption of these products. Anyone concerned about an allergic reaction should contact a physician.

Source: USDA, Food Safety and Inspection Service (FSIS). Emphasis and redaction by USDA, Economic Research Service.

Figure 2

Example of an FDA press release, January 13, 2011



Candy Dynamics Recalls Toxic Waste® brand Nuclear Sludge® Chew Bars all flavors -- Net wt. 0.7 oz (20 g) package

Contact:
Eileen O'Neal
317-228-5012

FOR IMMEDIATE RELEASE - January 13, 2011 - Circle City Marketing and Distributing doing business as Candy Dynamics, Indianapolis, IN, is issuing a voluntary recall of all Toxic Waste® brand Nuclear Sludge® Chew Bars, all flavors, Net wt. 0.7 oz (20 g) package. The product is imported from Pakistan.

A recent test performed by the California Department of Public Health has indicated that a lot (#8288A) of the cherry flavor of the above-listed product contains elevated levels of lead (0.24 parts per million; the U.S. FDA tolerance is 0.1 ppm) that potentially could cause health problems, particularly for infants, small children, and pregnant women.

Out of an abundance of caution, the company has determined to recall all lots and all flavors of the product distributed from the product's inception in 2007 through January 2011.

The products are identified as: Toxic Waste® Nuclear Sludge® Cherry Chew Bar (UPC 0 89894 81430 6), Toxic Waste® Nuclear Sludge® Sour Apple Chew Bar (UPC 0 10684 81410 7), and Toxic Waste® Nuclear Sludge® Blue Raspberry Chew Bar (UPC 0 89894 81420 7). Each chew bar has a net wt. of 0.7 oz (20 g).

No other "Toxic Waste®" brand product is affected by this recall.

No illnesses have been reported to date in connection with this problem.

The recalled Nuclear Sludge™ Chew Bars were distributed nationwide in retail stores and through mail orders.

The company has discontinued distribution of the cherry flavor and had previously discontinued distribution of the other two flavors.

Candy Dynamics is sending recall notices to its direct customers. Anyone in possession of the recalled product should telephone the company for information on destruction of the product. Please call [redacted] (Monday - Friday 9am - 5pm EST) for further information.

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Source: U.S. Food and Drug Administration (FDA). Emphasis and redaction by USDA, Economic Research Service.

Figure 3

Example of an FDA Enforcement Report entry

RECALLS AND FIELD CORRECTIONS: FOODS - CLASS II

PRODUCT
1) Toxic Waste brand Nuclear Sludge Cherry Chew Bar, Net wt. 0.7 oz (20 g) package, UPC 89894 81430; and 0.3 oz (8 g) package, UPC 8989481901. Imported from Pakistan. Product is an ultra sour taffy-like candy bar. Described as "hazardously" sour candy. Recall # F-0731-2011;

2) Toxic Waste brand Nuclear Sludge Sour Apple Chew Bar, Net wt. 0.7 oz (20 g) package, UPC 0 10684 81410 7; and Net wt. 0.3 oz (8 g) package, 8989481701. Imported from Pakistan. Product is an ultra sour taffy-like candy bar. Described as "hazardously" sour candy. Recall # F-0732-2011;

3) Toxic Waste brand Nuclear Sludge Blue Raspberry PLE Chew Bar, Net wt. 0.7 oz (20 g) package, UPC 89894 81420; and Net wt. 0.3 oz (8 g) package, UPC 8989481801. Imported from Pakistan. Product is an ultra sour taffy-like candy bar. Described as "hazardously" sour candy. Recall # F-0733-2011

CODE
Lot #8288A; All lots and all flavors of the product distributed from the product's inception in 2007 through January 2011.

RECALLING FIRM/MANUFACTURER
Recalling Firm: Circle City Marketing & Distributing, Carmel, IN, by press release on January 13, 2011 and January 27, 2011 and by letters beginning January 14, 2011.
Manufacturer: Asian Food Industries Ltd., Lahore, Pakistan. Firm initiated recall is ongoing.

REASON
A recent test performed by the California Department of Public Health has indicated that a lot (#8288A) of the Toxic Waste brand Nuclear Sludge Cherry Chew Bar contains elevated levels of lead (0.24 parts per million; the U.S. FDA tolerance is 0.1 ppm) that potentially could cause health problems, particularly for infants, small children, and pregnant women.

VOLUME OF PRODUCT IN COMMERCE
Undetermined

DISTRIBUTION
Nationwide, Canada, Korea, Italy, UK, Jordan, Denmark and Belgium

Source: U.S. Food and Drug Administration (FDA). Emphasis added by USDA, Economic Research Service.

Trends in Food Recalls

Between 2004 and 2013, FDA and FSIS oversaw 4,900 food product recalls in the United States.[8] Of these, FDA recalls accounted for 86.8 percent, and FSIS recalls of meat, poultry, and processed egg products accounted for 13.2 percent (table 1). Generally, the incidence of both FDA and FSIS food recalls increased throughout the decade with several notable outlier months—months where the number of recalls drastically deviated from the observed general trend (fig. 4).

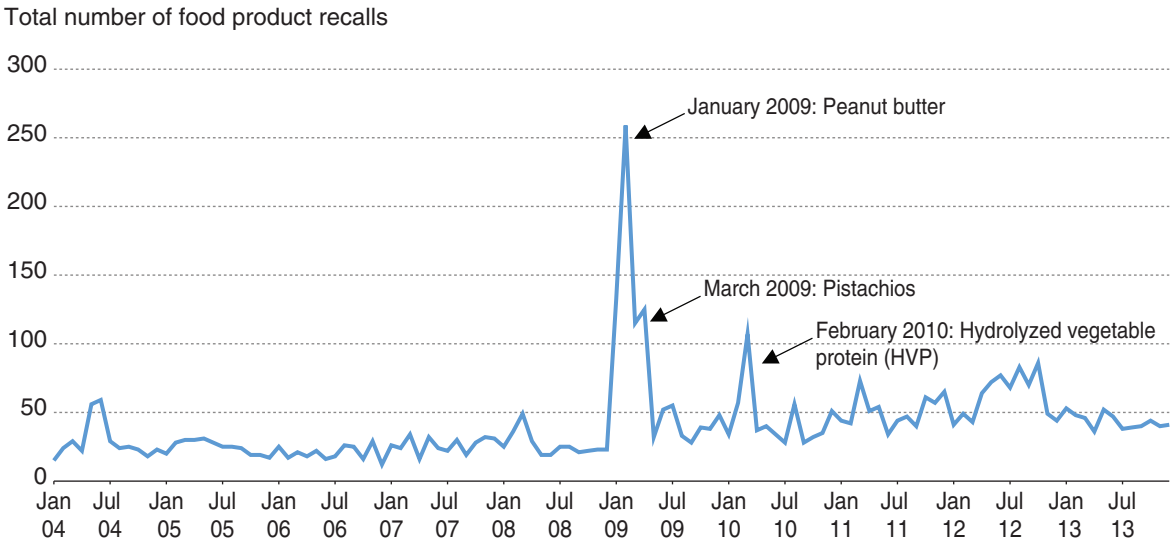
Table 1
Total number of food product recall events by agency and year, 2004-13

	FDA	FSIS	Total
2004	298	49	347
2005	243	53	296
2006	211	34	245
2007	260	58	318
2008	263	53	316
2009	888	69	957
2010	469	70	539
2011	509	103	612
2012	664	82	746
2013	449	75	524
Total:	4,254	646	4,900

Note: A recall event is a recall announcement from a manufacturer or distributor and may include multiple recalled items.
Source: USDA, Economic Research Service calculations using U.S. Food and Drug Administration (FDA) and USDA, Food Safety and Inspection Service (FSIS) press releases, FSIS Recall Notification Reports, and FDA Enforcement Reports.

[8] The unit of analysis throughout this report is a recall event and may be referred to simply as a recall. A recall event or recall is a recall announcement from a manufacturer or distributor and may include multiple recalled items. These items may be different products altogether or the same product packaged in different quantities.

Figure 4
Food product recall events by month, 2004-13



Note: A recall event is a recall announcement from a manufacturer or distributor and may include multiple recalled items.
Source: USDA, Economic Research Service calculations using U.S. Food and Drug Administration (FDA) and USDA, Food Safety and Inspection Service (FSIS) press releases, FSIS Recall Notification Reports, and FDA Enforcement Reports.

Several possible factors may explain this upswing in recalls, but conclusively stating a cause is difficult. One possibility is the increase in volume of food sold in the United States from 2004 to 2013. During this time, however, total U.S. food expenditures increased annually by an average of 1.4 percent (USDA, ERS, 2016a), whereas the total number of food product recalls increased annually by an average of 18.0 percent. Since the number of recalls increased faster than market growth, other factors are also likely at play.

Another possibility, though still unlikely, is that food has generally become less safe. While Hennessy and colleagues (2003) outlined systemic failures in the provision of safe food, it seems unlikely that any inherent deficiencies would lead to an increase in the number of recalls within the past decade. Moreover, if this were the case and the food supply was in fact becoming less safe, we would also expect to witness an increase in the number of reported foodborne illness outbreaks. However, Powell (2016) determined that from 1996 to 2013, illnesses due to bacterial pathogens commonly transmitted by food in the United States neither decreased nor increased.

A more likely possibility is that pathogen and risk detection technology improved from 2004 to 2013, and external audits of the technologies became more common, thereby increasing the number of detected health risks in food products. Indeed, in recent years, rapid-detection methods have evolved to become more time efficient, sensitive, specific, and labor saving when compared with older, conventional methods (see Law et al., 2014, for a detailed review of rapid-detection technologies). Moreover, fast-food restaurants and grocery retailers increasingly require food manufacturers to hire external auditors to assess manufacturer food safety practices. These audits have been associated with greater use of food safety testing and equipment technologies (Ollinger et al., 2011).

Alternatively, inspection efforts of Federal and State agencies may have had an impact on the number of recall events, independent of technology improvements. A recent report on FDA inspections of domestic food facilities by the HHS Office of the Inspector General (OIG) determined

that 17,032 domestic facilities were inspected in 2004, increasing to 19,369 facilities in 2011, and decreasing to 16,846 by 2013 (HHS, OIG, 2017).[9] While the number of facilities inspected fluctuated throughout the decade, the total number of domestic food facilities under FDA jurisdiction increased over that same time. Therefore, the share of food facilities inspected by FDA steadily decreased, from 29 percent in 2004 to 20 percent in 2013. However, analyzing the total number of FDA recall events against the total number of FDA inspections of domestic food facilities from year to year results in a Pearson correlation coefficient of 0.5, suggesting that inspections may, indeed, be positively associated with recalls.

Last, the passage of two major food policy laws likely had major impacts on the incidence of food product recalls. The first, the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004, effective January 1, 2006, requires all food labels to list major allergens. Under FALCPA and the Federal Food, Drug, and Cosmetic Act, the FDA, through inspections, ensures that food manufacturers comply with practices to reduce or eliminate cross-contact with allergens that are not intentional ingredients and that major food allergens are properly labeled. Thus, FALCPA likely led to an increase in the incidence of food product recalls due to undeclared allergens. The second major law, the FDA Food Safety Modernization Act (FSMA), is the most sweeping reform of food safety law in over 70 years. Under FSMA, the FDA, for the first time, has the authority to impose a mandatory recall and shut down operations at food production facilities. While FDA has only exercised this authority twice,[10] this new enforcement authority has the potential to change producer incentives to voluntarily disclose and recall risky products before being mandated to do so, perhaps leading to an increase in the number of food recalls upon enactment in 2011.

Examining recalls by the types of foods being recalled, health risks involved, severity, and distribution may provide greater insight into specific outliers, trends, patterns, and causes behind this general increase in the total number of recall events from 2004 to 2013. Identification of any patterns and trends may also provide targets for manufacturer and regulatory oversight efforts.

Recalls by Food

The most dramatic outlier event between 2004 and 2013 is the January 2009 recall of peanut butter linked to a *Salmonella* outbreak responsible for 714 known illnesses and 9 deaths (fig. 4). After peanut butter produced by Peanut Corporation of America (PCA) was implicated by epidemiologic and laboratory evidence, all identifiable food products that used PCA peanut butter and peanut paste as an ingredient were recalled.[11] And because peanut butter and peanut paste are common ingredients in cookies, crackers, cereal, candy, ice cream, and other foods, over 400 separate recalls occurred as a consequence. As the CDC (2009) stated, “this was an ingredient-driven outbreak, in

[9] The FDA Food Safety Modernization Act (FSMA) of 2011 mandated that FDA increase the frequency of its inspections of domestic food facilities based on risk. Specifically, FSMA required FDA to inspect all high-risk facilities at least once within 5 years of enactment, and every 3 years thereafter. Additionally, FDA is required to inspect non-high-risk facilities at least once within 7 years of enactment, and every 5 years thereafter. Prior to FSMA, there were generally no timeframes for food facility inspections (HHS, OIG, 2017).

[10] As of March 2018, FDA has only mandated recalls twice: the 2013 recall of *Salmonella*-tainted pet treats and the 2014 recall of dietary supplements linked to a nonviral hepatitis outbreak.

[11] The PCA outbreak is also notable for its subsequent criminal convictions. In September 2015, the former owner of PCA was sentenced to 28 years in Federal prison for knowingly shipping *Salmonella*-tainted peanut butter, the harshest criminal sentence ever imposed in a food safety case.

which a contaminated ingredient affected many different products that [were] distributed through various channels and consumed in various settings."

The next largest uptick in the number of monthly food product recalls is the March/April 2009 recall of pistachios contaminated with *Salmonella*. Setton Pistachio of Terra Bella, Inc., the second largest U.S. producer of pistachios, recalled over 1 million pounds of roasted pistachio products just months after the massive PCA peanut butter recall. However, unlike the peanut butter product recall, the pistachio recall was not prompted by a consumer illness investigation. Instead, routine testing by a commercial customer led to the discovery of *Salmonella* strains. Again, the pistachios were mostly sold to food wholesalers and manufacturers, who then packaged them for resale or incorporated them as ingredients in other products, such as ice cream and trail mix. In all, over 100 separate recalls were associated with the initial pistachio recall.

The third largest outlier is the February 2010 recall of products containing hydrolyzed vegetable protein (HVP), a flavor enhancer. All products containing HVP (in powder and paste form) by a single manufacturer, Basic Food Flavors, Inc., were recalled because of possible *Salmonella* contamination. Once again, commercial customer testing, rather than a consumer illness investigation, prompted this recall, and it is yet another example of an ingredient-driven recall that impacted downstream manufacturers and wholesale buyers of HVP. In total, over 80 recalls were associated with the initial recall of HVP; this included the recalls of spice blends, soups, sauces, gravies, and dressing.

While plotting the total number of food product recalls over time allows for clear identification of outliers, it is also informative to examine the types of foods recalled and to determine whether general time trends are present among certain foods. To do so, seven main food groups were defined to categorize food recalls: grain products, vegetables, fruit, dairy, meat and seafood, nuts, and other. These categories were further disaggregated into 99 individual categories, listed in Appendix B. These finer categories distinguish between different primary ingredients and various methods of preparation and packaging. For example, there are five root vegetable categories: fresh, frozen, canned, prepared, and dried. These categories are based on food categorization systems common in the nutrition literature[12] but adjusted to better suit the needs of food safety analysis. For example, following Painter et al. (2013), vegetable categories distinguish between fungi, leafy, root, sprouts, and vine-stalk vegetables, and meat categories distinguish between beef, pork, poultry, game, fish, crustaceans, and mollusks.

An examination of recall events by food product category reveals that the top six food products recalled from 2004 through 2013 were prepared foods and meals, nuts and nut products, baked goods, grain products, candy products, and sauces/condiments (table 2). These six foods accounted for the majority of all recalls (53.0 percent), and with the exception of some nut products, they are all highly processed foods.

[12] These categories are loosely based on the "What We Eat in America Food Categories" (USDA, ARS, 2016) and the food groups of the National Household Food Acquisition and Purchase Survey (USDA, ERS, 2016b).

Table 2

Total number and share of food product recall events by food, 2004-13

Food product	Frequency	Share (%)
Prepared foods and meals (excl. soups)	581	11.86
Nuts, seeds, and nut products	532	10.86
Baked goods (incl. packaged)	439	8.96
Grains and grain products (excl. baked goods)	412	8.41
Candy products	388	7.92
Sauces, condiments, and dressings	245	5.00
Fish and fish products	229	4.67
Beverages	219	4.47
Dairy-based desserts	211	4.31
Fruit and fruit products (excl. juice)	210	4.29
Bacon, sausage, and lunch meats	185	3.78
Beef and beef products	172	3.51
Cheese and cheese products	154	3.14
Spices and seasonings	138	2.82
Soups	114	2.33
Root vegetable products	92	1.88
Leafy vegetable products	76	1.55
Poultry and poultry products	76	1.55
Mixed and other vegetable products	66	1.35
Mollusks and mollusk products	65	1.33
Milk, cream, and yogurt products	64	1.31
Vine-stalk vegetable products	62	1.27
Nutrition bars	57	1.16
Sprouts	47	0.96
Fruit juice products	46	0.94
Sweeteners/jams/jellies/preserves	46	0.94
Crustaceans and crustacean products	46	0.94
Bean, lentil, pea, and legume products	39	0.80
Fungi products	38	0.78
Uncategorized products	36	0.73
Fresh herbs	31	0.63
Tofu and meat substitutes	26	0.53
Pork and pork products	26	0.53
Eggs and egg mixtures	24	0.49
Baby formulas and foods	21	0.43
Fats and oils	21	0.43
Vegetable juice products	7	0.14
Game, lamb, and other meat products	6	0.12

Note: The focus of this table is on food products rather than preparation; thus, the 99 categories of Appendix B are aggregated into 38 categories. Additionally, a recall event is a recall announcement from a manufacturer or distributor and may include multiple recalled items. Consequently, the total number of recall events by food type exceeds the total number of recall events in table 1 because 282 recalls include products in at least 2 different categories.

Source: USDA, Economic Research Service calculations using U.S. Food and Drug Administration (FDA) and USDA, Food Safety and Inspection Service (FSIS) press releases, FSIS Recall Notification Reports, and FDA Enforcement Reports.

To identify foods that may be predominantly responsible for the overall increase in food recalls, the average from the first 5 years can be compared to the average from the last 5 years for selected aggregate food categories to determine whether any differences are statistically significant (table 3).[13] For every food category, the average number of recalls increased in the second half of the decade, but the difference in means was statistically significant only for animal products, baked goods, and prepared foods at the 5-percent level and for grain and other food products at the 1-percent level. Overall, the average number of all food product recalls more than doubled from the first half of the decade to the second half, and the difference in means was statistically significant at the 1-percent level.

Table 3
Average number of annual food product recall events by food, 2004-13

Food	Average 2004-13	Average 2004-08	Average 2009-13
Grain products	41.2	24.4	58.0**
Vegetable products	44.6	31.8	57.4
Fruit products	25.6	20.2	31.0
Dairy products	42.5	23.0	62.0*
Meat, poultry, and seafood products	77.3	57.0	97.6*
Nut products	53.2	19.2	87.2
Other food products	89.9	54.2	125.6**
Prepared foods and meals	58.0	38.6	77.4*
Baked goods	43.9	23.8	64.0*
Candy products	38.8	22.6	55.0
All food products	490.0	304.4	675.6**

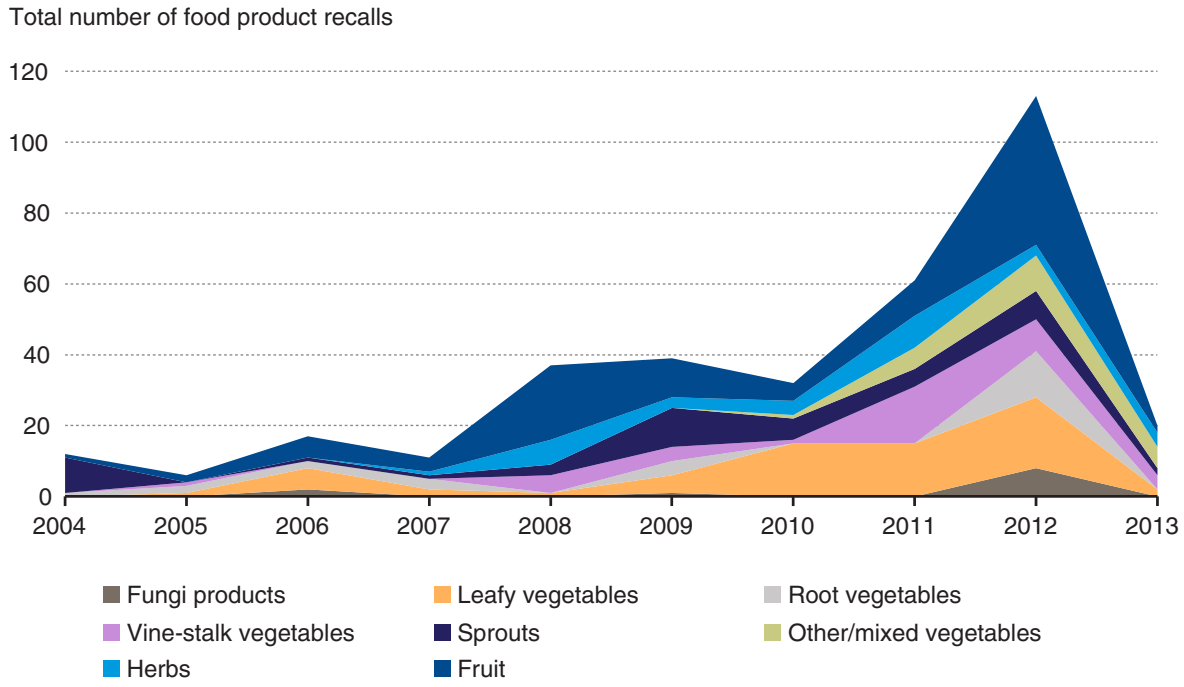
Note: Asterisk (*) and double asterisk (**) indicate that the t-test of a difference in the means for 2004-08 and 2009-13 is significant at the 5- and 1-percent levels, respectively. A recall event is a recall announcement from a manufacturer or distributor and may include multiple recalled items.

Source: USDA, Economic Research Service calculations using U.S. Food and Drug Administration (FDA) and USDA, Food Safety and Inspection Service (FSIS) press releases, FSIS Recall Notification Reports, and FDA Enforcement Reports.

Fresh produce and meat/poultry/seafood recalls are of particular interest as these foods represent the greatest potential health risk in terms of food safety. In fact, produce and meat-poultry commodities accounted for the majority of foodborne illnesses, hospitalizations, and deaths between 1998 and 2008 (Painter et al., 2013). The total number of fresh produce recalls increased steadily throughout the decade, spiking in 2012 following two major *Salmonella* outbreaks linked to domestic cantaloupes and imported mangoes, before drastically decreasing in 2013 (fig. 5). Only the difference in leafy green recalls for the first 5 years as compared to the last 5 years was statistically significant at the 5-percent level.

[13] In addition to the seven major food categories, three additional categories are also included (prepared foods and meals, baked goods, and candy), given the high frequency of recalls in these categories.

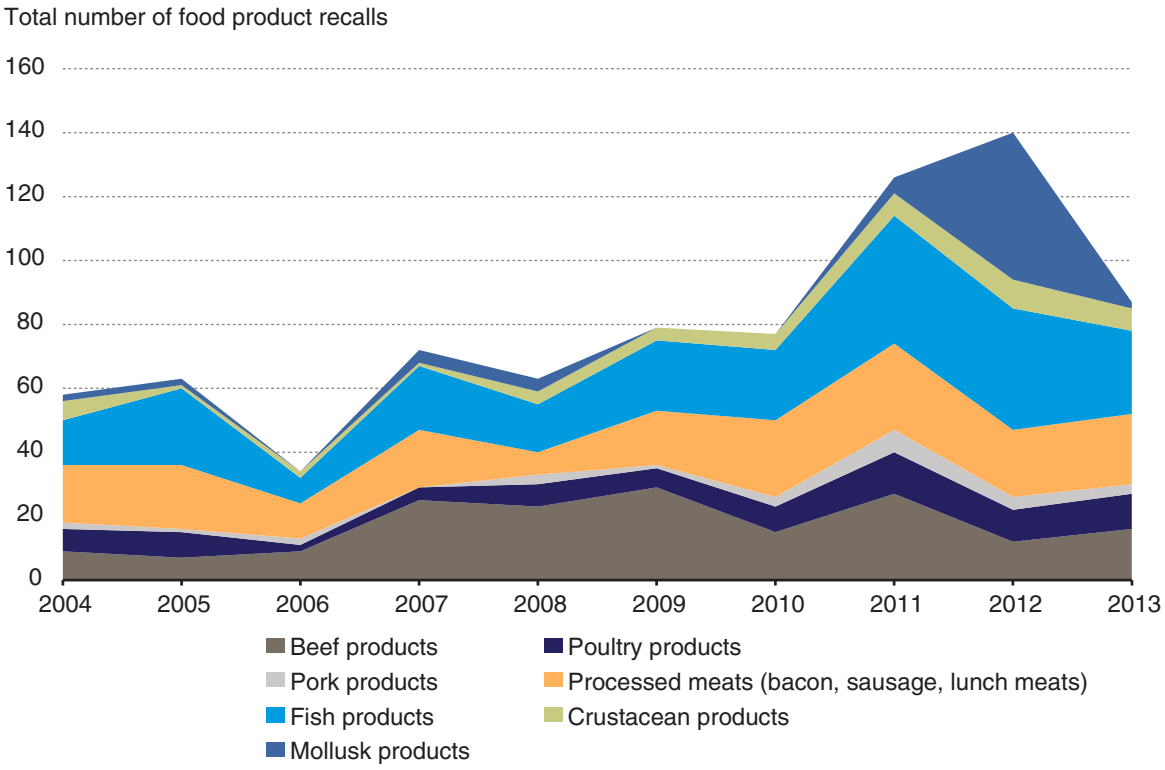
Figure 5
Fresh produce recall events by year, 2004-13



Note: A recall event is a recall announcement from a manufacturer or distributor and may include multiple recalled items.
Source: USDA, Economic Research Service calculations using U.S. Food and Drug Administration (FDA) press releases and Enforcement Reports.

Total meat, poultry, and seafood recalls also increased steadily throughout the decade (fig. 6). However, for specific meat, poultry, and seafood categories, the difference in means between the first half and second half of the decade was statistically significant at the 10-percent level only for processed meat, fish, and crustacean products. Last, the number of mollusk recalls spiked in 2012, following a temporary FDA ban on shellfish from South Korea.

Figure 6
Meat, poultry, and seafood recall events by year, 2004-13



Note: A recall event is a recall announcement from a manufacturer or distributor and may include multiple recalled items.
Source: USDA, Economic Research Service calculations using U.S. Food and Drug Administration (FDA) and USDA, Food Safety and Inspection Service (FSIS) press releases, FSIS Recall Notification Reports, and FDA Enforcement Reports.

Recalls by Reason

Recalls are initiated upon the discovery of a health risk. These health risks have been categorized into seven main groups: pathogen contamination, undeclared major allergens, undeclared substances, extraneous material, processing defects, mislabeling, and other. Pathogen contamination includes the discovery of Shiga toxin-producing *Escherichia coli* (STEC) (a sometimes life-threatening bacterium—commonly known as *E. coli*—that produces Shiga toxin, which may cause severe abdominal cramps, diarrhea, and vomiting), *Salmonella* (a bacterium that may cause diarrhea, fever, and abdominal cramps), *Listeria monocytogenes* (a bacterium that may cause fever and muscle aches, particularly in older adults, pregnant women, and immunocompromised individuals), and other pathogens (such as *Campylobacter*, *Staphylococcus aureus*, *Clostridium botulinum*, etc.).[14] Undeclared major allergens include the eight major allergens: wheat, eggs, peanuts, milk, tree nuts (e.g., almonds, pecans, and walnuts), soybeans, fish, and crustacean shellfish. Undeclared substances refer to food additives such as sulfites, colors, aspartame, and monosodium glutamate. Extraneous material recalls occur when plastic fragments, metal shavings, latex pieces, or other foreign materials are discovered to have been inadvertently introduced in food products. Processing defects include packaging defects, temperature abuse, improper pasteurization, and uneviscerated

[14] For an overview of the economic burden imposed annually by the 15 leading foodborne pathogens in the United States, see Hoffmann et al. (2015).

seafood, among other possible processing errors. Mislabeling often refers to a labeling error—for example, root beer bottled and mistakenly labeled as a cola beverage. The "other" category includes risks and reasons that did not adequately fit into the first six categories, such as elevated levels of histamine and inadequate pH levels. From 2004 through 2013, potential pathogen contamination was the leading cause of food product recalls (41.0 percent), followed by undeclared allergens (27.4 percent) (table 4).

Table 4
Total number of food product recall events by reason, 2004-13

Reason for recall (health risk)	Frequency	Share (%)
Undeclared allergens	1,343	27.41
Salmonella	1,308	26.69
Listeria monocytogenes	502	10.24
Undeclared substances	480	9.80
Extraneous material	256	5.22
Processing defect	205	4.18
Mislabeling	150	3.06
STEC (Shiga toxin-producing *Escherichia coli)*	149	3.04
Other reasons	140	2.86
Spoilage, off odor, or mold	78	1.59
Other pathogens	60	1.22
Import alert or illegal import	43	0.88
Unapproved color additive	42	0.86
Excessive lead levels	38	0.78
Insanitary conditions	35	0.71
Pesticide residue	30	0.61
Elevated histamine levels	27	0.55
Lack of USDA inspection	27	0.55
Elevated aflatoxin levels	15	0.31
Elevated patulin levels	15	0.31
Antibiotic residue	13	0.27
Excessive arsenic levels	12	0.24
Elevated bromate levels	9	0.18
Insect contamination	9	0.18
Elevated pH levels	8	0.16

Note: A recall event is a recall announcement from a manufacturer or distributor and may include multiple recalled items. Additionally, 99 recall events were initiated for more than 1 reason, and health risk information was missing for 1 observation.

Source: USDA, Economic Research Service calculations using U.S. Food and Drug Administration (FDA) and USDA, Food Safety and Inspection Service (FSIS) press releases, FSIS Recall Notification Reports, and FDA Enforcement Reports.

From 2004 through 2013, six food products accounted for 53 percent of all food product recalls (see table 2). For each of these foods, with the exception of nut products, undeclared allergens was the number one reason products were recalled, accounting for 34 to 62 percent of product recalls (table 5). The next most frequent reason was concern for potential *Salmonella* contamination, though for prepared foods, potential *Listeria* contamination was the second most common reason.

Table 5
Recall reasons for the top six recalled foods, 2004-13

Reason	Frequency	Reason	Frequency
Prepared foods (excl. soup)	581	Grains products (excl. baked goods)	412
Undeclared allergens	242 (42%)	Undeclared allergens	201 (49%)
Listeria monocytogenes	149 (26%)	*Salmonella*	86 (21%)
Salmonella	56 (10%)	Extraneous material	50 (12%)
Extraneous material	42 (7%)	Undeclared substances	37 (9%)
Undeclared substances	37 (6%)	Other reasons	32 (8%)
Other reasons	22 (4%)	Mislabeling	12 (3%)
Processing defect	16 (3%)	Other pathogens	3 (1%)
STEC[1]	14 (2%)	*Listeria monocytogenes*	1 (0%)
Mislabeling	14 (2%)	Processing defect	1 (0%)
Other pathogens	2 (0%)		
Nuts, seeds, and nut products	532	Candy	388
Salmonella	423 (80%)	Undeclared allergens	150 (39%)
Undeclared allergens	52 (10%)	*Salmonella*	122 (31%)
Undeclared substances	35 (7%)	Undeclared substances	58 (15%)
Other reasons	10 (2%)	Other reasons	40 (10%)
Extraneous material	9 (2%)	Extraneous material	21 (5%)
Mislabeling	6 (1%)	Mislabeling	15 (4%)
Listeria monocytogenes	4 (1%)	STEC	1 (0%)
Processing defect	2 (0%)	*Listeria monocytogenes*	1 (0%)
STEC	1 (0%)	Processing defect	1 (0%)
Baked goods[2]	439	Sauces and condiments	245
Undeclared allergens	274 (62%)	Undeclared allergens	84 (34%)
Salmonella	80 (18%)	*Salmonella*	65 (27%)
Undeclared substances	39 (9%)	*Listeria monocytogenes*	32 (13%)
Extraneous material	22 (5%)	Undeclared substances	18 (7%)
Other reasons	16 (4%)	Processing defect	14 (6%)
Mislabeling	9 (2%)	Other reasons	13 (5%)
Other pathogens	5 (1%)	Extraneous material	12 (5%)
Listeria monocytogenes	3 (1%)	Mislabeling	10 (4%)
STEC	1 (0%)	Other pathogens	4 (2%)

Note: Some recall events were initiated for more than 1 reason.

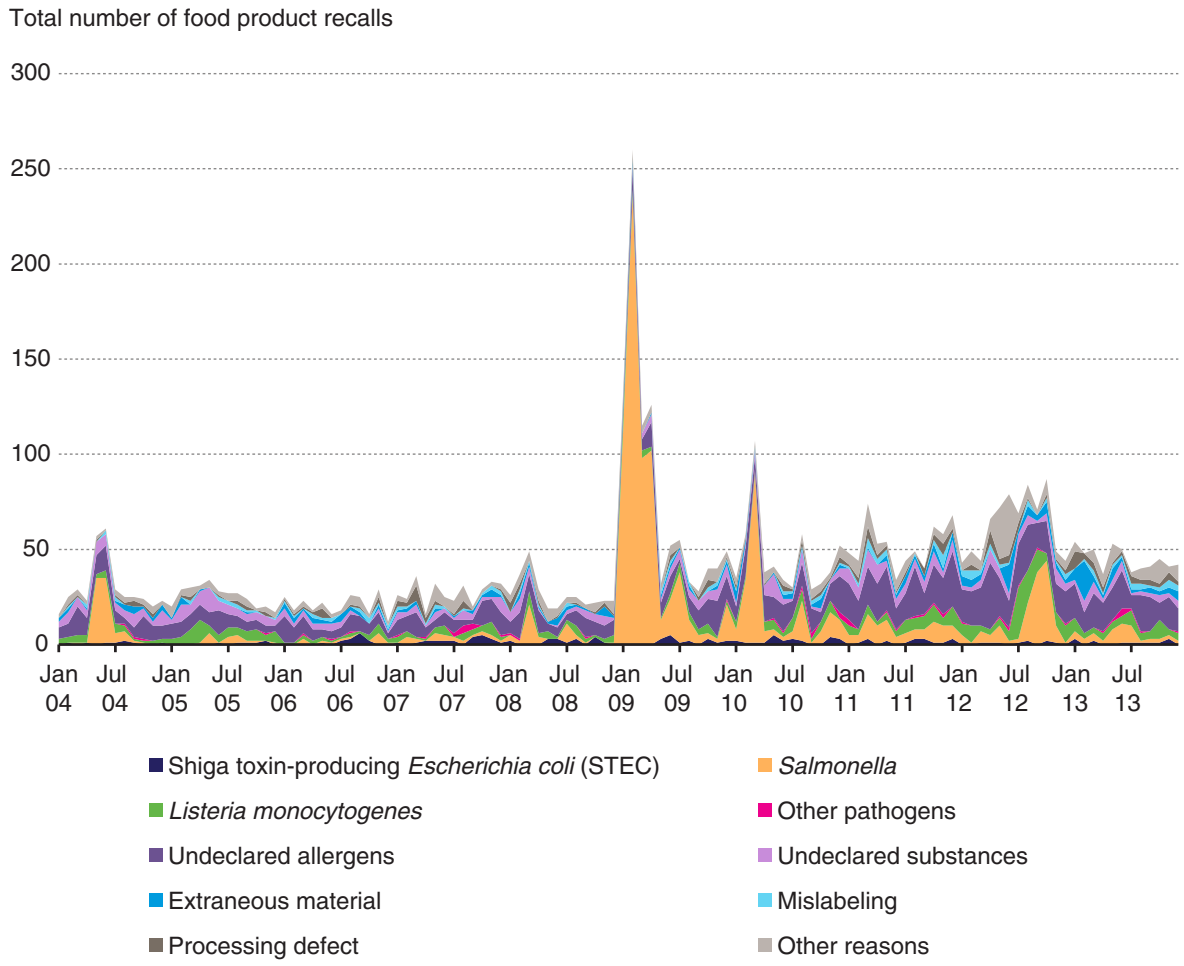
[1]STEC = Shiga toxin-producing *Escherichia coli*.

[2]Recall reason information is missing for one baked good observation.

Source: USDA, Economic Research Service calculations using U.S. Food and Drug Administration and USDA, Food Safety and Inspection Service press releases, FSIS Recall Notification Reports, and FDA Enforcement Reports.

Plotting the reasons for food product recalls over time yields further insight into whether a particular health risk is predominantly responsible for the general increase in food product recalls and again identifies outlier events (fig. 7). Once more, the ingredient-driven recalls of peanut butter, pistachios, and HVP due to possible *Salmonella* contamination are immediately apparent. Additionally, in contrast to the *Salmonella* recalls that appear to be mostly attributable to outlier events, the number of undeclared allergen recalls appears to increase throughout the decade.

Figure 7
Food product recall events by reason and month, 2004-13



Note: A recall event is a recall announcement from a manufacturer or distributor and may include multiple recalled items.
Source: USDA, Economic Research Service calculations using U.S. Food and Drug Administration (FDA) and USDA, Food Safety and Inspection Service (FSIS) press releases, FSIS Recall Notification Reports, and FDA Enforcement Reports.

To verify the existence of this trend and other trends, averages from the first 5 years can be compared to the last 5 years to determine whether any differences are statistically significant. These averages (table 6) suggest that, indeed, the number of recalls attributable to undeclared allergens, processing defects, and mislabeling were significantly greater in the second half of the decade compared with the first. And, as suspected, the greatest significant difference, in absolute terms, was due to undeclared allergens.

Table 6
Average number of annual food product recall events by reason, 2004-13

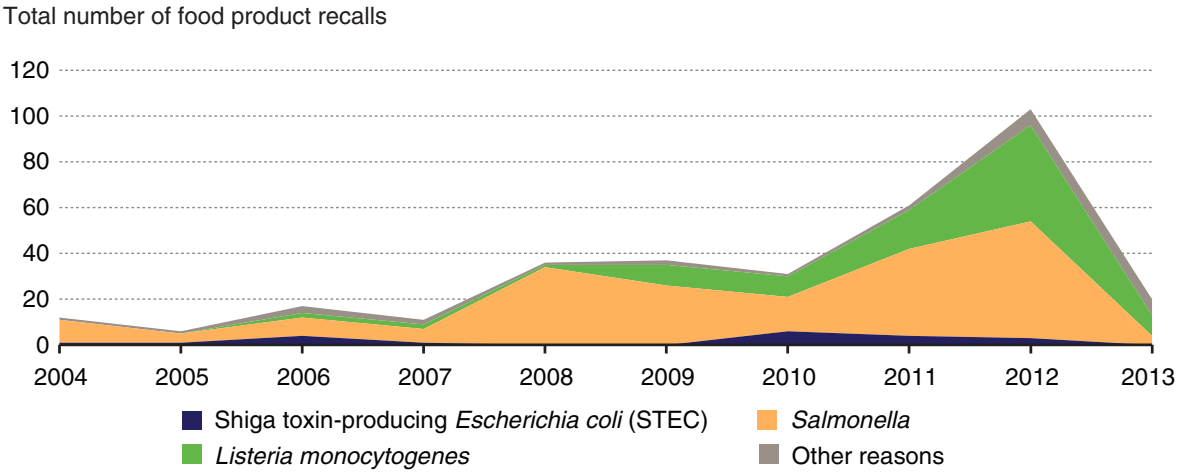
	Average 2004-13	Average 2004-08	Average 2009-13
Shiga toxin-producing *Escherichia coli*	14.9	13.6	16.2
Salmonella	130.8	36.2	225.4
Listeria monocytogenes	50.2	37.2	63.2
Other pathogens	6.0	4.4	7.6
Undeclared allergens	134.3	90.6	178.0*
Undeclared substances	48.0	45.2	50.8
Extraneous material	25.6	17.4	33.8
Processing defect	20.3	15.0	26.0*
Mislabeling	15.0	10.4	19.6*
Other reasons	54.5	41.2	67.4

Note: Asterisk (*) indicates that the t-test of a difference in the means for 2004-08 and 2009-13 is significant at the 5-percent level. A recall event is a recall announcement from a manufacturer or distributor and may include multiple recalled items.

Source: USDA, Economic Research Service calculations using U.S. Food and Drug Administration (FDA) and USDA, Food Safety and Inspection Service (FSIS) press releases, FSIS Recall Notification Reports, and FDA Enforcement Reports.

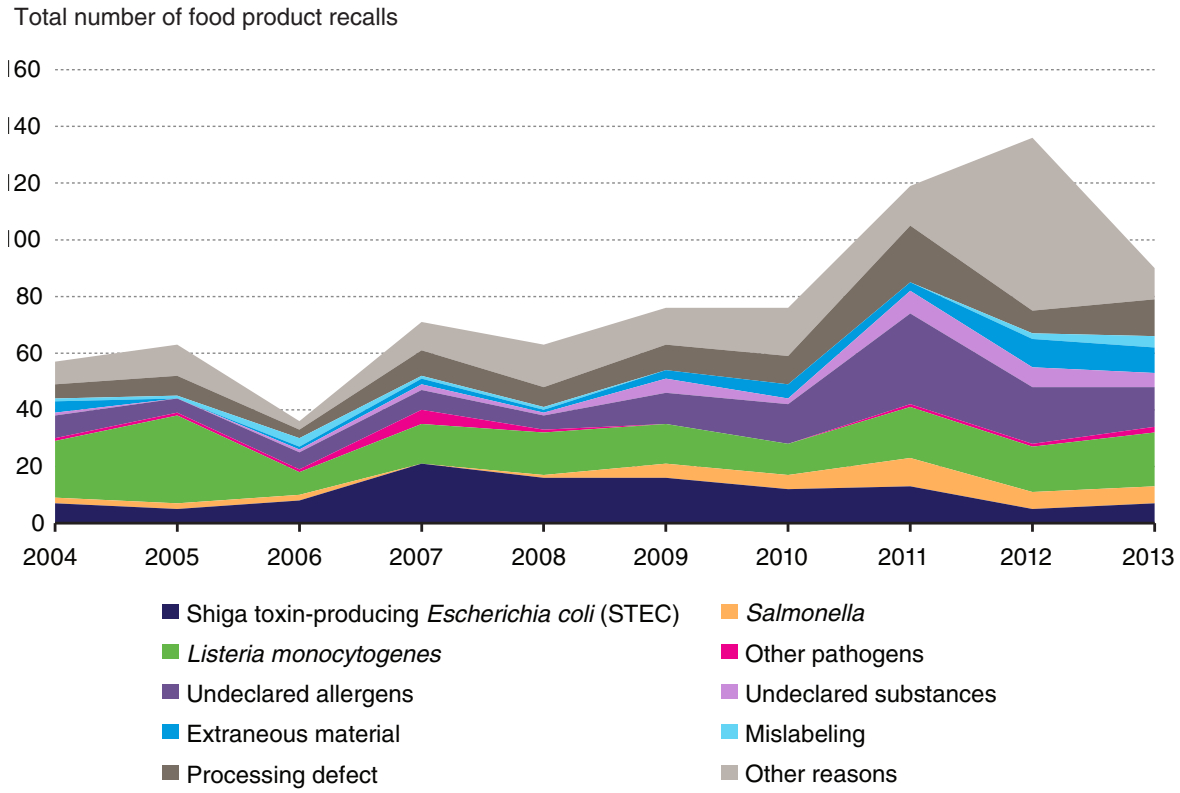
For fresh produce recalls, bacterial pathogen contamination—specifically *Salmonella, Listeria monocytogenes*, and STEC—accounted for 91.9 percent of all produce recalls (fig. 8). In contrast, *Salmonella, Listeria*, and STEC contamination accounted for only 40.0 percent of meat, poultry, and seafood recalls (fig. 9). Additionally, the difference in means between the first half of the decade and the second half was statisically significant at the 5-percent level for meat, poultry, and seafood recalls linked to *Salmonella* contamination, undeclared allergens, and undeclared substances.

Figure 8
Fresh produce recall events by reason and year, 2004-13



Note: A recall event is a recall announcement from a manufacturer or distributor and may include multiple recalled items.
Source: USDA, Economic Research Service calculations using U.S. Food and Drug Administration (FDA) press releases and Enforcement Reports.

Figure 9
Meat, poultry, and seafood recall events by reason and year, 2004-13



Source: USDA, Economic Research Service calculations using U.S. Food and Drug Administration (FDA) and USDA, Food Safety and Inspection Service (FSIS) press releases, FSIS Recall Notification Reports, and FDA Enforcement Reports.

Recalls by Health Risk Severity

Once a health risk is identified and a manufacturer decides to recall a product, FDA or FSIS determines the severity of the health risk posed to the general public by the implicated product and categorizes the recall into one of three severity classifications. As previously mentioned, Class I represents a health hazard situation in which there is reasonable probability that consuming the product will cause health problems or potentially death, Class II represents a potential health hazard situation in which there is a remote probability of adverse health problems from the consumption of the product, and Class III represents a situation in which consuming the product will not cause adverse health consequences. From 2004 through 2013, for recalls with classification information, 61.4 percent were Class I recalls, 30.6 percent were Class II recalls, and 9.5 percent were Class III recalls (table 7). Note, however, that 493 recalls, 10.1 percent of all recall observations, had missing classification information. With the exception of one, all of these recalls were overseen by FDA. As previously noted, the source for FDA recall information was FDA press releases and FDA Enforcement Reports. While not all FDA recalls are publicized with press releases, all FDA recalls should be logged in FDA Enforcement Reports. The press releases contain a great deal of data, but the severity classification is noted only in the FDA Enforcement Reports. Of the 492 recalls overseen by FDA with missing classification information, 97.0 percent (477 recalls) are recalls that were identified in press releases but could not be matched to an entry in the FDA Enforcement

Reports.[15] This may be because the item descriptions differed between the press release and the Enforcement Report and a match could not be made with complete confidence, the press release was issued prematurely and the recall was never actually completed, or the recall was never logged in an Enforcement Report. The number of recalls with missing classification information is greatest in 2009 and accounts for 43.0 percent of all missing observations. However, 2009 was an exceptional year with 888 recalls overseen by the FDA.

Table 7
Total number of food product recall events by class and year, 2004-13

Class	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	Total
I	202	175	116	170	183	603	336	318	367	236	2,706
II	58	65	70	79	70	116	153	229	276	233	1,349
III	33	30	35	38	38	33	35	57	63	57	419
Missing	57	31	27	33	25	212	22	23	52	11	493

Note: A recall event is a recall announcement from a manufacturer or distributor and may include multiple recalled items. Consequently, the total number of food recalls events by severity classification exceeds the total number of food recall events in table 1 because 64 recalls include products in at least 2 different severity classifications.

Source: USDA, Economic Research Service calculations using U.S. Food and Drug Administration (FDA) and USDA, Food Safety and Inspection Service (FSIS) press releases, FSIS Recall Notification Reports, and FDA Enforcement Reports.

The number of Class I, II, and III recalls increased steadily throughout the decade, and averages from the first 5 years can again be compared with the last 5 years to determine whether any differences are statistically significant. These averages indicate that the number of Class I, II, and III recalls were significantly greater in the latter half of the decade than the former, particularly the number of Class II recalls (table 8).

Table 8
Average number of annual food product recall events by class, 2004-13

Class	Average 2004-13	Average 2004-08	Average 2009-13
I	270.6	169.2	372*
II	134.9	68.4	201.4**
III	41.9	34.8	49.0*
Missing	49.3	34.6	64.0

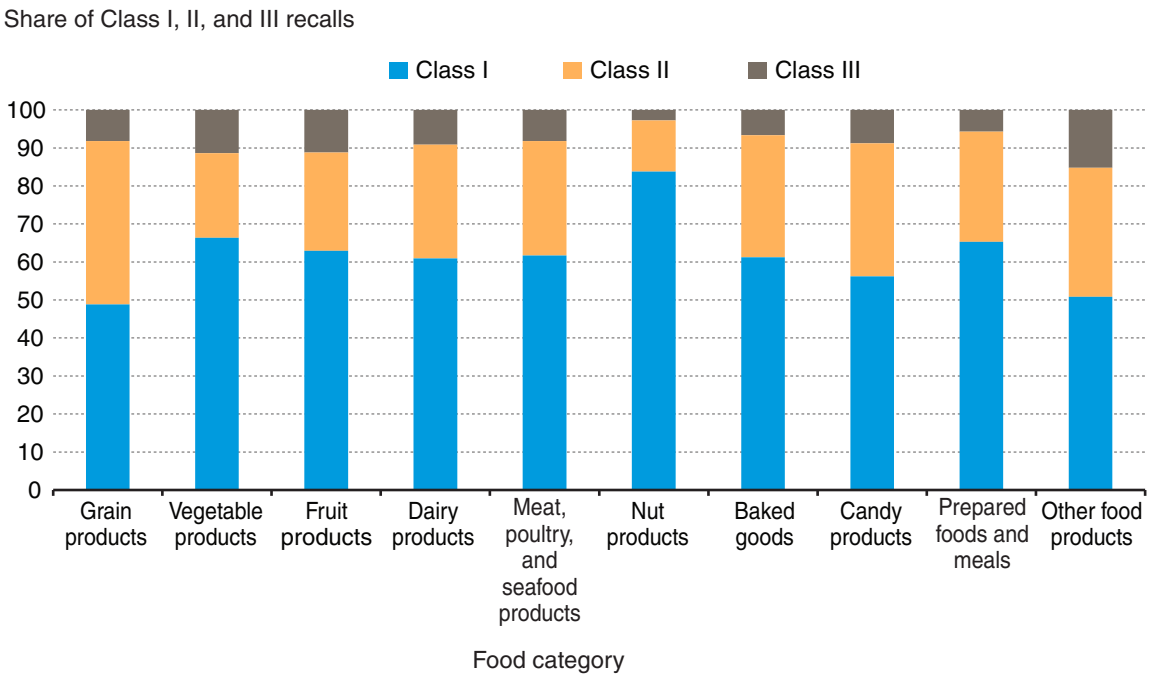
Note: Asterisk (*) and double asterisk (**) indicate that the t-test of a difference in the means for 2004-08 and 2009-13 is significant at the 5- and 1-percent levels, respectively. A recall event is a recall announcement from a manufacturer or distributor and may include multiple recalled items.

Source: USDA, Economic Research Service calculations using U.S. Food and Drug Administration (FDA) and USDA, Food Safety and Inspection Service (FSIS) press releases, FSIS Recall Notification Reports, and FDA Enforcement Reports.

[15] The remaining 3 percent are 2006 and 2007 recalls that were matched to an Enforcement Report, but the information in the Enforcement Report was incomplete.

To determine whether some foods are more likely to be recalled as a Class I recall as opposed to a Class II or III recall, figure 10 charts the share of Class I, II, and III recalls for 10 aggregate food categories. Between 2004 and 2013, nut products, when recalled, were statistically more likely to be classified as Class I recalls compared to other food categories. This suggests that when nuts, nut mixes, nut butters, and other nut products are the subject of a recall, they present a greater health risk to the general public.

Figure 10
Share of Class I, II, and III recall events by food type, 2004-13



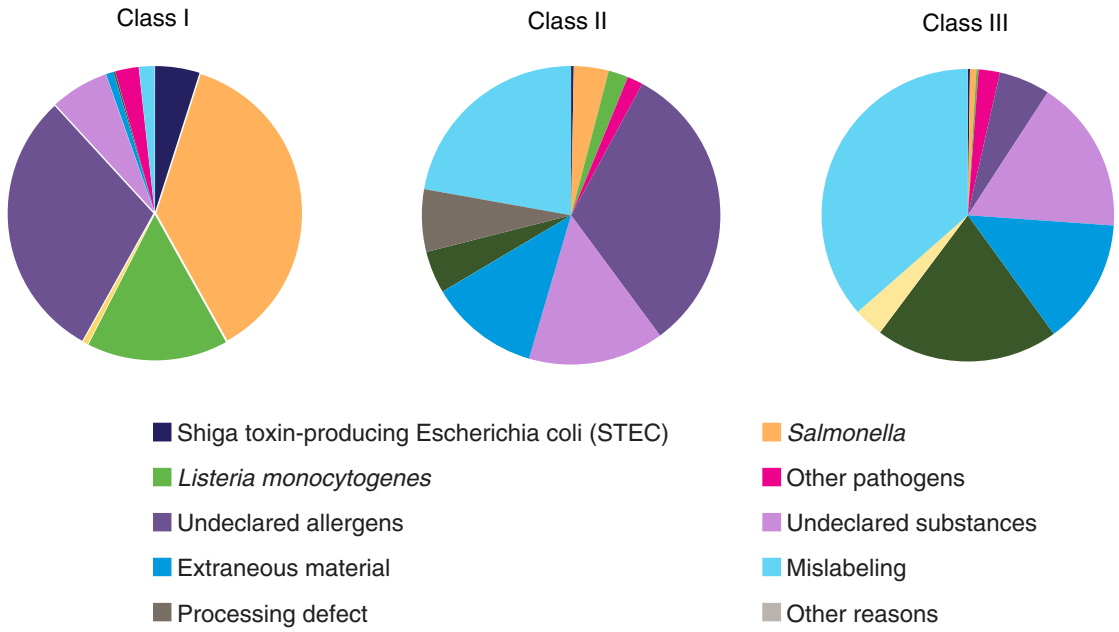
Note: Based on 4,628 observations; 524 observations have a missing risk classification. A recall event is a recall announcement from a manufacturer or distributor and may include multiple recalled items.
Source: USDA, Economic Research Service calculations using U.S. Food and Drug Administration (FDA) and USDA Food Safety and Inspection Service (FSIS) press releases, FSIS Recall Notification Reports, and FDA Enforcement Reports.

Though aggregation of foods into 10 major food categories allows a visual identification of general patterns among aggregate categories, trends also exist among the finer, disaggregated categories of Appendix B. For example, for recalled fresh produce with classification information, 80.0 percent of fungi, 83.9 percent of fresh herbs, 84.2 percent of vine-stalk vegetables, 87.5 percent of root vegetables, 91.8 percent of leafy vegetables, 93.5 percent of fruit, and 100 percent of sprouts were classified as Class I recalls. These statistics suggest that fresh produce products, when recalled, present a serious health risk. In contrast, for recalled meat and seafood products with classification information, 14.5 percent of mollusk products, 56.5 percent of crustacean products, 56.7 percent of fish products, 61.5 percent of pork products, 62.9 percent of processed meat products (bacon, sausage, lunch meats, etc.), 73.7 percent of poultry products, and 79.5 percent of beef products were classified as Class I recalls.

Another informative exercise is a review of the recall reasons that make up each severity class (fig. 11). Between 2004 and 2013, the majority of Class I recalls were due to bacterial pathogen contamination (e.g., STEC, *Salmonella, Listeria monocytogenes*, etc.), constituting 58.1 percent of

all Class I recalls. Moreover, bacterial pathogen contamination was almost always deemed a severe threat to public health, with 92.7 of these recalls classified as Class I.[16] The second leading cause of Class I recalls was undeclared allergens, responsible for 30.1 percent of Class I recalls. For Class II recalls, undeclared allergens were the leading cause, representing 32.0 percent of all Class II recalls, followed by undeclared substances (14.7 percent) and extraneous materials (11.9 percent). Recalls due to mislabeling and "other reasons" made up the majority of Class III, at 20.0 and 36.7 percent, respectively.

Figure 11
Share of Class I, II, and III recall events by food type, 2004-13



Note: Based on 4,406 observations; 493 observations have a missing risk classification, and 1 observation has missing health risk information. A recall event is a recall announcement from a manufacturer or distributor and may include multiple recalled items.
Source: USDA, Economic Research Service calculations using U.S. Food and Drug Administration (FDA) and USDA, Food Safety and Inspection Service (FSIS) press releases, FSIS Recall Notification Reports, and FDA Enforcement Reports.

Recalls by Geographic Distribution

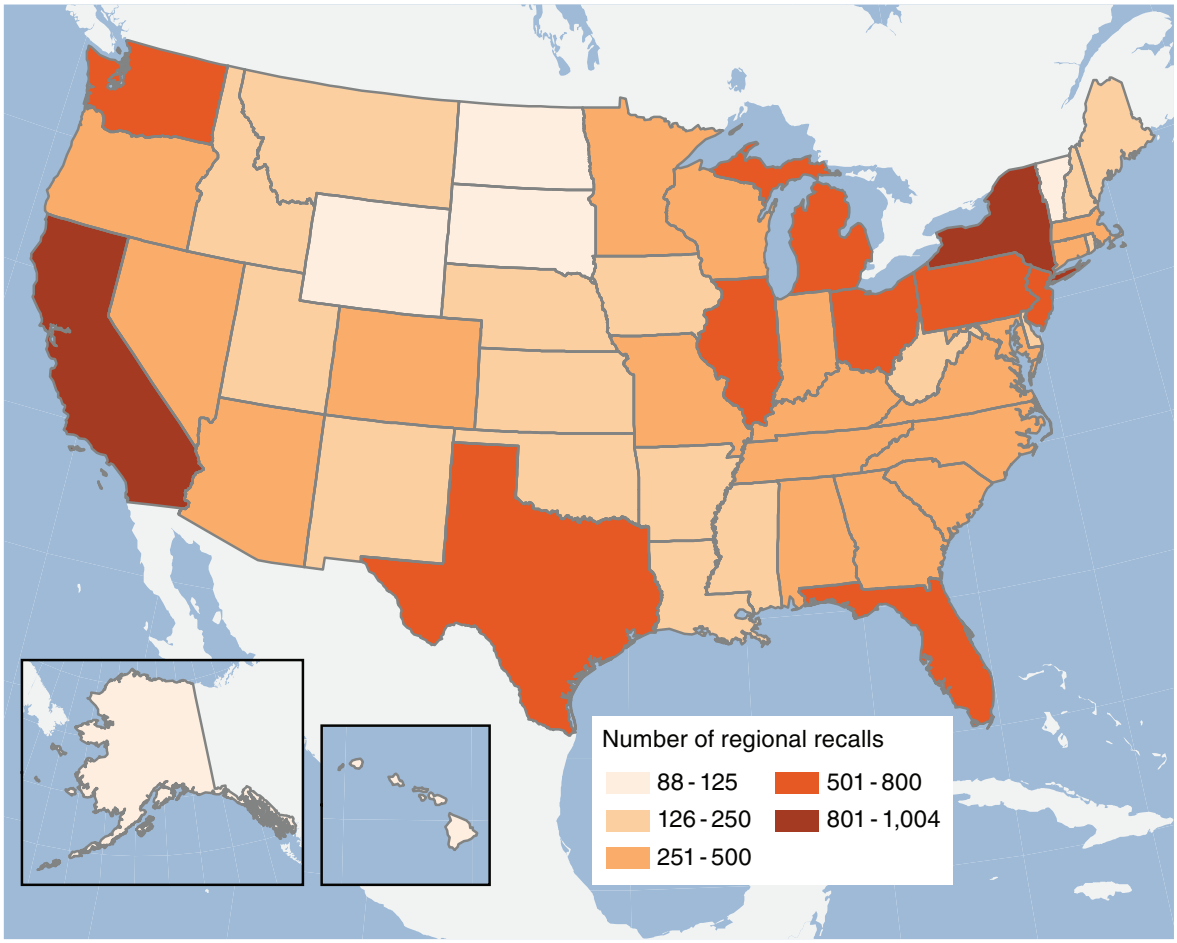
Most recalls are regional in nature. Recalled products are only occasionally distributed nationwide. In fact, from 2004 through 2013, only 25.2 percent of recalls included products intended for nationwide distribution.[17] The remaining recalls included products distributed to regions identified in the FDA or FSIS press releases, FSIS Recall Notification Reports, or FDA Enforcement Reports. The size of the distribution areas ranged from a single city or county to dozens of States, and the average

[16] FSIS always classified recalls due to bacterial pathogen contamination as Class I, suggesting that FDA and FSIS may employ different methodologies to assess risk severity.

[17] Geographic distribution is missing for 88 recalls (1.8 percent).

regional recall impacted five States.[18] California, New York, Texas, Pennsylvania, Illinois, and Florida received the greatest number of recalled products (fig. 12). This is expected, given that these are also the six most populous States, and, therefore, receive and consume the greatest volume of food in the United States.

Figure 12
Geographic distribution of regional food product recall events, 2004-13



Note: Based on 3,558 observations; 1,213 observations were nationwide, 41 observations had other geographic designations (e.g., Northeast, West Coast, etc.), and 88 observations had missing geographic information. A recall event is a recall announcement from a manufacturer or distributor and may include multiple recalled items.
Source: USDA, Economic Research Service calculations using U.S. Food and Drug Administration (FDA) and USDA, Food Safety and Inspection Service (FSIS) press releases, FSIS Recall Notification Reports, and FDA Enforcement Reports.

[18] As mentioned in the text, FDA Enforcement Reports were used to verify the information contained within FDA press releases. Sometimes, however, there was conflicting information regarding geographic distribution in the FDA Enforcement Reports and FDA press releases. Of the 4,254 FDA recalls, 377 (8.8 percent) had conflicting geographic information. In these cases, the geographic information from the press releases was used. For FDA recalls without press releases, geographic information from the Enforcement Reports was used.

Conclusion

Food product recall events increased by an average of 20 events a year from 2004 through 2013. However, this upward trend should not be interpreted to mean that foods are becoming riskier. Rather, an increasingly complex food supply system, technology improvements in health risk detection, increased regulatory oversight and enforcement, and the passing of two major food policy laws (FALCPA and FSMA) may have all contributed to the significant rise in food recalls. By examining trends and patterns, we can further pinpoint driving factors and form educated hypotheses behind the overall increase in food recalls. To do that, this report analyzed recall events over time by the types of foods recalled, the health risks involved, the severity of the health risks, and the geographic distribution of recalled products. Identification of any patterns and trends can provide guidance for manufacturer best practices and targets for regulatory oversight. Moreover, an analysis of this sort that considers both FDA and FSIS recalls has not previously been completed and fills an important void in the literature.

The results reveal that recalls increased across several major aggregate food categories (grain products, animal products, and prepared foods), increased across all three severity classes (particularly Class II), and occurred more frequently in highly populated States. Additionally, the results highlight two major recent trends. The first is the potential magnitude and impact of ingredient-driven recall events, the source of several extreme time trend outliers, including those involving peanut butter, pistachios, and HVP. Recalls of upstream ingredients can expand exponentially and impact dozens, if not hundreds, of downstream manufacturers that use the implicated ingredients. From 2004 through 2013, 22.4 percent of all recalls were the result of an upstream ingredient being recalled first. The widespread impact of these expanded recalls suggests that high-risk ingredients that are shipped to multiple manufacturers through various marketing channels for consumption in various settings may require greater oversight to prevent disastrous ripple effects for downstream manufacturers.

The second major insight from the analysis is the significant increase in the number of recalls due to undeclared allergens. From 2004 through 2013, undeclared allergens were a leading cause of food recalls, accounting for 27.4 percent of all recall events. Accurately labeling allergens is vital for public health, especially for the public health of children under age 18. Four out of every 100 children in the United States report having a food allergy (Branum and Lukacs, 2008), and the prevalence of reported food allergies is only increasing (Jackson et al., 2013). Effective in 2006, FALCPA requires that all eight major food allergens (wheat, eggs, peanuts, milk, tree nuts, soybeans, fish, and crustacean shellfish) be properly labeled on food products. Thus, FALCPA likely played a major role in the dramatic increase in the number of undeclared allergen recalls. Future work monitoring undeclared allergen recalls is needed to determine whether the total number of recalls continues to increase or whether the observed increase was part of an industry adjustment period as manufacturers adapted to the requirements of FALCPA. In any case, in contrast to pathogen contamination, which did not cause a significant increase in the total number of recalls, undeclared allergens are largely a labeling issue because unlabeled food products pose health risks only to individuals with allergies. Given the massive expense recalls present, this finding suggests that more time and effort spent reviewing labels to ensure they are accurate prior to sale would likely contribute to a reduction in recalls.

In all, food product recalls have significant impacts on both producers and consumers. For producers, recalls represent a massive expense that can potentially bankrupt manufacturers. For consumers, recalls signal unsafe foods, and concerns of foodborne disease can potentially influence consumer demand. Given the increasing number of recalls and the substantial direct and indirect costs of recalls on producers, consumers, and regulators, there is a fundamental need to identify and understand trends such as the ripple effects of ingredient-driven recall events and the increase in undeclared allergen recalls. These insights can provide guidance for manufacturer and regulator efforts, and potentially reduce recall costs and improve the overall quality and safety of the food supply.

References

Arnade, C., L. Calvin, and F. Kuchler. 2009. "Consumer Response to a Food Safety Shock: The 2006 Food-Borne Illness Outbreak of *E. coli O157:H7* Linked to Spinach," *Applied Economics Perspective and Policy* 31(4):734-50.

Arnade, C., F. Kuchler, and L. Calvin. 2011. "Food Safety and Spinach Demand: A Generalized Error Correction Model," *Agricultural and Resource Economics Review* 40(2):251-65.

Bakhtavoryan, R., O. Capps, Jr., and V. Salin. 2014. "The Impact of Food Safety Incidents Across Brands: The Case of the Peter Pan Peanut Butter Recall," *Journal of Agricultural and Applied Economics* 46(4):559-73.

Branum, A.M., and S.L. Lukacs. 2008. *Food Allergy Among U.S. Children: Trends in Prevalence and Hospitalizations*, NCHS Data Brief No. 10, National Center for Health Statistics.

Buzby, J.C., and P.D. Frenzen. 1999. "Food Safety and Product Liability," *Food Policy* 24(6):637-51.

Centers for Disease Control and Prevention (CDC). 2009. "Multistate Outbreak of *Salmonella* Infections Associated with Peanut Butter and Peanut Butter-Containing Products—United States, 2008-2009," *Morbidity and Mortality Weekly Report* 58(4):85-9.

Grocery Manufacturers Association (GMA). 2011. *Capturing Recall Costs: Measuring and Recovering the Losses*.

Hallman, W.K., C.L. Cuite, and N.H. Hooker. 2009. *Consumer Responses to Food Recalls: 2008 National Survey Report,* FPI Publication Number RR-0109-018, Food Policy Institute, Rutgers, The State University of New Jersey.

Hennessy, D., J. Roosen, and H.H. Jensen. 2003. "Systemic Failure in the Provision of Safe Food," *Food Policy* 28(1):77-96.

Hoffmann, S., B. Maculloch, and M. Batz. 2015. *Economic Burden of Major Foodborne Illnesses Acquired in the United States*, EIB-140, U.S. Department of Agriculture, Economic Research Service.

Jackson, K.D., L.D. Howie, and L.J. Akinbami. 2013. *Trends in Allergic Conditions Among Children: United States, 1997-2011*, NCHS Data Brief No. 121, National Center for Health Statistics.

Johnson, R. 2014. *The Federal Food Safety System: A Primer*, CRS Report No. RS22600, Congressional Research Service.

Kuchler, F. 2015. *How Much Does It Matter How Sick You Get? Consumers' Responses to Foodborne Disease Outbreaks of Different Severities*, ERR-193, U.S. Department of Agriculture, Economic Research Service.

Law, J.W.-F., N.-S. Ab Mutalib, K.-G. Chan, and L.-H. Lee. 2014. "Rapid Methods for the Detection of Foodborne Bacterial Pathogens: Principles, Applications, Advantages, and Limitations," *Frontiers in Microbiology* 5:770.

Ollinger, M., M.K. Muth, S.A. Karns, and Z. Choice. 2011. *Food Safety Audits, Plant Characteristics, and Food Safety Technology Use in Meat and Poultry Plants,* EIB-82, U.S. Department of Agriculture, Economic Research Service.

Painter, J.A., R.M. Hoekstra, T. Ayers, R.V. Tauxe, C.R. Braden, F.J. Angulo, and P.M. Griffin. 2013. "Attribution of Foodborne Illnesses, Hospitalizations, and Deaths to Food Commodities by using Outbreak Data, United States, 1998-2008," *Emerging Infectious Diseases* 19(3):407-15.

Powell, M.R. 2016. "Trends in Reported Foodborne Illness in the United States; 1996-2013," *Risk Analysis* 36(8):1589-98.

Pozo, V.F., and T.C. Schroeder. 2016. "Evaluating the Costs of Meat and Poultry Recalls to Food Firms Using Stock Returns," *Food Policy* 59:66-77.

Scallan, E., P.M. Griffin, F.J. Angulo, R.V. Tauxe, and R.M. Hoekstra. 2011a. "Foodborne Illness Acquired in the United States—Unspecified Agents," *Emerging Infectious Diseases* 17(1):16-22.

Scallan, E., R.M. Hoekstra, F.J. Angulo, R.V. Tauxe, M.A. Widdowson, S.L. Roy, J.L. Jones, and P.M. Griffin. 2011b. "Foodborne Illness Acquired in the United States—Major Pathogens," *Emerging Infectious Disease* 17(1):7-15.

U.S. Department of Agriculture (USDA), Agricultural Research Service (ARS). 2016. *What We Eat in America Food Categories 2013-2014.*

U.S. Department of Agriculture (USDA), Economic Research Service (ERS). 2016a. "Food Expenditures Series, Table 12: Food Expenditures at Constant Prices."

U.S. Department of Agriculture (USDA), Economic Research Service (ERS). 2016b. *National Household Food Acquisition and Purchase Survey (FoodAPS): Nutrient Coding Overview*.

U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS). 2013. *FSIS Directive 8080.1 (Revision 7). Recall of Meat and Poultry Products.*

U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS). 2015. "Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish."

U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG). 2017. *Challenges Remain in FDA's Inspections of Domestic Food Facilities*, Report No. OEI 02-14-00420.

U.S. Food and Drug Administration (FDA). 2013. *Regulatory Procedures Manual. Chapter 7 Recall Procedures.*

Appendix A. Data Variables Collected

Appendix A
Data variables collected

Variable
Date
Expansion date
Agency oversight
Item description:
Food category
Detailed item(s) description
Company
Brand
Single-ingredient indicator
Multiple-ingredient indicator
Meat-ingredient indicator
Reason:
Text description
Shiga toxin-producing *Escherichia coli* (STEC)
Salmonella
Listeria monocytogenes
Other pathogens
Undeclared allergen
Undeclared substance
Extraneous material
Mislabeling
Processing defect
Other reasons
Class (I, II, or III)
Geographic distribution
Discovery:
Text description
Consumer illness investigation
Firm testing/inspection
FDA testing/inspection
USDA testing/inspection
State testing/inspection
Customer testing/inspection
Other testing/inspection
Consumer complaint
Expanded recall
Other discovery
Marketing channel:
Text description
Retail
Foodservice
Institutions
Wholesale
Distributors
Manufacturers
Mail/internet/direct order
Other marketing channel
Press release or Recall Notification Report
Enforcement Report:
Enforcement Report date

Appendix B. Food Product Recall Categorization

Appendix B
Food product recall categorization

Food categories
Grain products:
Breads
Rice and pasta
Breakfast cereal
Flour, bread mixes, dough
Snacks
Cake and baking mixes
Baked goods (incl. packaged)
Vegetables:
Fungi:
Fresh
Canned
Prepared
Dried
Leafy vegetables:
Fresh
Frozen
Canned
Prepared
Dried
Root vegetables:
Fresh
Frozen
Canned
Prepared
Dried
Vine-stalk vegetables:
Fresh
Frozen
Canned
Prepared
Dried
Beans, lentils, peas, and legumes:
Fresh/dried
Frozen
Canned
Prepared
Other or mixed vegetables:
Fresh
Frozen
Prepared
Dried
Sprouts
Fresh herbs
Vegetable juices
Fruit:
Fresh
Frozen
Canned/bottled
Dried
Juices
Dairy:
Milk
Cream
Yogurt
Cheese
Processed cheese products and sauces
Dairy desserts
Meat, poultry, and seafood:
Beef:
Fresh
Frozen
Cooked (refrigerated/frozen)
Pork:
Fresh
Frozen
Cooked (refrigerated/frozen)
Game/lamb/other meat:
Fresh
Frozen

- Poultry:
  - Fresh
  - Frozen
  - Canned
  - Cooked (frozen/refrigerated)
- Bacon, sausage, and lunch meats
- Fish:
  - Fresh
  - Frozen
  - Canned or packaged
  - Dried
  - Smoked
- Crustaceans:
  - Fresh
  - Frozen
  - Canned or packaged
- Mollusks:
  - Fresh
  - Frozen
  - Canned or packaged

Nuts and seeds:

- Nuts, seeds, and nut mixes
- Processed nuts (e.g., nut butters)

Other foods:

- Eggs and egg mixtures
- Tofu and meat substitutes
- Beverages:
  - Coffee
  - Tea
  - Carbonated
  - Noncarbonated
  - Alcohol
  - Water
  - Beverage mix
- Fats and oils
- Salad dressing
- Gravies, sauces, condiments
- Spices/seasonings
- Nutrition bars
- Baby formula and food
- Sweets:
  - Sweeteners
  - Jellies/jams/preserved fruit
  - Candy
- Soups:
  - Soups, ready-to-serve, condensed, bases
  - Soups, dry
- Prepared foods and meals:
  - Ready-to-eat
  - Ready-to-eat sandwiches
  - Ready-to-eat salads with greens
  - Frozen or refrigerated (ready-to-heat)
  - Canned or packaged (shelf stable)