



# FMI Recommended Food Safety Practices for Leafy Greens

**PURPOSE:** The recurring outbreaks of *E. coli* 0157:H7 infections associated with romaine lettuce and leafy greens consumption are devastating to retailers and wholesalers, the produce industry and consumers. The purpose of this document is to assist in preventing contamination of leafy greens, increase communication across the entire supply chain, protect consumers and the safety of products they consume, and facilitate effective response to food safety incidents should they occur again. We encourage food retailers and wholesalers of all sizes to consider implementing these recommendations both to raise and consolidate standards for prevention, but also to reduce risk.

The primary goal of all retailers and wholesalers is to maintain the health and safety of our customers. To help our members ensure the safety of the products they sell, FMI is providing recommendations regarding food safety best practices for members' use when sourcing leafy greens. FMI recommends that members have robust food safety specifications in place and that they communicate the requirements clearly to their suppliers.

For the purpose of this document, Leafy Greens<sup>1</sup> include the following commodities (*mature or baby varieties*) whether purchased individually or as mixed greens:

- Arugula
- Baby Leaf Lettuce
- Butter Leaf Lettuce
- Cabbage
- Chard
- Endive
- Escarole
- Green Leaf Lettuce
- Iceberg Lettuce
- Kale
- Red Leaf Lettuce
- Romaine Lettuce
- Spinach (*all varieties*)
- Spring Mix

<sup>1</sup> <https://lgma.ca.gov/about-us/> Accessed July 20, 2022

## Recommended Food Safety Programs for Suppliers of Leafy Greens

FMI recommends that retailers and wholesalers ask their suppliers to become certified by food safety certification programs for growers of leafy greens and for handlers/shippers to assure hazards are properly identified and mitigated.

1. FMI recommends that FMI members purchase leafy greens from **growers** who are certified and have annual audits from any of the following programs:
  - Harmonized Produce GAP Audit (entry level)
  - GFSI Recognized Certification Program (*Program names as of July 2022*)
    - SQF Food Safety Code: Primary Plant Production
    - PrimusGFS Standard
    - GLOBALG.A.P. Integrated Farm Assurance Standard Sub-scopes: Fruit and Vegetables, Aquaculture
    - GLOBALG.A.P. Harmonized Produce Safety Standard (HPSS)
    - CanadaGAP Options B, C and D
    - ASIAGAP Control Points and Compliance Criteria (for Farms) Fruits and Vegetables
  - GFSI Technical Equivalence
    - USDA Harmonized GAP Plus+

In addition to having food safety management programs, certifications and audits with one of the above standards, FMI encourages growers to **follow through on all non-conformances** identified on audits, take appropriate corrective actions and close them out in a timely manner to protect the safety of the products they are producing. Audits and certifications should occur at least annually.

2. As another layer of assurance, FMI recommends that retailers and wholesalers encourage **shippers/handlers** in Arizona and California to become certified through the most current approved Leafy Green Marketing Agreement (LGMA) metrics. While LGMA has very specific metrics, a food safety program at the grower level is necessary to assure hazards are identified and properly mitigated.
3. **After any food safety event in the industry** (outbreaks included), growers/shippers/handlers should **review and update their food safety programs and update their hazard analyses** to consider all possible hazards that are known and reasonably foreseeable including, but not limited to, hazards associated with all sources of water, adjacent and nearby land use, domesticated and wild animal activity, and weather events. Outside of food safety events, potential hazards should be reviewed on an annual basis, when additional knowledge is available, or a change of any type is anticipated. Information should be shared and communicated among adjacent growers, in a timely manner, so that important changes in conditions are known and can be assessed accordingly.
4. **Farms** exempt from the Food and Drug Administration (FDA) Produce Safety rule should implement produce safety standards to verify that leafy greens are produced, packed, handled, and stored as safely as possible to minimize risks of microbial food safety hazards. Small farms should also adopt USDA's Good Agricultural Practices (GAP) and Good Handling Practices (GHP) or SQF Fundamentals for Primary Production (Basic or Intermediate levels). These written food safety programs provide a strong foundation upon which more stringent food safety standards can be built as farms work to strengthen their food safety practices.







## Background Information:

On behalf of our member retailers and wholesalers, FMI has concerns about hazards from water, adjacent and nearby lands, soil amendments, environmental conditions and domesticated and wild animals as a source of contamination. **While the definitive source(s) or route(s) of contamination in many of the recurring *E. coli* O157:H7 outbreaks linked to leafy greens are never determined, contributing factors that potentially led to the contamination of leafy greens have been identified.** For example, the outbreak strain from the Spring 2018 outbreak was found in a Yuma, Arizona irrigation canal near a cattle feeding operation and an outbreak strain from the Fall 2018 outbreak was found in the sediment of a reservoir located on a farm in Santa Barbara County, California. While the root causes of contamination was undetermined, water likely played a role and potentially contributed to the contamination of the romaine lettuce implicated in both of the outbreaks.

Water, along with other factors—soil amendments, growing practices, environmental conditions, animal activity, adjacent and nearby land use—are all important to on the farm food safety and are important risk factors that must be monitored and controlled on a regular basis. To be successful, food safety programs for leafy greens must include adequate practices to identify and control any hazards and to ensure water is safe and of adequate sanitary quality for its intended use. (*See Produce Safety Rule 21 CFR 112.41*)

FMI is concerned about the following **conditions which could introduce known or reasonably foreseeable hazards that must be controlled:**

### Agricultural Water

- Water that could be contaminated by hazards introduced directly or indirectly by conditions and practices on the farm, as well as, activities associated with adjacent and nearby lands. In particular, adjacent and nearby land uses related to animal activity (e.g., animal feeding and grazing operations of any size); wild or domesticated animal activity; application of soil amendments; presence of untreated or improperly treated human waste; environmental conditions; as well as contact with sources of contamination, such as, fecal material, dust, runoff, wind, farming activities (e.g., vehicles, harvest crews, harvest equipment, etc.) or cross contamination through mixing or backflow). Hazards should be assessed, evaluated and controlled to prevent contamination.
- Water sources depending on the environmental conditions, water application method, hazard assessment of the water and the degree of protection from sources of contamination. (The definition of agricultural water includes water that is intended to, or is likely to, come in to contact with covered produce or food contact surface.) The hazard assessment of water should consider whether water is intended to, or is likely to, contact the harvestable portion of the produce or food contact surfaces, including water used before, during and after harvesting (e.g., irrigation water, water used in preparing crop, water used for washing or cooling, water used to prevent dehydration, etc.). For example, water used in furrow or drip irrigation methods should be assessed for its likelihood of contact with the harvestable portion of the produce.
- Water delivery systems, including open and closed delivery systems. Water storage and conveyance should be regularly inspected to identify any conditions that could introduce hazards and necessary actions must be taken to prevent contamination.

- Areas subject to pooling water. Growers should take necessary steps to prevent the contamination of leafy greens in such areas.
- Improperly treated water. When water is treated, it should be with an EPA registered antimicrobial pesticide product that is effective to ensure the water is safe and of adequate sanitary quality for its intended use (21 CFR 112.46). Treatment of water must be validated and subsequently verified to ensure treatment is delivered in a manner so that the treated water is consistently safe and of adequate sanitary quality for its use. Treatment of water must be monitored at a frequency adequate to ensure it is consistently safe and of adequate sanitary quality for its use.

### **Soil Amendments**

- Soil amendments that did not reach the appropriate time/temperature controls for composting.
- Any cross contamination from untreated or undertreated soil amendments. Cross-contamination should be prevented.
- Pre-harvest applications of soil amendments. Any application or possible contamination occurring after pre-harvest assessments are complete, including during growing activities, harvesting and post-harvest (such as application of fertilizer or soil amendments, top dressing, water or weather event) should be evaluated prior to harvest.
- Application of soil amendments on adjacent and nearby lands.

### **Domesticated and Wild Animals**

- Presence of animal attractants such as water sources or standing water on or near the farm.
- Significant quantities of animals, animal excreta and/or crop destruction.
- Animal activity on adjacent or nearby lands, including, grazing, livestock operations and wildlife intrusion.

### **Environmental Conditions**

- Extreme weather events that may impact the agricultural water system or produce (e.g., damage to edible leaves) during growing activities to include heavy rain, air temperatures, heavy winds, and sun exposure.

Comprehensive hazard analyses are required to identify hazards and to determine the hazard and appropriate controls required for all identified hazards. The hazard analyses must be robust and appropriate for leafy greens. Hazard analyses should be written and should follow the typical procedures for hazard analyses completed by food safety professionals. FMI encourages retailers and wholesalers to discuss with their suppliers the potential hazards associated with the above conditions, along with the appropriate control measures in place.

Retailers should communicate their commitment to food safety to suppliers and ask suppliers to share information about their food safety programs.







## Testing of Water and Product

**Prevention** of contamination is the best way to protect the safety of food products. However, it is also important to have methods in place to verify that critical food safety controls are working. Testing of water and products can be useful when conducted properly, under controlled conditions and when samples are collected and tested using a scientifically valid method to provide statistically reliable results.

**FMI recommends the following:**

1. Laboratories used for water and product sample analysis should be ISO/IEC17025 Accredited with the appropriate methodology listed on the laboratory's Scope of Accreditation.
2. Water and product testing can be tools to assess whether appropriate food safety controls of the hazards are working as intended. Testing should be purposeful and appropriate. Methods used for water testing and, if applicable, for pre and post-harvest product testing should be validated for the detection of the appropriate indicator organism and/or pathogen, including the specific pathogen(s) of concern (e.g., Shiga toxin-producing *E. coli* and *Salmonella*). In addition, the testing protocol should detect sporadic contamination events and ideally should be designed with input from a statistician or following **International Commission on Microbiological Specifications for Foods (ICMSF) guidelines** to ensure statistical significance. All remediation procedures should be followed when positive tests are identified, and positive findings should be followed by a root cause investigation.
3. If product testing results in a confirmed positive, the lot (or field) should be discarded. Resampling may be appropriate for determining the root cause of contamination but should not be used as a means for the acceptance of product. Furthermore, these findings of root cause investigations should be communicated with neighboring growers to evaluate and determine if there is widespread contamination.

## Labeling

A voluntary labeling program, announced on November 26, 2018 for romaine lettuce was negotiated by the produce industry and the FDA to identify harvest location and date on all romaine lettuce in commerce. The purpose of providing harvest information on packages containing romaine is to allow consumers to easily identify the source of packaged romaine products in the event of a consumer advisory. Some modifications to this agreement have been made, however harvest location is still considered essential as is a date that can be linked to the harvest date.

**FMI recommends that retailers and wholesalers ask suppliers to provide harvest region and date for all cases of romaine lettuce and that this information be included on-pack for pre-packaged items.**

Additional considerations for Provenance Labeling:

- Store signage for bulk romaine products (unpackaged) is not necessary unless there is a specific advisory in place. Retailers may choose to post signage at the point of display or work with suppliers to provide individual labeling (bands, ties, etc.) that accurately conveys information about the product to customers.

- Retailers and wholesalers should request harvest information from suppliers and maintain the information (specifically for bulk romaine) in the event of a future consumer advisory. Requesting this information on the bills of lading and/or the advance shipment notices (ASN) will help assure the retailers and wholesalers are in possession of the harvest location and a trackable date for each shipment of romaine lettuce. This information should not be used in lieu of more granular traceability information but could be helpful as a secondary source or quick check to verify accuracy and provide information should it be necessary.
- Accuracy of information on packaged products is important and products must not mislead consumers (specifically private brands). Although this is a voluntary initiative, consequences of failing to provide accurate information bring the product out of compliance with FDA's labeling laws.
- For comingled product, the word "and" should be used to indicate multiple regions.
- The regions should be consistent with the regions defined by the Leafy Greens Taskforce and identified in the Questions and Answers on Voluntary Romaine Growing Region/Harvest Date Labeling. Please see: <https://www.freshproduce.com/resources/food-safety/romaine-provenance-labeling/>

## Traceability

To further assist with traceability during outbreak investigations for any leafy greens, FMI recognizes the need for all industry stakeholders to collaboratively work toward development and implementation of practical, widely adopted, standardized systems (such as, but not limited to, the Produce Traceability Initiative) that would allow immediate access and sharing of critical source identifier information for all leafy greens. This supports the transferring and availability of the following key information utilizing standard, compatible definitions maintained in consistent ledger locations:

- Unique company identifier (such as GS1 company pre-fix)
- Unique product identifier (such as GS1 Global Trade Item Number or GTIN, includes company pre-fix)
- Harvest location
- Production region(s) Harvest: (date)
- Lot/batch identifier (the narrower the better)
- Date and time stamps of events (shipping, receiving, transforming)
- Quantities of product shipped/received







In order to simplify traceability for the industry, we encourage the use of a standard GS1-128 barcode. Standardized information is necessary to ensure data is linked as product moves through the supply chain.

**The application identifiers are:**

- (01) GTIN—14-digit numeric sequence
- (13) Packaging date—6-digit numeric sequence (YYMMDD)
- (10) Batch number (grower Lot)—1-20-digit alpha-numeric sequence

Additional information on the label may include the product description, harvest date, and country of origin.

**Bills of lading** and/or **Advance Shipment Notices (ASNs)** should include traceability information including the harvest location and lot information for easy access in the event of foodborne illness investigations.

The emphasis should be on sharing accurate data with supply chain partners. It is likely that traceability information will change over time and systems should be flexible to accommodate advances in technology.

## Public Health Investigations

It is in retailers' and wholesalers' best interest to help public health officials with foodborne illness investigations to identify the source of contamination as quickly as possible. Identifying the source of the food that caused the illness in a timely manner is often one of the most challenging parts of the investigation and often retailers and wholesalers possess critical information to link an ill person to the food they purchased. FMI recommends that all members continue to cooperate with public health officials (local, state and federal) to provide the information they request to complete their investigation. Speed and accuracy are both imperative and anything FMI members can do to assist will benefit everyone but, most importantly, will help protect public health.

## Approved Suppliers and Product Shortages

In the event there are product shortages for any reason, retailers should have specifications, along with procedures, in place for approving suppliers in the interim. Specifications should be set by each retailer or wholesaler independently and should be established prior to purchasing from a supplier. Specifications should always address food safety expectations.

## What do retailers and wholesalers need to do?

- FMI recommends retailers and wholesalers purchase leafy greens from growers who have strong food safety management programs in place and are certified and have annual audits from any of the following programs:
  - Harmonized Produce GAP Audit (entry level)
  - GFSI Recognized Certification Program (*Program names as of July 2022*)
    - SQF Food Safety Code for primary production
    - PrimusGFS Standard
    - GLOBALG.A.P. Integrated Farm Assurance Standard Sub-scopes: Fruit and Vegetables, Aquaculture
    - GLOBALG.A.P. Harmonized Produce Safety Standard (HPSS)
    - CanadaGAP Options B, C and D
    - ASIAGAP Control Points and Compliance Criteria (for Farms) Fruits and Vegetables
  - GFSI Technical Equivalence
    - USDA Harmonized GAP Plus+
- Talk with suppliers and let them know the importance of food safety to your company.
- Work with suppliers to ensure they assess, evaluate and control hazards associated with adjacent and nearby land use, including, animal feeding and grazing operations, regardless of size; wild or domestic animal activity; operations involving soil amendments or wastewater treatment; or any other use that could introduce a hazard.
- Talk with suppliers about addressing hazards in the production of leafy greens including hazards associated with water, soil amendments, and domestic and wild animal activity.
- Encourage shippers/handlers in Arizona and California to be LGMA certified.

**Contact FMI Food and Product Safety with questions or for additional information.**

**Acknowledgment:** FMI Food Protection Committee for writing and reviewing this document.

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## FMI Checklist for Sourcing Leafy Greens

**Every grower of leafy greens has a food safety management system in place and is certified to one of the following programs:**

- Harmonized Produce GAP Audit (Entry level)
- GFSI Recognized Certification Program (*Program names as of July 2022*)
  - SQF Food Safety Code: Primary Plant Production
  - PrimusGFS Standard
  - GLOBALG.A.P. Integrated Farm Assurance Standard Sub-scopes: Fruit and Vegetables, Aquaculture
  - GLOBALG.A.P. Harmonized Produce Safety Standard (HPSS)
  - CanadaGAP Options B, C and D
  - ASIAGAP Control Points and Compliance Criteria for Farms, Fruits and Vegetables
- GFSI Technical Equivalence
  - USDA Harmonized GAP Plus+

**For leafy green handlers in California and shippers in Arizona, the handler/shipper is certified by a USDA audit and is following LGMA Food Safety Best Practices.**

**Ensure suppliers are addressing hazards in the production of leafy greens including hazards associated with adjacent and nearby land use, water, soil amendments, and domestic and wild animals.**

**Traceability information is available from supplier.**

**Harvest location and date is provided from supplier.**

**Supplier approval program is in place and is being followed prior to any purchase of leafy greens. Anytime leafy greens are purchased (even in times of product shortages, the supplier approval program is followed and food safety standards are applied for leafy greens).**

