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Dear Colleagues:

The Food and Drug Administration (FDA) has released its Environmental Assessment (EA) report concerning the serious outbreak of *E. coli* O157:H7 infections associated with consumption of romaine lettuce that occurred earlier this year. The findings of this outbreak and their implications make it clear that FDA's relationships with its state partners and the leafy greens industry are more important than ever. The findings also show that our approaches to prevent leafy greens contamination must change to protect public health.

We each have an important role in making that happen. It is industry's role to ensure that the foods they bring to market are safe for consumers to eat. Therefore, we urge all segments of the leafy greens industry to review their operations and make all necessary changes.

FDA sets standards for the safe growing, harvesting, packing, processing and holding of produce, and works in collaboration with our state counterparts to ensure compliance with these standards. We look for continued leadership and collaboration at the state level. We also see a need to improve our response actions during outbreaks in areas that include facilitating EAs, laboratory testing and information sharing.

The purpose of this letter, which is being sent to you in conjunction with the [EA report](https://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm624546.htm) (<https://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm624546.htm>), is to make the case for what we believe each of us must do going forward.

### Safety Has Been an Ongoing Concern

This outbreak was the largest multistate outbreak of *E. coli* O157 infections in the United States since 2006, with 210 reported illnesses from 36 states, resulting in 96 hospitalizations, 27 cases

of hemolytic uremic syndrome, and five deaths. Bold action is needed to prevent future outbreaks, especially ones of this magnitude, and to restore consumer confidence in the safety of leafy greens available on the market.

The safety of raw whole and fresh-cut (e.g., bagged salad) leafy greens is a longstanding issue. As far back as 2004, FDA issued letters to the leafy greens industry to express our concerns about outbreaks associated with this commodity. Leafy greens are mostly consumed raw, without cooking or processing steps to eliminate microbial hazards. Therefore, the way they are grown, harvested, packed, held, processed and distributed is crucial to ensuring that contamination with pathogens is minimized.

Between 2009 and 2017, FDA and our partners at the Centers for Disease Control and Prevention identified 28 foodborne outbreaks of Shiga-toxin producing *E. coli* (STEC) with a confirmed or suspected link to leafy greens in the United States, an average of more than three outbreaks per year. This period follows implementation of measures by the leafy greens industry to address safety concerns after a large 2006 outbreak of *E. coli* O157:H7 caused by bagged spinach. Information about these 28 outbreaks was discussed in a meeting with produce industry representatives, including the Arizona Leafy Greens Marketing Agreement (LGMA) and California LGMA, on April 12, 2018, and again on July 31, 2018, at a meeting of the Leafy Greens Food Safety Task Force established in response to this year's outbreak.

In November 2015, FDA issued the final rule “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” (21 CFR part 112), commonly referred to as the FDA Food Safety Modernization Act (FSMA) [Produce Safety Rule](https://www.fda.gov/food/guidance-regulation/fsma/ucm334114.htm) (<https://www.fda.gov/food/guidance-regulation/fsma/ucm334114.htm>). The rule, for the first time, sets science-based regulatory standards for covered produce. The compliance dates are staggered by farm size; January 2018 was the compliance date for large entities. Large covered growers, packers and shippers are now required to comply with most of the provisions of this rule to minimize food safety hazards associated with leafy greens and other covered produce. Although, as you know, certain provisions covering the microbial quality standards for agricultural water, including irrigation water that comes into contact with produce, have been delayed while the standards are being reconsidered in light of concerns about their complexity. FDA is working with industry to address those concerns while still protecting public health.

The objective of the FDA-led EA was to identify factors that potentially contributed to the introduction and spread of the outbreak strain of *E. coli* O157:H7 in romaine lettuce associated with this outbreak. The report of the EA, in which three samples of irrigation canal water were found to contain *E. coli* O157:H7 that matched the outbreak strain, is now [posted](https://www.fda.gov/food/recalls-outbreaks-emergencies/outbreaks/ucm624546.htm) (<https://www.fda.gov/food/recalls-outbreaks-emergencies/outbreaks/ucm624546.htm>) on the FDA website to inform stakeholders about the results of the EA team's sampling, interviews with growers, and other observations.

### Recommendations for the Leafy Green Industry

We urge all segments of the leafy greens industry to review their current operations, procedures, policies and practices in light of the findings of this EA, the Produce Safety Rule, and other

relevant FSMA regulations (where applicable), as well as other available science-based information relevant to the reduction or elimination of pathogens on leafy greens. Firms should thoroughly review their operations and make necessary modifications to ensure that they are taking appropriate measures to provide a safe product to consumers.

Other actions that can, and should, be undertaken immediately to advance food safety include, but are not limited to, the following:

#### Prevent Contamination of Leafy Greens

- Based on the EA findings and other available information, industry should assess the need for and develop commodity-specific procedures, policies and best practices to enhance the safety of leafy greens. This effort should address, at a minimum, how leafy greens growers can:
  - assure that all agricultural water (water that directly contacts the harvestable portion of the crop) used by growers is safe and adequate for its intended use (including agricultural water used for application of crop protection chemicals);
  - assess and mitigate risks related to land uses near or adjacent to growing fields that may contaminate agricultural water or leafy greens crops directly (e.g., nearby cattle operations or dairy farms, manure, or composting facilities);
  - verify that food safety procedures, policies, and practices, including supplier controls for fresh-cut processors, are developed and consistently implemented on farms (both domestic and foreign) and in fresh-cut produce manufacturing/processing food facilities to minimize the potential for contamination and/or spread of human pathogens; and
  - when a foodborne pathogen is identified in the growing or processing environment, in agricultural inputs (e.g., agricultural water), in raw agricultural commodities or in fresh-cut ready-to-eat produce, a root cause analysis should be performed to determine the likely source of the contamination, if prevention measures have failed, and whether additional measures are needed to prevent a reoccurrence.

We realize that both the AZ and CA LGMAs recently updated their requirements. However, whether and what additional measures are needed based on the findings of the EA should be assessed to assure all appropriate actions have been taken to minimize contamination risks.

#### Improve Traceability to Facilitate Rapid Public Health Response and Communication

FDA strongly encourages the leafy greens industry to adopt traceability best practices and state-of-the-art technology to assure quick and easy access to key data elements from farm to fork when leafy greens are involved in a potential recall or outbreak. Leafy greens are a highly perishable commodity, and traceability information should facilitate the rapid tracking of involved product throughout the entire supply chain to expedite its removal from commerce, prevent additional consumer exposures, and properly focus any recall actions.

A key element that would assist tracing efforts during an outbreak is the ability to identify specific farms or ranches that contribute to production lots if product has been commingled. While it is important to understand where the product was grown and not simply the location of the business entity that shipped or processed it, it is equally important to be able to determine which farm(s) and growing region are responsible for supplying the contaminated product. This information is crucial to the development of accurate public health messages to protect the public from exposure and empower consumers to take appropriate actions. Without the ability to identify the growing region or specific suppliers of suspected shipments, public messaging by FDA and other public health partners during recalls or outbreaks is of necessity broad, possibly implicating farms and growing regions that are not responsible for the contamination. If supplier data are maintained when the product is commingled, it is easier to narrow the number of suspected shipments and suppliers of the contaminated product once it is processed.

### Facilitate Research Relevant to Preventing Contamination of Leafy Greens with Pathogens

FDA encourages the leafy greens industry to appropriately fund and actively engage in leafy greens food safety research to:

- Identify the potential sources of microbial pathogens, including STECs or other enteric pathogens;
- Understand the specific routes by which pathogens, including STECs, are likely to contaminate leafy greens so it can be prevented in the future; and
- Develop data-driven and risk-based measures to reduce, control or eliminate contamination of leafy greens by human pathogens.

### Recommendations for State and Federal Regulators

Local in-depth knowledge and actions are critical in helping resolve potential routes of contamination of leafy greens in the Yuma growing region and other growing areas. FDA urges government and non-government entities, produce growers and trade associations in Yuma and Imperial Counties to further explore possible source(s) and route(s) of contamination associated with the outbreak strain of *E. coli* O157:H7 and with other foodborne pathogens. This information is critical to developing and implementing short- and long-term remediation measures to reduce the potential for another outbreak associated with leafy greens or other fresh produce commodities.

For our part, FDA will soon be collecting and analyzing romaine lettuce samples via a surveillance sampling assignment for contamination with human pathogens to determine whether products placed in commerce are adulterated under Section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(a)(1)). If pathogens are detected in samples, FDA will take appropriate actions and follow up with fresh-cut leafy greens processors and their growers/suppliers to determine if these foods were produced under insanitary conditions that render them adulterated under Section 402(a)(4) of the FD&C Act (21 U.S.C. 342(a)(4)) and harmful to consumers. FDA will also explore regulatory options and consider appropriate enforcement actions against firms and farms that grow, pack, or process fresh lettuce and leafy greens under insanitary conditions.

FDA is also committed to improving response times in:

- facilitating EAs;
- providing results from FDA laboratory testing; and,
- communicating with all stakeholder groups, including buyers, consumers and the leafy greens industry.

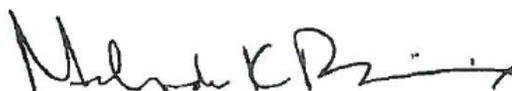
On October 19, 2018, FDA published a draft compliance and implementation guidance for the Produce Safety Rule, as well as draft guidance for the fresh-cut produce industry, which we believe will help the leafy greens industry develop compliance plans.

We recognize and appreciate the efforts that the leafy greens industry has taken to date, and more must be done as the *status quo* is unacceptable from a public health and consumer perspective. We are hopeful and confident that the leafy greens industry and state partners will continue to work proactively with us to pursue our mutual goal of a safe food supply for all Americans.

Sincerely,



Stephen Ostroff, M.D.  
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and Veterinary Medicine



Melinda K. Plaisier  
Associate Commissioner  
for Regulatory Affairs

CC: Yuma Fresh Vegetable Association  
Produce Marketing Association  
United Fresh Produce Association  
Yuma Safe Produce Council  
Western Growers Association  
Florida Fruit and Vegetable Association