



**U.S. FOOD & DRUG
ADMINISTRATION**



2020 LEAFY GREENS STEC ACTION PLAN

March 2020



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The FDA has an unwavering commitment to advancing the safety of fresh leafy greens. Leafy greens are among the most widely consumed vegetables and an important part of an overall healthy diet. While millions of servings are consumed safely every day, this produce commodity has been implicated too often in outbreaks of foodborne illness, and we believe that FDA, along with leafy greens sector stakeholders, can do more.

Between 2009 and 2018, FDA and Centers for Disease Control and Prevention (CDC) identified 40 foodborne outbreaks of Shiga toxin-producing *E. coli* (STEC) infections in the U.S. with a confirmed or suspected link to leafy greens. While most strains of *E. coli* are harmless, STEC can cause bloody diarrhea, anemia, blood-clotting problems, and kidney failure – conditions that are potentially life-threatening. The most common STEC, *E. coli* O157:H7, is the type most often associated with outbreaks.

Most leafy greens are grown outdoors, where they are exposed to soil, animals, and water, all of which can be a source of pathogen contamination. In addition, leafy greens are mostly consumed raw, without cooking or other processing steps to eliminate microbial hazards. The Produce Safety Rule under the FDA Food Safety Modernization Act (FSMA) sets science-based standards to help ensure that water, soil amendments (e.g., fertilizer or compost), food contact surfaces and other materials that touch produce during growing, harvesting, packing, and holding do not contribute to produce contamination. The Produce Safety Rule also addresses animal intrusion into fields and worker hygiene.

Due to the reoccurring nature of outbreaks associated with leafy greens, FDA has developed this commodity-specific action plan. What follows is an overview of the actions FDA plans to take in 2020 to advance work in three areas: (1) prevention, (2) response, and (3) addressing knowledge gaps.

Expediting the improved safety of leafy greens will require collaboration between FDA and stakeholders in the public and private sectors, including industry and our regulatory partners. This plan is designed to help foster a more urgent, collaborative, and action-oriented approach.

Prevention

With implementation of the FSMA Produce Safety Rule, great progress has been made in laying the foundation for a prevention-oriented approach to produce safety. However, further steps are needed to address prevention and incorporate knowledge gained in recent years. Areas of focus and actions FDA will pursue in 2020 include:

- **Advance Agricultural Water Safety:** In recent outbreaks associated with romaine lettuce consumption, the microbial contamination of agricultural water was identified as a potential contributing factor. These findings, along with stakeholder input, highlighted the diversity of agriculture production, reinforcing the importance of ensuring that we have standards that are workable across a wide variety of farms, water sources, and uses. Further work is needed to advance prevention standards and mitigation strategies.
 - **2020 Action:** Advance a proposed rule for agricultural water for covered produce other than sprouts.
 - **2020 Action:** Emphasize to growers the importance of using good agricultural practices (GAPs) for agricultural water while we are working on the proposed rule.
 - **2020 Action:** Support Environmental Protection Agency approval of an FDA-developed protocol that chemical companies may use in obtaining registration of antimicrobial products for use in treating irrigation water.
- **Enhance Inspection, Auditing, and Certification Programs:** Inspections, audits, and certification programs can each play critical roles in helping farms identify deficiencies in their approach to food safety. Recent leafy greens outbreaks have revealed gaps in audit standards and certification programs that need bolstering in order to maximize their effectiveness as food safety verification tools. In addition, as FDA and states continue implementing routine produce inspections, prioritization of leafy greens inspections can serve an important role in expeditiously identifying food safety concerns.
 - **2020 Action:** Prioritize routine inspections and on-farm readiness reviews, in partnership with states, for leafy greens farms covered by the Produce Safety Rule.
 - **2020 Action:** Provide technical assistance to efforts by industry and other stakeholders to enhance audit standards and verification activities related to agricultural water, adjacent or nearby land use, and soil amendments.
- **Buyer Specifications:** Retail and food service produce buyers can play an important role in ensuring the safety of leafy greens. Some buyers have begun to strengthen their food safety specifications for purchasing leafy greens.
 - **2020 Action:** Engage retailer and food service stakeholders on the role of strengthened buyer specifications, such as enhanced third party-audits, end-to-end traceability, and root cause analysis activities in enhancing the safety of leafy greens.
- **Leafy Green Data Trust:** With the food industry becoming increasingly digital and new

data streams arising from advances in technology, it is more important than ever that there be mechanisms for data to be shared by government and industry to avoid duplication of efforts and to inform prevention with the most robust data sets available.

- **2020 Action:** Initiate work with stakeholders to create a voluntary public-private data trust for leafy greens, a bank of large volumes of data generated by industry (e.g., traceability data, audits, microbiological testing data, etc.) that can be accessed for analytical work to further strengthen preventive approaches.

- **Microbiological Surveys for STEC Detection and Enhanced Sampling**

Protocols: FDA is conducting assignments to test samples of romaine lettuce grown in the Central Coast, Central Valley, and Imperial Valley in California and in Yuma, Arizona, for pathogenic *E. coli* and *Salmonella* to support prevention efforts. In addition, there has been discussion within the leafy greens sector in recent years about which sampling methodologies are most effective in detecting contaminated product at the time of harvest. Continuing and advancing surveillance sampling work has the potential to prevent contaminated product from reaching consumers and can inform future mitigation strategies.

- **2020 Action:** Continue FDA’s focused sampling assignments for romaine lettuce, publicly communicating results in a timely manner.
- **2020 Action:** Work with stakeholders to share knowledge on new technologies and sampling approaches (what to sample, when to sample, where to sample, how often to sample, etc.) that increase the ability to detect STEC, with the goal of more effective industry sampling and testing.

- **Increase Awareness and Address Concerns Around Adjacent and Nearby Land Use:** Adjacent and nearby land use, particularly land use involving livestock production, has the potential to be a source of pathogens, especially STEC, that can contaminate produce. More focus and work are needed to better understand how to evaluate and mitigate potential hazards.

- **2020 Action:** Provide education and technical assistance to government partners and industry stakeholders regarding potential impacts of adjacent and nearby land use on produce safety.

- **Establish/Strengthen Regular Outreach and Communication Programs for Stakeholders in Growing Regions:** Communications between FDA, farmers and other stakeholders are critical. FDA must be aware of challenges that arise across the diverse landscape of growing regions in this country, each of which has unique climate and environmental conditions. A well-established channel of communication will foster and support these exchanges of key information.

- **2020 Action:** Actively discuss region-specific issues in real time with a broad array of Yuma growing region stakeholders.
- **2020 Action:** Actively discuss region-specific issues in real time with a broad array of California growing region stakeholders.

Response

Ensuring that outbreak response activities are conducted as quickly and thoroughly as possible is essential for preventing illnesses. In addition, it is critical that FDA and stakeholders share lessons learned to inform future prevention. Areas of focus and actions FDA will pursue in 2020 include:

- **Publish Salinas Outbreak Investigation Report:** Between November and December 2019, FDA and multiple state and federal partners were involved in the investigation of three outbreak investigations related to three separate *E. coli* O157:H7 strains and the consumption of romaine lettuce or leafy greens. It is important to share further information about the investigation approach and factors that potentially contributed to the contamination.
 - **2020 Action:** Publish an outbreak investigation report including traceback and sampling activities conducted in the Salinas Valley growing region of California.
- **Conduct Follow-Up Surveillance During the Fall 2020 California Growing/Harvest Season:** Leafy greens grown in the Salinas Valley of California have been associated with several recent outbreaks of pathogenic STEC. FDA and state partners conducted on-farm investigations in late 2019 to identify factors that may have contributed to the outbreaks. Traceback investigations have identified farms that may have supplied contaminated product. Maintaining surveillance efforts during the 2020 growing/harvest season on these farms may enhance the ability of FDA and government partners to prevent future contamination.
 - **2020 Action:** Conduct follow-up surveillance inspections during the romaine growing/harvest season of farms identified in previous outbreaks.
- **Promote Tech-Enabled Traceability:** Public health agencies have gotten better at detecting foodborne illnesses, but our ability to trace back to the source of contaminated foods has been hampered, in part, by the lack of modernized food traceability capabilities. Achieving end-to-end traceability throughout the leafy greens supply chain could make it possible to rapidly trace a contaminated food to its source, which can help shorten outbreaks, narrow product warnings, and prevent illnesses.
 - **2020 Action:** Issue a proposed rule for implementing FSMA Section 204 related to the records required for tracking and tracing designated foods, which may serve as a foundation for traceability throughout the entire food system.
 - **2020 Action:** Prioritize work with leafy green stakeholders to design and initiate a pilot on concepts needed for traceability to further scale, such as testing interoperability of tracing systems and public-private data sharing.
- **Improve Utilization of Shopper Card Data:** Point-of-purchase recordkeeping, such as shopper cards, can improve the speed and accuracy of traceback investigations by helping retail facilities determine what specific products were purchased and may have been consumed. However, more work is needed to streamline the process for gathering these data.

- **2020 Action:** Work with retailers and government partners to improve the timely collection and transmission of purchase information during an open traceback investigation, including providing technical assistance in efforts to develop electronic data requests and data-sharing templates to support rapid traceback and convergence analysis.
- **Accelerate Whole Genome Sequencing Data Submission by States:** Whole genome sequencing (WGS) reveals the complete DNA make-up of an organism. We use this technology to determine the relatedness among foodborne pathogens and clinical cases during foodborne illness outbreaks. WGS also facilitates the identification of illnesses that may be part of an outbreak, as well as any links to food or environmental samples. Ensuring that samples are processed and reported in an expedited fashion is critical for efficient outbreak investigations.
 - **2020 Action:** Work with CDC and state departments of health to determine ways to expedite sample analysis and reporting into PulseNet and the existing public National Center for Biotechnology Information database.
- **Advance Root Cause Analysis Activities:** The repeat nature of STEC outbreaks in leafy greens illustrates the importance of root cause analyses to characterize how the contamination took place, inform what preventive measures are needed, and prevent future outbreaks. New models for conducting root cause analyses may increase the effectiveness of these tools.
 - **2020 Action:** Strengthen root cause analysis procedures, coordinating with federal, state, local, tribal and territorial partners to ensure rapid deployment as soon as an outbreak is traced to a specific site.
 - **2020 Action:** Collaborate with federal, state, industry, consumer, and academic stakeholders to advance, standardize, and socialize root cause analysis protocols for food safety.
- **Enhance Outbreak and Recall Communications:** Communications during outbreaks are essential for spurring swift industry action and notifying consumers of potentially contaminated products. In addition, outbreak communications are important for informing industry of ongoing food safety issues within the leafy greens sector. Continuous improvements are needed to ensure that communication during outbreaks and recalls is effective in reaching all industry and consumer stakeholders.
 - **2020 Action:** Collaborate with government partners to review and evaluate outbreak communication mechanisms and propose enhancements for continuous improvement.

Addressing Knowledge Gaps

While FDA and stakeholders have greatly expanded what is known about leafy greens safety, there are still knowledge gaps, which could be explored in new ways through the use of emerging technologies. Addressing these knowledge gaps is critical to advancing future prevention. Areas of focus and actions FDA will pursue in 2020 include:

- **Conduct Longitudinal Studies:** FDA has launched an initiative with support from the Arizona Department of Agriculture, and in conjunction with the University of Arizona Cooperative Extension, the Wellton-Mohawk Irrigation and Drainage District, and members of the leafy greens industry to better understand the ecology of human pathogens in the Yuma growing region. Exploratory discussions have also been initiated in the Salinas and Santa Maria regions of California. These multi-year efforts may provide information on how pathogens survive in various reservoirs (e.g., prevalence in water reservoirs) and how they move throughout the environment, leading to potential produce contamination prior to harvest.
 - **2020 Action:** Support ongoing Yuma Longitudinal Study.
 - **2020 Action:** Initiate Salinas/Santa Maria Longitudinal Study.
- **Data Mining and Analytics on Previous Outbreaks:** As outbreak investigations are conducted, more data are generated around a foodborne illness outbreak than are initially available for traceback purposes. When considered across outbreaks, these data (e.g., rainfall levels, temperature, economic indicators, strain genetic information, etc.) may hold additional clues for understanding factors contributing to or exacerbating outbreaks.
 - **2020 Action:** Collaborate with CDC, state and other federal partners to conduct a retrospective analysis of past leafy green outbreaks, mining available data and evaluating potential contributing factors.
 - **2020 Action:** Collaborate with research organizations to evaluate the role of seasonality in STEC outbreaks involving leafy greens.
- **Adjacent and Nearby Land Use:** Activities occurring on nearby or adjacent land can influence or contribute to produce contamination. Information about adjacent or nearby land uses can help growers implement effective mitigation strategies.
 - **2020 Action:** Collaborate with federal and state partners, research organizations, and industry stakeholders to identify existing data and knowledge on the impact of adjacent and nearby land use on leafy greens growing areas. Prioritize collection of additional data and information that will help growers implement effective science-based mitigation strategies.
 - **2020 Action:** Work with government partners and industry stakeholders to explore the feasibility of implementing pre-harvest best management strategies for cattle raised near leafy green growing areas and encourage research into pre-harvest mitigation strategies for cattle.

- **Compost Sampling Assignment with California:** Biological soil amendments of animal origin (e.g., composts and manures) can provide a vehicle for pathogen transference to produce. Proper composting techniques reduce the risk of pathogen survival, but the persistence level of pathogens in certain widely utilized composting techniques is not currently known.
 - **2020 Action:** Continue analyzing samples of commercial compost for the presence of foodborne pathogens to inform baseline understanding and encourage the standardization and collection of data around compost.