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Foodborne Illnesses and Outbreaks from Fresh Produce

The produce industry continues to be associated with a series of foodborne illness outbreaks across multiple U.S. states and Canada, resulting in hundreds of illnesses and hospitalizations, as well as kidney failure and death in some cases. Many in Congress have expressed concern that foodborne illness outbreaks are continuing to occur despite ongoing regulatory oversight by the Food and Drug Administration (FDA) and state public health authorities and given the enhanced authorities and resources provided to food safety officials following the enactment of comprehensive food safety legislation as part of the FDA Food Safety Modernization Act in 2010 (FSMA, P.L. 111-353). FSMA required the development and implementation of produce safety standards for certain fruits and vegetables, among other regulatory actions.

Foodborne Illnesses Linked to Produce

The Centers for Disease Control and Prevention (CDC) defines a “foodborne disease outbreak” as occurring when two or more people get the same illness from the same contaminated food or drink. Based on previous CDC outbreak investigations, microbial hazards associated with fruits and vegetables include pathogenic (disease-causing) strains of Shiga toxin-producing *E. coli* (STEC), *Salmonella*, Norovirus or Norwalk-like virus, and *Listeria monocytogenes*. Other produce-related hazards have involved *Vibrio*, *Shigella*, *Cryptosporidium*, *Giardia*, *Cyclospora*, *Toxoplasma gondii*, and Hepatitis A virus. Microbial hazards may be introduced through agricultural and processing water (used in production or transported via runoff), soil amendments (such as manure and municipal biosolids), worker hygiene, field and packing facility sanitation, and produce transportation and distribution.

During the last three years (2016-2018), FDA, CDC, and state and local officials have investigated several multistate outbreaks involving leafy greens, salad mix, sprouts, cucumbers, papaya, frozen strawberries, prepared fresh and frozen vegetables, pre-cut melons, pistachios, and dried coconut. Norovirus, *Salmonella*, and *E. coli* are among the leading cause of illnesses linked to produce. Multiple foodborne illness and outbreak investigations involved *E. coli* O157:H7 illnesses that were linked to leafy greens. Of these, one was linked to romaine lettuce grown in California, and another was linked to romaine lettuce grown in Arizona. Other investigations involved *E. coli* linked to leafy greens (not traced back to a common supplier) and involved *Listeria monocytogenes* linked to packaged salad.

Figure 1 and **Figure 2** show reported outbreak and illness trends for all produce and a subset of produce for leafy greens based on data from the CDC’s National Outbreak Reporting System (NORS). These data indicate the number of single and multistate outbreaks associated with produce

ranged from about 30 to 60 per year and sickened from 900 to nearly 3,000 people annually (1998-2016) (**Figure 1**). Leafy greens, a subset of the produce category, accounted for between 20% and 40% of these reported outbreaks and 10% to 40% of all produce-related illnesses (1998-2016). Over this period, single and multistate outbreaks associated with leafy greens ranged from about 10 to 20 per year and sickened between 100 and 1,100 annually (**Figure 2**).

Figure 1. Foodborne Illness Outbreaks, All Produce

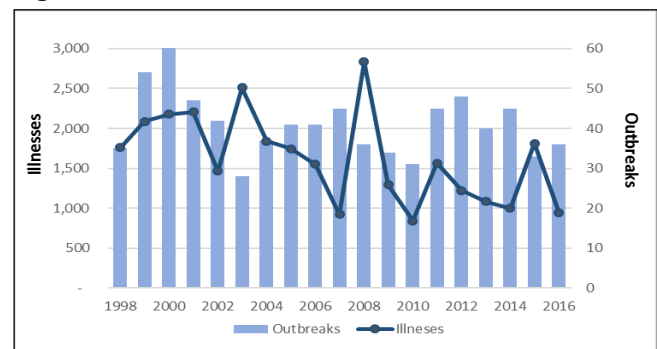
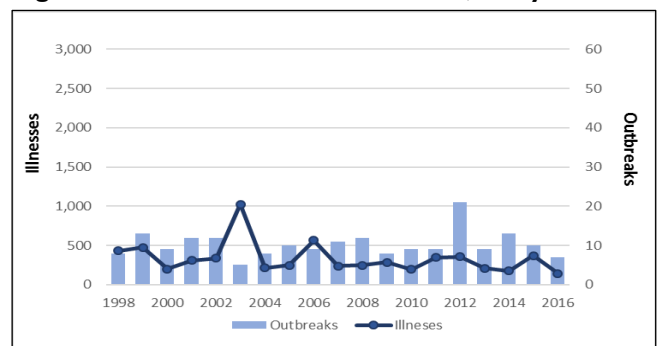


Figure 2. Foodborne Illness Outbreaks, Leafy Greens



Source: CRS from NORS data, <https://www.cdc.gov/nors/index.html>. Produce includes fruits, nuts (excluding peanuts), vegetables, sprouts, root crops, and herbs. Leafy greens is a subset of all produce and includes all lettuce, greens, and cabbage (excluding sprouts).

Notes: Includes confirmed and suspected cases across reported single and multistate outbreaks and all attributed causes and settings (restaurants and institutions, e.g., schools, hospitals, and prisons).

Analysis by the Center for Science in the Public Interest, a public health advocacy group, indicates that foodborne illness outbreaks associated with produce were more common and sickened more people than any other food category. A 2008 United Nations study ranks leafy greens as the “highest priority” in terms of microbiological hazards within the fruit and vegetable category. This ranking is based on the sheer number of outbreaks and the types of microbial hazard associated with leafy greens, but it also reflects the size and scale of production and trade in leafy greens. Other factors include the diversity and complexity of production of leafy greens and potential for amplification

of foodborne pathogens through the food chain due to certain post-harvest activities (e.g., whether packaged in-field or pre-cut and bagged). Available information tracked by CDC as part of its Foodborne Diseases Active Surveillance Network indicate that, across all food groups, infections caused by certain STEC infections have been decreasing, while the incidence of *Salmonella* infections has not changed significantly. Making such generalizations, however, is often complicated by differences in laboratory testing methods and/or differences depending on the strain of a microorganism.

FDA Standards for Produce Safety

FSMA amends the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§301 *et seq.*), which governs foods under FDA's jurisdiction. Under FSMA, FDA has developed and implemented mandatory food safety and traceability requirements for farmers, packers, and processors of domestically produced and imported products. Selected provisions that broadly address produce are shown in the text box.

Selected FSMA Provisions Related to Produce Inspections of Records (§101)

- Allows FDA to inspect records related to the “manufacture, processing, packing, distribution, receipt, holding, or importation” of certain food and feed.

Registration of Food Facilities (§102)

- Requires that food facilities be subject to biennial registration renewal. Provides that FDA may suspend a facility's registration in certain cases.

Hazard Analysis and Risk-Based Preventive Controls (§103)

- Requires FDA to establish mandatory preventive controls for food facilities except for “small” and “very small” businesses.

Standards for Produce Safety (§105)

- Requires FDA to establish mandatory minimum standards for the safe production and harvesting of fruits and vegetables except for “small” and “very small” businesses.

Targeting of Inspection Resources (§201)

- Requires FDA to identify high-risk facilities, increase the frequency of inspection of domestic and foreign facilities, identify and conduct inspections at ports of entry, and improve inter-agency coordination and cooperation.

Tracking and Tracing Food, Records (§204)

- Requires FDA to establish pilot projects to improve traceability of foods and to establish additional recordkeeping requirements for certain “high-risk foods.”

Surveillance (§205)

- Requires CDC to enhance foodborne illness surveillance systems and to conduct an assessment of state and local food safety and defense capacities.

For more information, see CRS Report R43724, *Implementation of the FDA Food Safety Modernization Act (FSMA, P.L. 111-353)*.

At the farm production level, FSMA principally affects produce growers by directing FDA to establish produce safety standards (§105). FDA finalized its produce safety regulation in 2015 (80 *Federal Register* 74353). FDA's produce rule addresses certain identified routes of potential contamination, covering water and soil amendments used in production, domesticated and wild animal intrusions in production area, worker training and hygiene, and equipment and sanitation practices used in production. The regulation covers fruits and vegetables (including mixes),

mushrooms, sprouts, peanuts, tree nuts, and herbs. FDA estimates that the regulation covers as many as 40,000 domestic produce farms and nearly 15,000 foreign farms. Foods not covered by regulation include foods that are rarely consumed raw (listed at 21 CFR 112.2(a)(1)), foods that go to commercial processing, foods produced for personal consumption, and certain foods identified as low risk. Produce that undergoes certain commercial processing, such as bagged salads and leafy greens, are further covered by FDA's rule on preventive controls affecting food facilities (§103). Other FSMA requirements affecting on-farm activities include facility registration, inspection, and records access. Certain qualified farms and facilities are exempt from regulation depending on business size, among other factors.

Deadlines for complying with FDA's produce rule are being phased in over time and vary depending on the crop and farm size. In some cases, FDA has granted more time to some farms to implement and comply with certain requirements. For example, in September 2017, FDA proposed to extend the compliance deadline for agricultural water testing because of concerns about the feasibility and cost involved (82 *Federal Register* 42963). Under the extension, larger farms have until 2022 to comply with the rule's water requirements, while small and very small farms have until 2023 and 2024, respectively, to comply.

FSMA also addresses food traceability (§204). Traceability refers to the ability to fully trace the movement of food and ingredients through each specific stage of production, processing, and distribution and to be able to identify the origin of food and ingredients when a food or finished product is found to be unsafe. Full traceability often requires extensive recordkeeping and/or other types of traceback mechanisms. FSMA required FDA to establish pilot projects and improve its capacity to effectively and rapidly track and trace foods in the event of an outbreak. FSMA also required FDA to designate high-risk foods that require additional recordkeeping to protect public health. FDA's pilot projects were completed in 2012. However, FDA has not yet identified or established enhanced recordkeeping requirements for high-risk foods.

Considerations for Congress

As foodborne illness outbreaks continue to occur, some continue to question the effectiveness of FDA's food safety regime. Regarding lapses in produce safety, some advocacy groups point to FDA's repeated delays in fully implementing key FSMA produce standards, including postponing compliance with the rule's water quality testing requirements, as a contributing factor. Some groups further blame FDA for not fully implementing FSMA's traceability requirements, especially regarding high-risk foods. Critics also continue to cite the agency's low rates of inspection and enforcement of FDA-regulated farms and food facilities. Others claim that FDA has not been provided with the resources to hire the additional inspectors that are needed to fully implement and adequately enforce the produce standards. Still others point to a possible lack of coordination between FDA and state and local authorities, which often bear most of the responsibility for inspecting farms and food facilities within their jurisdictions.

Renée Johnson, Specialist in Agricultural Policy

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