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Abstract

Background: Although the Food and Drug Administration has always responded to foodborne outbreaks of FDA-regulated products, FDA's Coordinated Outbreak Response and Evaluation Network (CORE) was established in 2011 to provide a dedicated multidisciplinary team to coordinate the evaluation, investigation, and notably, guide prevention efforts of foodborne illness outbreaks. CORE also utilizes FDA outbreak data to inform prevention initiatives.

Methods: Using data from the FDA CORE Outbreak Database and the FDA Emergency Operations Network system, foodborne illness outbreaks of FDA-regulated food products were analyzed by product category; year; pathogen; and number of illnesses, hospitalizations, and deaths.

Results: Since 1996, FDA was involved in 48 outbreaks associated with sprouts; resulting in more than 2500 cases; 186 hospitalizations and 3 deaths. The majority of outbreaks were attributed to alfalfa sprouts (n=30), followed by clover; (n=7) mung bean (n=6) and sprouted chia powder (n=1). *Salmonella* was the most common pathogen identified (n=35), followed by *E.coli* (n=11) and *Listeria* (n=2).

Conclusion: CORE works with its FDA, federal, state, local public health, agriculture and laboratory colleagues. Numerous product and regulatory actions were implemented as a result of these sprout outbreak investigations, including import alerts; market recall of product; warning letters, injunction and company closure. Although the number of outbreaks has decreased slightly since 1996, sprout contamination continues to pose a serious public health concern. The Food Safety Modernization Act (FSMA) Final Produce Safety Rule of Nov. 2015, establishes science-based new requirements to help prevent the contamination of sprouts and other produce. Outreach to the sprout industry is being planned in conjunction with the Sprout Safety Alliance to help sprout producers implement best practices in the safe production of sprouts.

Introduction and Methodology

CORE's mission is to coordinate and enhance FDA's detection, response and prevention efforts related to FDA-regulated food, feed, and cosmetic outbreaks in collaboration with our partners at the local, state and federal levels. The CORE network evaluates early information for clusters of illnesses, responds to outbreaks where an in-depth investigation is required, determines root causes of outbreaks when possible, and ensures implementation of lessons learned and preventive strategies to minimize future public health threats.

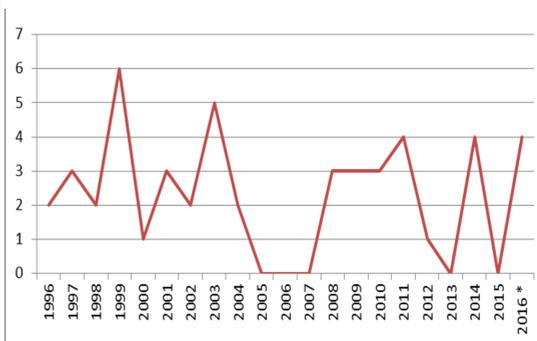
CORE coordinates outbreak activities with both internal and external partners; CDC performs the epidemiological investigations and analysis, FDA's Office of Regulatory Affairs conducts firm investigations and inspections, and subject matter experts at FDA's Center for Food Safety and Applied Nutrition provide expertise with product safety issues and compliance.

FDA utilizes the Emergency Operations Network System (EON) to capture incidents regarding FDA-regulated products that are, or may be responsible for causing injury, illness or adverse events. The system captures the large volume of information the response may generate, in "near real-time," including early investigational activities and analytical findings, and creates a historical record of response-related information. Aside from this system, CORE maintains an Excel Outbreak Database, which summarizes outbreak data. These two systems were queried to determine the number of multi-state outbreaks attributed to sprouts, 1996 through August 2016. Descriptive statistics were used to illustrate the sprout type, pathogens, and case numbers associated with these incidents.

Results

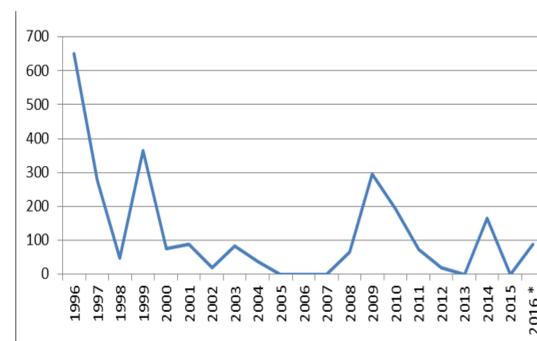
From 1996 to August 2016, FDA was involved in 48 outbreaks associated with sprouts; resulting in more than 2500 cases of illnesses, 186 hospitalizations and 3 deaths. Although the number of outbreaks per year has been sporadic, the number of cases has decreased since 1996 (Fig. 1 and 2). The majority of outbreaks were attributed to alfalfa sprouts (n=30), followed by clover; (n=7) mung bean (n=6), unspecified sprouts (n=2), and sprouted chia powder (n=1) (Fig. 3). *Salmonella* was the most common pathogen identified (n=35), followed by *E.coli* (n=11) and *Listeria* (n=2) (Fig. 4). The three deaths were attributed to one *Listeria* outbreak (n=2) and one *Salmonella* outbreak (n=1).

Fig. 1 Outbreaks Attributed to Sprouts by Year, 1996-2016



* As of August 2016

Fig. 2 Illnesses Attributed to Sprouts by Year, 1996-2016



* As of August 2016

Fig. 3 Number of Outbreaks by Sprout Type, n=48

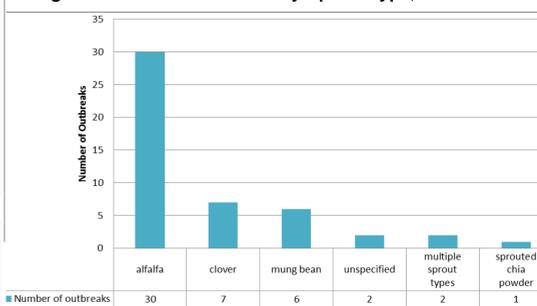
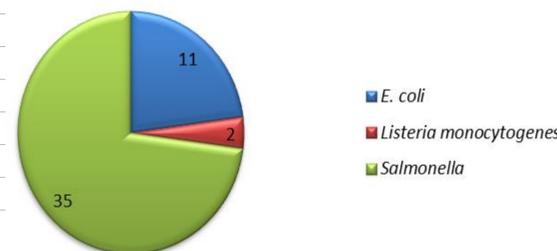


Fig. 4 Number of Outbreaks by Pathogen, n=48



Consumer/Patient Messaging

FDA's Center for Food Safety and Applied Nutrition publishes food safety pamphlets for people at risk for foodborne illnesses. People at risk include young children, elderly, pregnant women, and those who may be immunocompromised. The pamphlets refer to raw and lightly cooked sprouts as a high risk food and advise vulnerable populations to not eat this type of product. The food safety pamphlets are available at:

www.fda.gov/Food/FoodborneIllnessContaminants/PeopleAtRisk/default.htm



What can consumers do to reduce the risk of illness if they want to eat sprouts? *

- Wash sprouts thoroughly under running water before eating or cooking. Washing may reduce bacteria that may be present, but it will not eliminate it.
- Cook sprouts thoroughly. Cooking kills harmful bacteria and reduces the risk of illness.

* www.fda.gov/food/foodborneillnesscontaminants/buystoreservefoodsafely/ucm114299.htm

Investigative Findings and the Produce Safety Rule

Inspections at sprout operations involved in outbreaks revealed that most establishments had deficiencies with worker health and hygiene practices. Deviations were also noted with insanitary facilities/equipment; seed storage and treatment; and pest control. These issues are addressed in the FSMA Produce Safety Rule. The Rule, Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption, includes standards for sprout operations. Compliance with the rule should improve food safety.

Outbreak investigations resulted in numerous recommendations to enhance sprout safety. Outbreaks have spurred FDA research due to identified gaps in knowledge. Lessons learned from outbreaks help inform guidance and education curricula that are currently under development.

Discussion and Conclusion

A coordinated effort to respond to foodborne illness outbreaks enables FDA to streamline and more quickly identify, respond to, and prevent outbreaks to secure a safer food supply. Product and regulatory actions were implemented as a result of these sprout outbreak investigations, including import alerts; market recall of product; warning letters, injunction and company closure. Although the number of outbreaks has decreased slightly since 1996, sprout contamination continues to pose a serious public health concern. The FSMA Final Produce Safety Rule of Nov. 2015, establishes science-based new requirements to help prevent the contamination of sprouts and other produce. Outreach to the sprout industry is planned in conjunction with the Sprout Safety Alliance to help sprout producers implement best practices in the safe production of sprouts.

The Product Safety Alliance, Food Safety Preventive Controls Alliance and the Sprout Safety Alliance are developing training programs to help domestic and foreign businesses understand the requirements of the Preventive Controls regulations and the Produce Safety Rule. The Sprout Safety Alliance is serving as a network hub and resource for the sprout industry and the federal and state regulatory agencies.

Physician reports of potential foodborne illnesses to local and state health agencies contribute to a public health surveillance system that can promptly detect and respond to outbreaks, and impact the recognition of novel food vehicles (e.g., chia seed). Rapid investigation can lead to identification of causative factors leading to product contamination and provide evidence to promote food safety efforts.

Acknowledgements

The CORE Network is part of a nationwide integrated food safety system. CORE works in partnership with the CDC, USDA, FDA Centers, and all FDA regional and district offices. CORE also allies with State public health and agriculture agencies, as well as international partners. This ongoing coordination and collaboration results in timely detection, response, and prevention of foodborne illness outbreaks.

Visit CORE at:



www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/default.htm