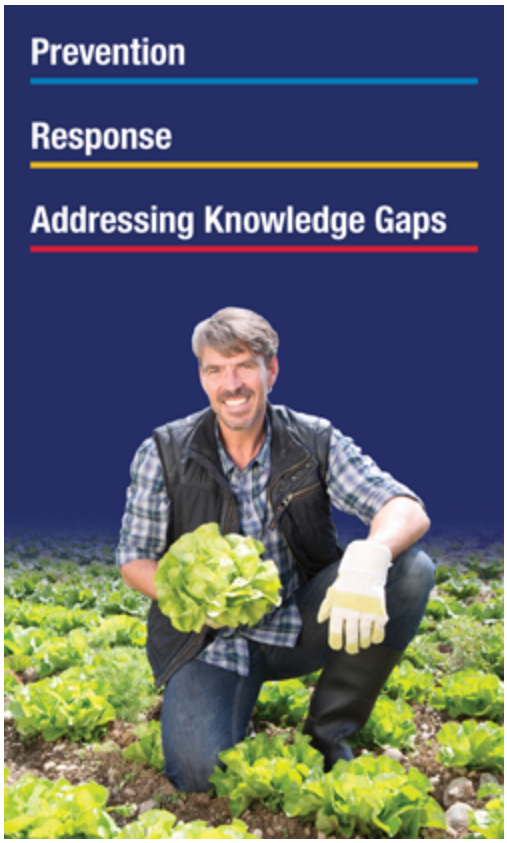
Leafy Greens STEC Action Plan

FDA and USDA Scientists Research Seasonal Effects Linked to E.coli Outbreaks in Bagged Romaine (/food/hfp-constituent-updates/fda-and-usda-scientists-research-seasonal-effects-linked-ecoli-outbreaks-bagged-romaine)

The FDA and the U.S. Department of Agriculture's Agricultural Research Service published a study (https://environmentalmicrobiome.biomedcentral.com/articles/10.1186/s40793-021-00393-y) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) on the relationship between the lettuce microbial ecology and the potential for E. coli O157:H7 survival. This research is significant in helping to reduce foodborne illnesses linked to the consumption of leafy greens. It also aligns with FDA's efforts to advance its Leafy Greens STEC Action Plan.



Priority Areas Infographic (/media/147371/download?attachment)
(PDF 3MB)

Introduction

Leafy greens are among the most widely consumed vegetables and an important part of an overall healthy diet. However, while millions of servings are consumed safely every day, leafy greens have been repeatedly associated with illnesses caused by Shiga toxin-producing E. coli (STEC), the most common of which is E. coli O157:H7. FDA is committed to breaking this cycle of reoccurring outbreaks.

Over the last several years, the FDA and partners in the public and private sectors have worked to enhance the safety of leafy greens through the development and implementation of the Leafy Greens STEC Action Plan (LGAP). This work includes prioritized inspections, focused sampling, stakeholder engagement and collaboration, data sharing, root cause investigations, and advancements in the science of detection and prevention.

Collectively, this work has expanded our body of knowledge about how and why outbreaks linked to leafy greens have occurred, which has guided and informed the evolution of the action plan over the years. Still, we know that we cannot fix the issue of leafy green contamination on

our own. Industry leadership, along with collaboration among growers, processors, retailers, state partners, and the broader agricultural community, is critical to preventing foodborne illness.

The following table provides the approaches for three priority areas: Prevention, Response, and Addressing Knowledge Gaps, as well as accomplishments that have been made since the action plan launched in March 2020 (updated and current as of October 2023)

Prevention: Advance Agricultural Water Safety

Agricultural water can be a major conduit of pathogens that can contaminate produce and a number of recent outbreaks involving leafy greens have had water contamination as a potential contributing factor. The following actions are intended to enhance the safety of agricultural water used in the production of leafy greens.

Approaches	Key Accomplishments 2020-2023
1.1 Complete a rulemaking for the agricultural water provisions of the Produce Safety Rule for covered produce other than sprouts.	• Published a proposed rule for agricultural water provisions (/news-events/press-announcements/fda-proposes-changes-food-safety-modernization-act-rule-enhance-safety-agricultural-water-used) of the Produce Safety Rule for covered produce other than sprouts; open for public comments. • Convened two virtual public meetings to discuss the agricultural water proposed rule (/food/hfp-constituent-updates/fda-hold-public-meetings-discuss-proposed-changes-agricultural-water-requirements-produce-safety) on 2/14/2022 and 2/25/2022. • Developed and launched an online tool to assist growers (/food/food-safety-modernization-act-fsma/agricultural-water-assessment-builder) in evaluating potential risks posed by their water sources and determining potential management options. This work also falls under the New Era of Smarter Food Safety Core Element 2.4 on Inspection, Training, and Compliance Tools (/food/new-era-smarter-food-safety/new-era-smarter-food-safety-blueprint). • Released paper-based versions of the agricultural water assessment builder tool in both English and Spanish. • The FDA Published and requested comment on a supplemental notice of proposed rulemaking (/food/hfp-constituent-updates/fda-proposes-compliance-date-extension-pre-harvest-agricultural-water-requirements) regarding compliance dates for pre-harvest agricultural water requirements on July 18,2022.

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Approaches	Key Accomplishments 2020-2023
1.2 Engage with stakeholders to collaboratively advance the safety of agricultural water through education, outreach, and technical assistance.	• In both 2020 and 2021, the FDA engaged with numerous growers about the importance of using Good Agricultural Practices (/regulatory-information/search-fda-guidance-documents/guidance-industry-guide-minimize-microbial-food-safety-hazards-fresh-fruits-and-vegetables), especially as they apply to agricultural water, including via the California and Arizona Leafy Green Marketing Agreements (LGMA) and the International Association of Food Protection Annual Meeting (https://www.foodprotection.org/annualmeeting/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer). • In 2021, the FDA, with national and state partners, developed and piloted an agricultural water systems workshop in North Carolina. The pilot, targeted at growers and regulatory partners, was held on November 3 and 4, 2021. • In 2022, with national and state partners, developed and piloted an agricultural water systems workshop that incorporated proposed pre-harvest agricultural water requirements. ◦ The pilot was held November 8, 2022 in Athens, GA with the cooperation of University of Georgia. ◦ Currently in the planning stages to hold similar workshop in Alabama, Florida and Mexico • In 2021 and 2022, FDA subject matter experts participated in several stakeholder meetings and webinars to discuss requirements for harvest and post-harvest agricultural water and the potential changes to the pre-harvest standards. • The FDA developed and distributed a fact sheet and held several engagements to help growers prepare to comply with the harvest and post-harvest agricultural water requirements and answer questions about compliance and implementation. ◦ Fact Sheet: Compliance with Subpart E Requirements for Harvest and Post-Harvest Agricultural Water (/food/food-safety-modernization-act-fsma/requirements-harvest-and-post-harvest-agricultural-water-subpart-e-covered-produce-other-sprouts)

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Approaches	Key Accomplishments 2020-2023
1.3. Reduce contamination through the development and use of agricultural water treatment options.	• Co-developed a protocol with the Environmental Protection Agency (/news-events/press-announcements/fda-announces-new-protocol-development-and-registration-treatments-preharvest-agricultural-water) (EPA) for developing data in support of new and amended registrations for preharvest agricultural water treatments. • Announced two updates to the protocol (/food/food-safety-modernization-act-fsma/efficacy-protocol-reduction-foodborne-bacteria-preharvest-agricultural-water) (May 2022) to make it more feasible for stakeholders to develop and register their treatments. • Engaged actively, along with EPA, with chemical manufacturers in support of treatment development. • Engaged with LGMA and EPA to improve the protocol to be reflective of real-world practices. • Updated (/food/hfp-constituent-updates/fda-updates-protocol-development-and-registration-treatments-preharvest-agricultural-water) the protocol (January 2023) to remove *Listeria monocytogenes (L. monocytogenes)* from the organism test panel to help facilitate the registration of antimicrobial treatments against STECs (and other *E. coli*) and *Salmonella* in pre-harvest agricultural water, the availability of which will be a significant resource for farms to protect their crops against these pathogens.

Prevention: Enhance Inspections, Audits and Certification Programs

Enhanced inspections, audits, and certifications can help ensure that growers are prepared for compliance with the Produce Safety Rule, provide insights to regulators regarding compliance trends, and help regulators address misunderstandings that may lead to future food safety issues on a farm. The following actions reflect how FDA intends to work with states and industry stakeholders to prioritize and enhance inspections, audits, and certifications across the leafy greens industry.

Approaches	Key Accomplishments 2020-2023
2.1 FDA and state partners will prioritize inspections based on information collected during past foodborne illness outbreaks.	• FDA shared a list of leafy greens farms identified through foodborne illness outbreak traceback investigations with state partners in California to inform produce farm inspection prioritization during the growing season. • As noted in 9.1, the FDA and the California Department of Food and Agriculture (CDFA) conducted collaborative sampling and inspections of leafy greens farms that had been previously linked to an outbreak of foodborne illness or an outbreak signal.
2.2 Continue providing 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.	• The FDA participated in a series of Leafy Greens Marketing Agreement (LGMA) and Western Growers Association (WGA) meetings offering technical assistance to the LGMA's metrics review process and perspective on how current metrics and updates relate to the Produce Safety Rule (2020). • The FDA participated in CA LGMA technical committee meetings, offering technical assistance on metrics review and the development of an adjacent lands risk assessment tool. FDA provided perspective on how potential updates/changes and the new risk assessment tool aligned with the Produce Safety Rule and FDA current thinking (2021). ◦ In 2023 the California and Arizona LGMA's launched the Environmental Risk Assessment tool (https://lgma.ca.gov/lgma-connect/environmental-risk-assessment-tool).

Prevention: Buyer Specifications

Retailers are often the intermediaries between the grower and the consumer. As such, many set standards – buyer specifications – that produce growers need to meet for retailers to buy and sell their products. The FDA has identified steps we can take, including technical assistance to buyers, to improve the safety of leafy greens.

Approaches	Key Accomplishments 2020-2023
3.1 Continue to engage and provide technical assistance to 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.	• The FDA has and continues to engage with trade associations to discuss opportunities and barriers to the implementation of best management practices and also provided technical assistance on recommendations for leafy green buyers, including buyer specification. • The FDA provided technical assistance to the Food Marketing Institute (FMI) when they updated the FMI Recommended Food Safety Practices for Leafy Greens (https://www.fmi.org/docs/default-source/food-safety/leafy-greens-guide19_aug19.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer). • The FDA hosted a Low- or No-Cost Tech-Enabled Traceability Challenge (/food/new-era-smarter-food-safety/meet-winners-fdas-low-or-no-cost-food-traceability-challenge) to encourage stakeholders to develop traceability hardware, software, data analytics platforms that are low-cost or no-cost to the end user (2021). • The Institute of Food Technologists (IFT) released a report (/food/hfp-constituent-updates/ift-report-recommends-collaboration-and-innovation-advance-food-traceability), commissioned by FDA, that evaluated the food traceability trends based on the submissions from FDA's 2021 traceability challenge (2023). • The FDA is currently developing an internal Product Tracing System (PTS) (/food/food-safety-modernization-act-fsma/frequently-asked-questions-fsma-food-traceability-rule) to receive and analyze industry's food traceability data and more effectively and rapidly trace food within the United States. To demonstrate PTS capabilities, the FDA produced a video for the 2023 International Association for Food Protection (IAFP) European Symposium, in collaboration with the German Federal Institute for Risk Assessment (BfR). The PTS will enhance existing foodborne outbreak response processes, especially those by the FDA Coordinated Outbreak Response and Evaluation (CORE) Network (/food/outbreaks-foodborne-illness/about-core-network).

Prevention: Leafy Greens Data Trust

Shared data can help to inform our understanding of leafy greens outbreaks and mitigation strategies that can be used to prevent future outbreaks. Therefore, the FDA is interested in exploring options for public-private data trusts that help to facilitate the sharing of data.

This work also falls under Core Element 2.2 "Strengthen Predictive Analytics Capabilities" of the New Era of Smarter Food Safety Blueprint (/food/new-era-smarter-food-safety/new-era-smarter-food-safety-blueprint).

Approaches	Key Accomplishments 2020-2023
4.1 Engage and collaborate internally and externally to explore methods for public-private data trusts.	• The FDA met with Western Growers Association and offered support, through the form of a letter, for widespread participation from industry in the Western Growers Association data sharing/analytics program (2020). • Subject matter experts from the FDA joined a newly formed Western Growers Food Safety Stakeholder Committee to explore use of the Western Growers Food Safety Data-Sharing Platform (2021). • Western Growers partnered with Crème Global (https://www.wga.com/wgs-magazine/6-ws-of-groundbreaking-food-safety-data-sharing-project/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) to develop a food safety data sharing tool. The tool can capture food safety data generated during pre-season, pre-harvest, and post-harvest activities. It currently focuses on pre-harvest data and other metadata. • Western Growers completed the project phase with five pilot participants. The first version of the tool was released late in 2021. Currently, Western Growers is focused on recruitment of additional industry members and expanding marketing and communication efforts. • A session entitled "Driving a Cultural Change in Produce Safety through the Use of a Novel Confidential Data Sharing Platform (https://iafp.confex.com/iafp/2022/onlineprogram.cgi/Paper/28148) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)" focused on this work at the International Association for Food Protection Annual Meeting on 8/2/2022.

Prevention: Microbiological Surveys for STEC Detection and Enhanced Sampling Protocols

The agency conducts microbiological sampling assignments to identify potential contamination events associated with leafy greens and to help prevent contaminated leafy greens from entering commerce, when possible. The following actions reflect the agency's plans for enhanced sampling to improve the safety of leafy greens.

Approaches	Key Accomplishments 2020-2023
5.1. Conduct additional, focused sampling assignments for romaine lettuce grown in Arizona and California, as necessary.	• In FY20-21 the FDA completed a focused sampling assignment of romaine lettuce grown in Arizona (/food/sampling-protect-food-supply/microbiological-surveillance-sampling-fy20-21-sample-collection-and-analysis-romaine-lettuce-raw). • The FDA posted the result of romaine lettuce product sampling conducted in 2019 (/food/sampling-protect-food-supply/microbiological-surveillance-sampling-fy19-romaine-lettuce-commercial-coolers-yuma-arizona) and 2021 (/food/sampling-protect-food-supply/microbiological-surveillance-sampling-fy21-sample-collection-and-analysis-romaine-lettuce-obtained). • The FDA conducted a product sampling assignment consisting of over 500 samples of lettuce (iceberg, leaf, and romaine) grown in Salinas Valley, from mid-May to the end of the harvest season in November 2021. A summary report (/food/sampling-protect-food-supply/microbiological-surveillance-sampling-fy21-sample-collection-and-analysis-lettuce-grown-salinas) was published in September 2022. • State partners participating in Laboratory Flexible Funding Model Cooperative Agreement Program (LFFM) (/food/funding-opportunities-provided-office-domestic-partnerships/grants-cooperative-agreements-food#LFFM) collected 1,399 samples of leafy greens (including, but not limited to: romaine, iceberg, spinach, kale, arugula, microgreens) for detection of Shiga toxin-producing *E. coli* (STEC) between September 2020 and June 2022. STEC was not confirmed in any samples. • The FDA initiated phone assessments in the summer of 2023 during which they contacted produce farms that were located in areas likely impacted by the unprecedented flooding in California earlier in the year. The purpose of the calls was to assess the impact that the flooding may have had on the operation and what mitigation measures the farm took, as necessary, to assure food safety. The results of the phone assessments were shared with CDFA for further assessment and follow up, as appropriate. • In the summer of 2023 the FDA launched an assignment to collect and test environmental samples from harvest equipment (/food/sampling-protect-

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Approaches	Key Accomplishments 2020-2023
	food-supply/fy-2324-inspection-and-environmental-sampling-leafy-green-harvest-equipment-listeria-monocytogenes). The assignment is underway.
5.2 Continue working with stakeholders to share knowledge on new technologies and sampling approaches.	• The FDA completed several enhanced detection and isolation protocols (/food/laboratory-methods-food/additional-chemistry-and-microbiology-resources-used-foods-program) for the sampling of STEC and Salmonella. These methods were shared at the CFSAN/ORA Environmental Microbiology Methods Summit, the FDA Office of Regulatory Science / Office of Applied Research and Safety Assessment roundtable and at an Association of Official Analytical Chemists (AOAC)-convened national environmental methods symposium. The methods are now fully utilized by FDA field staff during sampling. • The FDA has posted an SOP for the use of Dead-End Ultrafiltration (DEUF) for the Detection of Bacterial Pathogens from Agricultural Water and a training video on FDA.gov (/food/laboratory-methods-food/additional-chemistry-and-microbiology-resources-used-foods-program). • The FDA participated (https://www.aoac.org/aoac-training-courses-old/sampling-practices-for-accurate-test-results/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) in the delivery of an AOAC Training for environmental sampling in 2020. • The FDA has completed final validation of a DEUF sampling protocol for the collection of STEC in surface water. The FDA anticipates the protocol to be published in the FDA's Bacteriological Analytical Manual (BAM) soon. ◦ The agency is currently working to validate a similar protocol focus on Salmonella and anticipated validation to be completed in 2024. • The FDA is actively working to enhance sampling methods for collecting STEC and Salmonella from wind and dust. • The FDA is currently in the process of validating a high-risk STEC PCR assay for secondary identification of additional high-risk virulence factors in STEC associated with romaine lettuce and other leafy greens.

Prevention: Increase Awareness and Address Concerns Around Adjacent and Nearby Land

Several recent leafy greens outbreak investigations have emphasized that conditions and practices on adjacent and nearby land can play a critical role in contributing to produce contamination. The strategies identified below are intended to raise awareness and minimize the risks stemming from certain activities and conditions on adjacent and nearby land.

Approaches	Key Accomplishments 2020-2023
6.1 Provide education and technical assistance regarding potential impacts of adjacent and nearby land use on leafy green safety.	• Provided technical assistance to LGMA workgroups on hazards associated with adjacent and nearby land use activities. • FDA developed and release a fact sheet on Adjacent and Nearby Land Use and its Impact on Produce Safety (/food/food-safety-modernization-act-fsma/adjacent-and-nearby-land-use-and-its-impact-produce-safety).

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Approaches	Key Accomplishments 2020-2023
6.2 Engage with government partners as well as local, regional, and national industry stakeholders to identify strategies for minimizing risks presented by the presence of livestock on adjacent and nearby land.	• Leafy Green Safety Coalition of Retailers established to strengthen prevention practices and traceback and to improve scientific basis for assuring the safety of leafy greens. • In June 2021, the California Agricultural Neighbors (CAN) issued their Interim Report (https://www.cdfa.ca.gov/is/docs/can_interim_report.pdf) on best practices to help enhance localized food safety efforts. The work conducted by CAN Dialogue Group fostered a deeper understanding among Salinas Valley agricultural neighbors (row crop fields, rangeland, and vineyards) of the practices that commonly take place throughout the year. The work of the group identified collective themes for discussion, recommendations for consideration, and opportunities where we can expand on current knowledge and understanding of the issues. Four Action strategies are underway: ◦ Action 1: Foster Neighbor-to-Neighbor Interactions and Conversations - this work group developed conversational talking points focused on ‘across the fence’ discussions about activities and practices that each side should be aware of, and timing of those activities. A pilot program is under development for the Salinas Valley area to validate these discussion items utilizing row crop fields bordering rangelands. ◦ Action 2: Build a Research Roadmap for the Salinas Valley – using multiple sources for identifying data gaps and potential areas of risk, this work group developed and formulated a research roadmap that feeds into the development of a risk assessment process. ◦ Action 3: Create a Quantitative Microbial Risk Assessment (QMRA) Framework – with assistance from subject matter experts, this work group will develop the risk assessment framework utilizing the research roadmap as a guide for data gaps, leading to insight into the value of data gained through research in specific areas. ◦ Action 4: Build and Maintain Capacity to Transfer Knowledge from Research into Applied Practice – now with an approved charter, this work group will consider best practices in communicating knowledge

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Approaches	Key Accomplishments 2020-2023
	and data into production practice development and implementation. Research capacity and funding sources will also be considered as key metrics to keeping the information flow to the applied space. • CAN meets monthly as a Steering Committee to review progress, discuss policy nuances, and gain additional knowledge as necessary. A larger Dialogue Group is set for a meeting in late Fall 2023 to keep industry professionals, researchers, and regulatory officials informed of CAN progress. • AFDO Healthy People 2030 STEC Leafy Green Work Group established with the object to reduce the number of infections due to STEC outbreaks.

Prevention: Establish and Strengthen Regular Outreach and Communication Programs for Stakeholders in Growing Regions

Building relationships with our partners in leafy green growing regions can help us to better understand and respond to contamination events in those areas. The following strategies focus on building our relationship with our leafy green stakeholders in California and Arizona, the two biggest production areas for leafy greens sold in the US.

Approaches	Key Accomplishments 2020-2023
7.1 Continue ongoing dialogue on region-specific issues in real time with a broad array of Yuma growing region stakeholders.	• The FDA established biannual meetings between the FDA, the Arizona Department of Agriculture, and the Yuma Fresh Vegetable Association to discuss leafy greens safety issues. Two meetings were held in 2022 and one meeting in 2023.

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Approaches	Key Accomplishments 2020-2023
7.2 Continue ongoing dialogue on region-specific issues in real time with a broad array of California growing region stakeholders.	• The FDA established and continues monthly meetings between the FDA, the California Department of Food and Agriculture (CDFA), and the California Department of Public Health (CDPH) to discuss leafy greens safety issues. These monthly meetings coordinate collaborative efforts to enhance the safety of leafy greens, including ongoing work on the CA Longitudinal research study, California Agricultural Neighbors workgroup, AFDO Healthy People 2030 Committee produce workgroup, prioritizing leafy greens farm inspections, and sampling assignments.

Response: Investigation Reports

Investigation reports provide insights into the potential routes of contamination that stakeholders can use to better assess their own farms and situations. The reports can also help to identify contamination trends over time. The FDA intends to continue to release investigation reports following STEC outbreaks linked to leafy greens.

Approaches	Key Accomplishments 2020-2023
8.2 Continue releasing new investigation findings to shed light on the potential routes and possible mitigation strategies for STEC contamination of leafy greens.	• In 2020 (/food/outbreaks-foodborne-illness/factors-potentially-contributing-contamination-romaine-lettuce-implicated-three-outbreaks-e-coli) and early 2021 (/food/outbreaks-foodborne-illness/factors-potentially-contributing-contamination-leafy-greens-implicated-fall-2020-outbreak-e-coli), the FDA published the investigation reports on the 2019 and 2020 STEC outbreaks linked to the consumption of leafy greens which outlined the epidemiological and traceback information, on-farm investigation approaches, and key findings. Following each release, the FDA engaged with the industry and trade associations to discuss the findings and encourage collaboration to work toward preventing future outbreaks.

Response: Conduct Follow-Up Surveillance During the Fall California Growing / Harvest Season

Public health officials sometimes learn about outbreaks long after the contamination event occurred, and in the case of leafy greens it can even be after the harvest season has ended, which makes investigations difficult. Therefore, the agency will work with state partners to conduct surveillance inspections and sampling of farms that may have been linked to previous outbreaks to identify potentially contributing factors and to help prevent future contamination events.

Approaches	Key Accomplishments 2020-2023
9.1 Continue to coordinate with the California Department of Food and Agriculture (CDFA), in coordination with California Department of Public Health (CDPH), to conduct focused follow-up investigations and limited produce sampling of farms/ranches identified by foodborne illness outbreak traceback investigations.	• In 2020, the FDA, in consultation with CDFA, issued a mission critical assignment to conduct follow-up investigations of farms in the Salinas, California growing region during harvest. • In 2021, CDFA conducted follow-up produce safety inspections of leafy greens farms and associated ranches that were identified by traceback investigation in 2020 leafy greens foodborne illness outbreaks. Results of these CDFA inspections were of the 38 priority farms inspected, none were categorized as having Official Action Indicated and 20 farms were categorized as having Voluntary Action Indicated with no significant deficiencies identified. • The FDA and CDFA conducted an on-farm sampling and inspections during FY22-23 of farms/ranches in the Salinas Valley, California, region that have been linked to an outbreak of foodborne illness or an outbreak signal. The FDA led work on the sampling, while CDFA conducted the inspections. The results were analyzed together and will be described in a forthcoming report.

Response: Promote Tech-Enabled Traceability

When foodborne illness outbreaks occur, efficient product tracing helps government agencies and those who produce and sell food to rapidly find the source of the product and where contamination may have occurred. This can facilitate faster removal of the affected product from the marketplace, reducing incidences of foodborne illnesses. The strategies below are intended to help enhance the traceability of leafy greens and other products.

These strategies are also a part of Core Element 1 "Tech-Enabled Traceability" of the New Era of Smarter Food Safety Blueprint (/food/new-era-smarter-food-safety/new-era-smarter-food-safety-blueprint).

Approaches	Key Accomplishments 2020-2023
10.1.1 Advance the traceability of leafy greens through the issuance of the Food Traceability Final Rule.	• In September 2020, the FDA published in the Federal Register a proposed rule (https://www.federalregister.gov/documents/2020/09/23/2020-20100/requirements-for-additional-traceability-records-for-certain-foods) to establish additional traceability recordkeeping requirements (beyond what is already required in existing regulations) for persons who manufacture, process, pack, or hold foods the agency has designated for inclusion on the Food Traceability List (/food/food-safety-modernization-act-fsma/food-traceability-list), including leafy greens. • In November 2022, the FDA issued (/food/hfp-constituent-updates/fda-announces-final-rule-food-traceability-under-fsma) a final rule on food traceability. The compliance date for all persons subject to the recordkeeping requirements is Tuesday, January 20, 2026.

10.2.1 Collaborate on an industry led effort to develop further documentation of the leafy greens pilot completed in 2020 including (1) providing additional details on how each pilot team executed their tracebacks, (2) developing considerations for future pilot project methodologies and real world traceback investigations, and (3) providing education and outreach materials.	• The FDA collaborated with an industry-led Leafy Green Traceability Pilot (https://www.ift.org/press/press-releases/2020/december/2/leafy-green-traceability-pilots) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) to plan, initiate, and work with identified volunteers/industry experts to execute pilot scenarios that replicated a traceback investigation; and review and synthesize the data in a report published by the Leafy Greens Task Force in December 2020. • Lessons learned from the Leafy Green Traceability Pilot report completed by industry groups informed efforts described in the New Era of Smarter Food Safety Core Element 1.3 (/food/new-era-smarter-food-safety/new-era-smarter-food-safety-blueprint).

Response: Improve Utilization of Shopper Card Data

Many customers use shopper loyalty cards during purchases, which can provide critical information about purchase history during an outbreak. The FDA is exploring strategies for how we can better utilize available shopper card information during outbreak and recall events.

These strategies are also a part of Core Element 1 "Tech-Enabled Traceability" of the New Era of Smarter Food Safety Blueprint (/food/new-era-smarter-food-safety/new-era-smarter-food-safety-blueprint) and the Foodborne Outbreak Response Improvement Plan (/food/new-era-smarter-food-safety/new-era-smarter-food-safety-fdas-foodborne-outbreak-response-improvement-plan).

Approaches	Key Accomplishments 2020-2023

11.1 Continue 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.	• The FDA served as the co-lead with US Department of Agriculture's Food Safety Inspection Service (USDA FSIS) in the Shopper History Outbreak Partnership (SHOP) Workgroup. Working with state representatives this workgroup has begun development of a best practices document regarding the use of shopper history during foodborne illness investigations. • The FDA provided technical assistance to the Conference for Food Protection (CFP) Foodborne Illness Investigation Committee. This group—comprising federal, state, and local regulators, as well as industry, academic, and consumer stakeholders—is determining how consumer purchase data could be utilized during foodborne illness investigations at the state and local levels. • The FDA has drafted and piloted the use of a Digital Data Request Template for retailers to quickly provide traceability information that links back to consumer purchase data of cases within an outbreak investigation. These templates build upon the goals outlined within the FDA Foodborne Outbreak Response Improvement Plan (/media/154712/download?attachment), which focuses on smarter ways to digitize and routinize the traceback process.

Response: Accelerate Whole Genome Sequencing (WGS) Data Submissions by States

As a method and tool for public health, WGS provides the highest resolution of current molecular subtyping methods and provides definitive evidence to detect and characterize pathogens. Genomic data from foodborne pathogens, by itself and in combination with other information, is a robust resource that can help us rule out or rule in specific strains during outbreak events. The more strains added to public databases such as PulseNet (https://www.cdc.gov/pulsenet/index.html) and GenomeTrakr (/food/whole-genome-sequencing-wgs-program/genometrakr-network), the greater the opportunities we have to find similar or matching strains that can provide insight into the source of the outbreak.

This work is also listed under New Era of Smarter Food Safety Core Element 2.5 "Outbreak Response (/food/new-era-smarter-food-safety/new-era-smarter-food-safety-blueprint)."

Approaches	Key Accomplishments 2020-2023

12.1 Continue work with Centers for Disease Control and Prevention (CDC), state departments of health, and global laboratories to accelerate sequencing submissions to public databases such as PulseNet and GenomeTrakr.	• The FDA improved the process for sample analysis and reporting, including pushing genome assemblies rather than raw data of FDA isolates to PulseNet; established a dashboard to retrieve assemblies that are generated in real-time for FDA isolates; and devoted resources to increase staffing to assist with pushing data to PulseNet. • The number of states submitting data has increased to 32, including 17 private laboratories and 8 federal partners.

Response: Advance Root Cause Analysis

Findings from root cause analyses can serve an important function in helping industry modify practices to avoid identified risks and can provide more robust data for predictive analytics. The following strategies are intended to enhance future root cause analysis work.

This work is also part of Core Element 2.1 "Invigorate Root Cause Analysis" of the New Era of Smarter Food safety Blueprint (/food/new-era-smarter-food-safety/new-era-smarter-food-safety-blueprint).

Approaches	Key Accomplishments 2020-2023
13.1 Coordinate with federal, state, local, tribal and territorial, and international partners to strengthen root cause analysis procedures and ensure rapid deployment as soon as an outbreak is traced to a specific site.	• In 2020, the FDA conducted multiple discussions with produce industry trade and buyer groups to encourage widespread industry adoption of root cause analysis and the FDA participated in industry-led education outreach efforts on this topic. • In 2021, In collaboration with the AFDO Healthy People 2030 Committee Produce Workgroup, FDA is working to address three main areas of Root Cause Analysis (RCA)/Root Cause Investigation (RCI): (1) Conducting RCA/RCI, (2) data sharing, and (3) implementation of RCA/RCI. The workgroup has identified the tools currently available and most often used for RCA/RCI.

Response: Enhance Outbreak and Recall Communications

Enhanced outbreak and recall communications can provide transparency around emerging food safety issues to ensure that industry, consumers, and other stakeholders are on the lookout for issues, even before a specific product/source is identified.

This work is also being conducted as part of the New Era of Smarter Food Safety Core Element 2.5 "Outbreak Response (/food/new-era-smarter-food-safety/new-era-smarter-food-safety-blueprint)."

Approaches	Key Accomplishments 2020-2023
14.1 Continue to collaborate with government partners to review and evaluate outbreak communication mechanisms and propose enhancements for continuous improvement.	• In 2020 the FDA launched the core investigation table (/food/outbreaks-foodborne-illness/investigations-foodborne-illness-outbreaks) summarizing ongoing outbreak investigations. This webpage, which is updated weekly, increased transparency and the availability of risk communication information for stakeholders about currently developing foodborne outbreaks. • In 2021 the FDA conducted an independent review of FDA's foodborne illness outbreak response process and recommendations were prepared and published (/media/154484/download?attachment). • Based on the 2021 independent review, FDA's Foodborne Illness Outbreak Response Improvement Plan (/food/new-era-smarter-food-safety/new-era-smarter-food-safety-fdas-foodborne-outbreak-response-improvement-plan) was developed and published in 2022. FDA continues to work on improvements identified in the plan. • On September 29, 2023, the FDA held a public meeting entitled "Modernizing Food and Drug Administration Recalls of all FDA-Regulated Commodities "The meeting was an opportunity for stakeholders to share information and feedback on recall modernization including strategies for enhancing public warnings.

Addressing Knowledge Gaps: Longitudinal Studies

Understanding how pathogens survive, move, and possibly contaminate produce prior to harvest – and over the course of time – can help us better understand how pathogens in the environment can impact the safety of leafy greens. Multi-year longitudinal studies will contribute new knowledge on how various environmental factors may influence bacterial persistence and distribution in a growing region, and how those factors may impact the risk of produce becoming contaminated.

Approaches	Key Accomplishments 2020-2023
15.1 Continue to support the ongoing Yuma Longitudinal Study to shed light on how human pathogens survive, move, and possibly contaminate produce prior to harvest.	• In 2019 the FDA formally initiated a multi-year Yuma Longitudinal Study (/food/hfp-constituent-updates/fda-partners-university-arizona-wellton-mohawk-irrigation-and-drainage-district-and-yuma-area-leafy) to better understand the ecology of human pathogens in the environment in the Yuma agricultural region. This initiative is a multi-year study which will focus on how these pathogens survive, move, and possibly contaminate produce prior to harvest. The FDA is now in its third year of the study. The second year of the study slowed due to restrictions associated with the COVID-19 pandemic, but the study is now back on track and extensive environmental sampling has resumed. Numerous samples of water, sediment, and air continue to be collected and analyzed for STEC and Salmonella. • The FDA is on track to complete sample collection and analysis under this study by the end of 2023 and to release findings in 2024.
15.2 Continue to support the ongoing California Longitudinal Study focusing on manure waste and other run-off targets from large dairy operations and surrounding ecosystems.	• In 2020 the FDA initiated a multi-year California Longitudinal Study (/news-events/fda-brief/fda-brief-fda-california-agricultural-stakeholders-launch-multi-year-study-enhance-food-safety). The California longitudinal multi-year study will examine how pathogens survive, move through the environment, and possibly contaminate produce, through work with water quality, food safety, and agricultural experts from CDFA, the Western Center for Food Safety at UC Davis, representatives from various agriculture industries, and members of the leafy greens industry. The study is now entering its second year. The first year of the study slowed considerably due to restrictions associated with the COVID-19 pandemic. However, the study is moving back on track and regular sampling is now underway at several environmental and agricultural sites in the Salinas growing area. • In 2023, this study entered its third year and remains on track.

Addressing Knowledge Gaps: Data Mining and Analytics on Previous Outbreaks

Analyzing data and information from past outbreaks can be used identify insights into factors that may be contributing to leafy greens outbreaks over time. These insights can help inform the development of strategies to help prevent further outbreaks.

Approaches	Key Accomplishments 2020-2023
16.1 Collaborate with Centers for Disease Control and Prevention (CDC), as well as state and other federal partners, to conduct retrospective analyses of past leafy greens outbreaks	• The FDA along with Centers for Disease Control and Prevention (CDC) collaborators published the study, "Lessons Learned from a Decade of Investigations of Shiga Toxin–Producing Escherichia coli Outbreaks Linked to Leafy Greens, United States and Canada (https://pubmed.ncbi.nlm.nih.gov/32946367/)" in the journal, Emerging Infectious Diseases.
16.2 Continue to collaborate with research organizations to characterize the role of seasonality and regional factors in STEC outbreaks involving leafy greens.	• The Center for Produce Safety evaluated the role of seasonality in STEC outbreaks involving leafy greens. Five CPS Briefs were developed in 2021: 1) Hypothesis Risk Matrix, 2) Leafy Greens Production, 3) Regional Cattle Management Profile, 4) Genomics & SNPs, and 5) Bioaerosol Risk (all issue briefs can be found under the resources tab on the Center for Produce Safety's Website (https://www.centerforproducesafety.org/resources.php) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).) • FDA collaborated with USDA's Agricultural Research Service to publish, Seasonality, shelf life and storage atmosphere are main drivers of the microbiome and *E. coli* O157:H7 colonization of post harvest lettuce cultivated in a major production area in California (https://environmentalmicrobiome.biomedcentral.com/articles/10.1186/s40793-021-00393-y) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Addressing Knowledge Gaps: Adjacent and Nearby Land Use

Several recent leafy greens outbreak investigations (/food/outbreaks-foodborne-illness/outbreak-investigation-reports) have emphasized that conditions and practices on adjacent and nearby land can play a critical role in contributing to produce contamination. The following strategies are intended to help us close knowledge gaps on how activities and conditions on adjacent and nearby land can contribute to leafy green contamination and what mitigation strategies might be employed to address the issue.

Approaches	Key Accomplishments 2020-2023
17.1 Continue to collaborate with federal and state partners, research organizations, and industry stakeholders to provide technical assistance and explore research on the impact of adjacent and nearby land use on leafy green growing areas. Prioritize collection of additional data and information that will help growers implement effective science-based mitigation strategies.	• The FDA communicated with federal agencies and food industry groups to evaluate opportunities and barriers related to implementing science-based practices and mitigations. Outcomes from these discussions included technical assistance activities and over ten outreach engagements with partners and several industry representatives. • FDA participated in a session titled "RT4 The Intersection of Adjacent and Nearby Land Use and Produce Safety (https://iafp.confex.com/iafp/2022/onlineprogram.cgi/Session/7879) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)" at the International Association for Food Protection Annual Meeting on August 1, 2022. The session highlighted recent findings and activities and to discuss opportunities and barriers related to produce safety and adjacent and nearby land use topics.
17.2 Continue working with government partners and industry stakeholders to explore the implications of cattle raised near leafy green growing areas and research into pre-harvest mitigation strategies related to cattle.	• In 2020, the FDA provided technical assistance to a locally led, locally convened effort called California Agricultural Neighbors (CAN) workgroup that is being led by the CDFA and Monterey County Farm Bureau to identify what actions can be taken now to reduce the risk of STEC contamination of leafy greens in this specific growing region. • CDFA has sponsored a Phase 1 study (being conducted by UC Davis) on the use of a cattle vaccine (E. coli 0157 SRP vaccine) to evaluate the safety in cow-calf production operations and the transference of antibodies from cows to their calves. This was the first step in a multi-phase research project.

Addressing Knowledge Gaps: Compost Sampling Assignment with California

A major concern when it comes to produce contamination is the microbiological status of manure and compost used in the growing process. Understanding the effectiveness of intervention strategies designed to reduce or eliminate the presence of pathogens in compost can help inform FDA's understanding of routes of contamination in the growing area.

Approaches	Key Accomplishments 2020-2023
18.1.1 Finalize and post a document summarizing all actionable data for consideration in directing future policy, guidance, and research activities around the safe and effective use of biological soil amendments of animal origin. 18.1.2 Advance second round of contractor-based sampling now underway to analyze additional compost samples.	• The FDA, utilizing an external contract laboratory, commenced collecting and analyzing numerous samples for microbial pathogens, including finished brown compost collected from the Southwest Arizona and Imperial Valley, California leafy green growing regions and soil samples collected by the FDA from the Yuma region. In addition, the FDA collaborated with the California Department of Food and Agriculture (CDFA) who collected and analyzed samples during Fall 2020 sampling. Progress for compost samplings slowed somewhat in 2020 due to COVID-19 restrictions. • In 2021, the FDA, utilizing an external contract laboratory, collected and analyzed 644 manure and soil samples for *Salmonella*, STEC and *Listeria monocytogenes*.
18.2 CDFA with state partners, will conduct additional surveillance sampling of biological soil amendments of animal origin. Results of this surveillance work will serve as important data points to ensure the entire system works in an effective, integrated way to help ensure soil amendments are processed and handled in a manner to reduce or eliminate microbial pathogens.	• CDFA collected and tested compost and processed (heat-treated) manure samples from 39 facilities starting in fall 2019 through 2021. One compost sample contained STEC and *Listeria monocytogenes*. Elevated fecal coliform populations were found in finished compost in 11 facilities sampled. All but one composts with elevated fecal coliform levels used either green-waste, green-waste & food-waste, or green-waste and grape pomace as feed stocks (green-waste is non-manure biodegradable waste). The findings reinforce current policy around the use of compost as promulgated under the Produce Safety Rule.