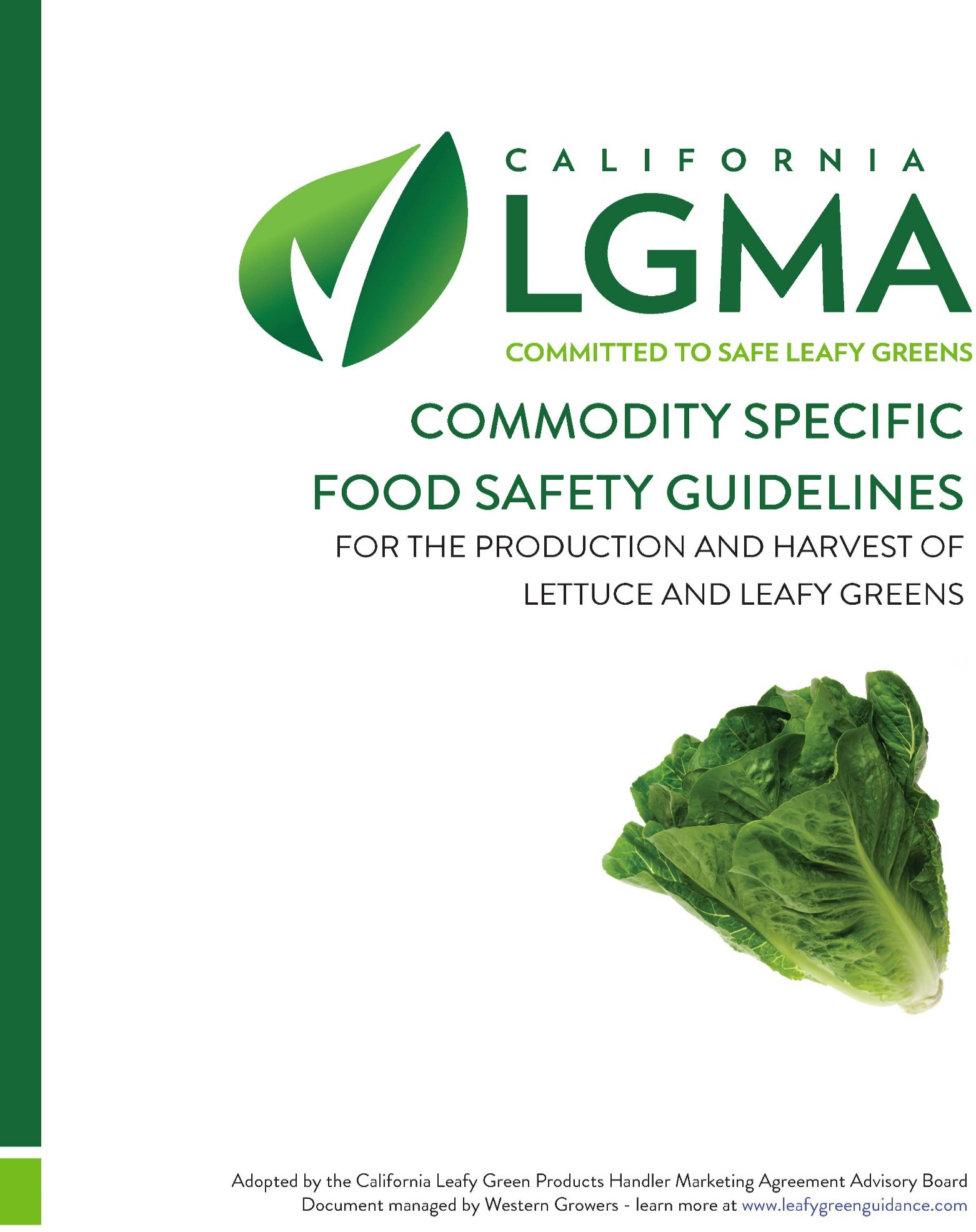
AUGUST 2, 2021

This document supersedes all previously published versions of the Commodity Specific Food Safety Guidelines for the Production and Harvest of Leafy Greens including those dated March 23, 2007, April 18, 2007, June 5, 2007, October 16, 2007, June 13,

2008, July 10, 2009, January 29, 2010, August 4, 2010, July 22, 2011, January 20, 2012, August 31, 2012, August 2, 2013,

January 29, 2016, August 10, 2017, September 28, 2018, April 19,2019, October 24, 2019, and August 20, 2020.

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| GLOSSARY | |
| **ACCREDITATION** | A rigorous assessment conducted by an independent science-based organization to assure the overall capability and competency of a laboratory and its quality management systems. |
| **ACTIVE COMPOST** | Compost feedstock that is in the process of being rapidly decomposed and is unstable. Active compost is generating temperatures of at least 50˚ Celsius (122˚ Fahrenheit) during decomposition; or is releasing carbon dioxide at a rate of at least 15 milligrams per gram of compost per day, or the equivalent of oxygen uptake. |
| **ADEQUATE / ADEQUATELY** | That which is needed to accomplish the intended purpose in keeping with good public health practice. |
| **ADJACENT / NEARBY LAND** | Land within a proximity that could potentially affect safe production of leafy greens. |
| **AERATED STATIC PILE** | Composting process where active ingredients are covered with an insulating material and air is forced through the product. The product is maintained at a minimum of 131 degrees Fahrenheit for 3 days. |
| **AERIAL APPLICATION** | Any application administered from above leafy greens where water may come in contact with the edible portion of the crop; may be delivered via aircraft, sprayer, sprinkler, etc. |
| **AEROSOLIZED** | The dispersion or discharge of a substance under pressure that generates a suspension of fine particles in air or other gas. |
| **AGRICULTURAL / COMPOST TEA** | A water extract of biological materials (such as compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, table waste, or yard trimmings), excluding any form of human waste, produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase. Agricultural / Compost teas are held for longer than one hour before application and are considered non-synthetic crop inputs for the purposes of this document. |
| **AGRICULTURAL MATERIAL** | *Agricultural Material* means waste material of plant or animal origin, which results directly from the conduct of agriculture, animal husbandry, horticulture, aquaculture, silviculture, vermiculture, viticulture and similar activities undertaken for the production of food or fiber for human or animal consumption or use, which is separated at the point of generation, and which contains no other solid waste. With the exception of grape pomace or material generated during nut or grain hulling, shelling, and processing, agricultural material has not been processed except at its point of generation and has not been processed in a way that alters its essential character as a waste resulting from the production of food or fiber for human or animal consumption or use. Agricultural material includes, but is not limited to, manures, orchard and vineyard prunings, grape pomace, and crop residues. |
| **AGRICULTURAL TAILWATER** | Excess run off water which is generated and collected during the process of irrigation. |

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| **MICROORGANISMS** | Yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having public health significance and those subjecting leafy greens to decomposition or that otherwise may cause leafy greens to be adulterated. |
| **MONITOR** | To conduct a planned sequence of observations or measurements to assess whether a process, point or procedure is under control and, when required, to produce an accurate record of the observation or measurement. |
| **MONTHLY** | Because irrigation schedules and delivery of water is not always in a grower’s control “monthly” for purposes of water sampling means within 35 days of the previous sample. |
| MONOCULTURE ROMAINE | Whole tall head romaine that does not include baby romaine, spring mix, and mixed varieties in beds within a field. |
| **MORTALITY COMPOST** | *Mortality Compost* is compost created through a process to manage livestock mortalities. The use of crop inputs, made from mortality composting processes, shall follow all local, state and federal regulations. |
| **MOST PROBABLE NUMBER (MPN)** | Estimated values that are statistical in nature; a method for enumeration of microbes in a sample, particularly when present in small numbers. |
| **MUNICIPAL WATER** | Water that is processed and treated by a municipality to meet USEPA drinking water standards. |
| **NON-DETECT** | Non-detect means not present but consideration should be given to the limit of detection of the approved laboratory method used for biological or chemical analysis. |
| **NON-SYNTHETIC SOIL AMENDMENTS AND CROP INPUTS OF ANIMAL ORIGIN** | Any soil amendment and/or crop input that contains animal manure, an animal product, and/or an animal by-product that is reasonably likely to contain human pathogens. Includes agricultural or compost teas for the purposes of these guidelines. |
| **OPEN DELIVERY SYSTEM** | A water storage or conveyance system which is partially or fully open and unprotected such that water is exposed to the environment at any point from the water source to the point of use. |
| **PACKING** | Placing leafy greens into a container other than packaging them and also includes activities performed incidental to packing (*e.g.,* activities performed for the safe or effective packing of leafy greens (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)). |
| **PARTS PER MILLION (PPM)** | Usually describes the concentration of something in water or soil; one particle of a given substance for every 999,999 other particles. |
| **PATHOGEN** | A disease-causing agent such as a virus, parasite, or bacteria. |
| **PEST** | Any objectionable animals or insects, including birds, rodents, flies, and larvae. |
| **POOLED WATER** | An accumulation of standing water; not free flowing. |
| **POST-CONSUMER WASTE** | *Post-consumer waste* is a waste type produced by the end consumer of a material stream. Generally, this is discarded materials after something has been used. Post-consumer waste can include items such as packaging and unconsumed food. |

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| **POTABLE WATER** | Water that is safe to drink or to use for food preparation without risk of health problems. |
| **PRE-CONSUMER WASTE** | A food item that was produced for consumption but that was never purchased, consumed or used. |
| **PROCESS AUTHORITY** | A regulatory body, person, or organization that has specific responsibility and knowledge regarding a particular process or method; these authorities publish standards, metrics, or guidance for these processes and/or methods. |
| **READY-TO-EAT (RTE) FOOD**  ***(EXCERPTED FROM USFDA 2005 MODEL FOOD CODE)*** | 1. "Ready-to-eat food" means FOOD that:    1. Is in a form that is edible without additional preparation to achieve FOOD safety, as specified under one of the following: 3-401.11(A) or (B), § 3-401.12, or § 3-402.11, or as specified in 3-401.11(C); or   (d) May receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes.   1. "Ready-to-eat food" includes:    1. Raw fruits and vegetables that are washed as specified under § 3- 302.15;    2. Fruits and vegetables that are cooked for hot holding, as specified under § 3-401.13;   (e) Plant FOOD for which further washing, cooking, or other processing is not required for FOOD safety, and from which rinds, peels, husks, or shells, if naturally present are removed. |
| **RECONDITIONED/RE- PROCESSED** | Finished product that is added to a new production lot and goes through the entire validated production process. The old, finished product is now part of the new lot and testing of the new lot must follow all current requirements for LGMA testing before the product is used. |
| **RESPONSIBLE PARTY** | The signatory is deemed to be the responsible party for purposes of the Commodity-Specific Food Safety Guidelines for the Production and Harvest of Lettuce and LeafyGreens. The signatory must assign or identify personnel to supervise or otherwise be responsible for food safety SOPs requiring responsible party oversight. |
| **RIPARIAN AREA** | A vegetated ecosystem along a waterbody through which energy, materials, and water pass. Riparian areas characteristically have a high-water table and are subject to periodic flooding and influence from the adjacent waterbody. These systems encompass wetlands, uplands, or some combination of those two landforms. They will sometimes, but not in all cases, have all the characteristics necessary for them to be also classified as wetlands (USEPA 2005) |
| **RISK** | A function of the likelihood (high, medium, low) of occurrence of an adverse health effect and the severity of that effect, consequential to a hazard(s). |
| **RISK MITIGATION** | Actions to reduce the likelihood or severity of a risk presented by a hazard. |
| **ROOT CAUSE ANALYSIS** | A process for systematic investigation where incident-specific information is assembled, and problem-solving techniques are used to analyze and evaluate why an incident or event happened. |

# LIST OF APPENDICES

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#### LETTUCE/LEAFY GREENS COMMODITY SPECIFIC GUIDANCE

* **PRODUCTION & HARVEST UNIT OPERATIONS**
* 1. PURPOSE
* The issues identified in this document are based on the core elements of Good Agricultural Practices. The specific
* recommendations contained herein are intended for lettuce and leafy greens only. If these specific
* recommendations are effectively implemented this would constitute the best practices for a GAP program for the
* production and harvest unit operations of lettuce and leafy greens.
* 2. GENERAL REQUIREMENTS
* In addition to the area-specific requirements discussed in latter sections, there are several general requirements
* that are part of an effective best practices program. These requirements are outlined below.

### The Best Practices Are:

*  A written Leafy Greens Compliance Plan shall be prepared that specifically addresses the Best Practices listed
* in this document. This plan shall address at least for the following areas: water, soil amendments,
* environmental factors, work practices, and field sanitation.
*  Handlers shall have an up-to-date growers list with contact and location information on file.
*  The handler shall comply with the requirements of The Public Health Security and Bioterrorism Preparedness
* and Response Act of 2002 (farms are exempt from the Act) including those requirements for recordkeeping
* (traceability) and registration...
*  Designate an individual responsible for their operation’s food safety program. Twenty-four-hour contact
* information shall be available for this individual in case of food safety emergencies.
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*  Laboratories used for any analytical parameters (microbial, chemical, etc.) required in the metrics must be
* certified and/or accredited for the analytical methods being reported and the matrices being analyzed (water,
* soil, soil amendment, product, etc.). Certification and accreditation must be recognized by State, Federal, or
* internationally bodies (ISO).
* o Note: It may be appropriate for proprietary or modified methods to be used but there must be assurances
* that the results are consistent with accredited methodologies.
*  Perform root cause analysis (investigation) after any incident that has a high likelihood of causing a foodborne illness or injury (i.e., high risk adjacent land concern, positive pre-harvest pathogen test, water system non-compliance, high risk health or hygiene incident, soil amendment concern, traceability failure, field fecal contamination, etc.).
* 3. RECORDS
* The best practices below complement, but do not supersede recordkeeping requirements in FDA regulations.

### The Best Practices Are:

*  Signatory must assign or identify personnel to supervise (or otherwise be responsible for) your operations to
* ensure compliance with the requirements of this part. This must be documented.
*  All records must include (as applicable to the record):
* o The name (or an identifier e.g., a number that can be linked to the farm/ranch name) and location of the
* farm
* o Actual values and observations obtained during monitoring
* o An adequate description (e.g., commodity name / specific variety / brand name and any lot number or
* other identifier) of the leafy green product applicable to the record
* o The location of the growing area (e.g., a specific field) applicable to the record
* o The date and time of the activity documented
*  All records must be:
* o Created at the time an activity is performed or observed
* o Accurate, legible, and indelible
* o Dated and signed / initialed by the person (or a member of the crew / team) performing the activity
* documented (does not include the supervisor of those performing the activity)
* o Reviewed, dated, and signed after the records are made by a supervisor or responsible party within the
* timeframes specified in the leafy greens compliance plan (e.g., harvesting records, soil
* amendments/crop inputs, training, water).
*  All records and documents of policies, procedures, and activities to fulfill requirements related to the Leafy
* Greens Compliance Plan shall be maintained on-site, at an off-site location, or accessible electronically and shall
* be available for inspection by the end of the day the audit is conducted.
*  Existing records (e.g., records that are kept in compliance with other federal, state, or local regulations or for
* any other reason) do not need to be duplicated if they contain all of the required information and satisfy the
* requirements herein. Existing records may be supplemented as necessary to include all of the required
* information and satisfy the requirements of this section. Records must be kept in the original, electronically, or
*  The standards established in these best practices that are applicable to the employee’s job
* responsibilities.
* o For harvest personnel, the training program must also address the following minimum requirements
* related to harvesting activities:
*  Recognizing lettuce/leafy greens that must not be harvested, including product that may be
* contaminated with known or reasonably foreseeable hazards.
*  Inspecting harvest containers, harvest equipment, and packaging materials to ensure that they are
* functioning properly, clean, and maintained so as not to become a source of contamination of
* lettuce/leafy greens with known or reasonably foreseeable hazards.
*  Correcting problems with harvest containers, harvest equipment, or packaging materials or
* reporting such problems to the supervisor (or other responsible party), as appropriate to the
* person’s job responsibilities.
*  At least one supervisor or responsible party (e.g., the food safety professional) for each grower providing leafy
* green products must have successfully completed food safety training at least equivalent to that received under
* standardized curriculum recognized as adequate by the FDA.
*  Establish and keep records of training that document required training of personnel, including the date of
* training, topics covered, and the person(s) trained. Records must be reviewed, dated, and signed, within a ~~week~~
* reasonable time per companies SOP after the records are made, by a supervisor or responsible party.
* 5. ENVIRONMENTAL ASSESSMENTS
* This section addresses assessments that shall be completed and documented prior to the first seasonal planting,
* within one week prior to harvesting and during harvest operations. These environmental assessments are intended
* to identify any issues related to the produce field, adjacent and nearby land use, and/or animal hazards that may
* present a risk to the production block or crop (see Tables 0 and 6).

### The Best Practices Are:

* Product testing is required when pre-harvest environmental risk assessments deem it necessary.
* Prior to the first seasonal planting and within one week prior to harvest, perform and document an environmental risk assessment of the production field and surrounding area. Focus these assessments on evaluating the production field for possible animal hazards or other sources of human pathogens of concern, assessing adjacent and nearby land use for possible sources that might contaminate the production field, and evaluating nearby water sources for the potential of past or present flooding.

##### o Assessment of Produce Field

* Evaluate all produce fields for evidence of animal hazards and/or feces. If any evidence is found, follow
* procedures identified in the “Production Locations - Encroachment by Animals and Urban Settings.”
* Evaluate potential environmental sources of contaminants near production locations after a change in
* weather conditions or weather events that could impact the original risk assessment of the field or
* block and follow procedures identified in the “Production Locations - Climatic Conditions and
* Environment” section below.

##### o Assessment of Adjacent and Nearby Land Use

* Conduct and document a detailed risk assessment that evaluates risk level of all land and water~~ways~~
* sources adjacent and nearby to all production fields for possible sources of human pathogen of concern.

### TABLE 0. Crop Land and Water Source Adjacent and Nearby Land Use

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | |  | **Considerations for Risk Analysis** | |
| **Adjacent and Nearby Land Uses**  **(Hazards)** | | **Current Metric** | **Factors to consider when assessing severity and likelihood of a hazard** | **Risk mitigating Factors** |
| **Animal operations** | **AFOs** | 30 feet  (no composting) 400 feet (with composting) | Distance, topography, water runoff, number of animal units, wind direction, history | Pre-harvest pathogen testing, water treatment, vegetative buffers, barriers, increased buffers, animal and insect monitoring |
| **CAFO** | 1200 feet / 1 mile | Distance, topography, water runoff, number of animal units, wind direction, history | Pre-harvest pathogen testing, water treatment, vegetative buffers, barriers, increased buffers, animal and insect monitoring |
| **Grazing Lands** | 30 feet | Distance, topography, water runoff, number of animal units, wind direction, history | Pre-harvest pathogen testing, water treatment, vegetative buffers, barriers, increased buffers, animal and insect monitoring |
| **Domestic Animals/Hobby Farms** | 30 feet | Distance, topography, water runoff, number of animal units, wind direction, history | Pre-harvest pathogen testing, water treatment, vegetative buffers, barriers, increased buffers, animal and insect monitoring |
| **Compost/Soil Amendment Operations** | **Compost Operations**  (Manure or Animal Products) | 400 feet | Distance, timing of production, production process, volume of production, topography, water runoff, wind direction, history | Preventive barriers, pre-harvest pathogen testing, knowledge of process, water treatment |
| **Non-synthetic Soil Amendment Pile**  (containing manure or animal products) | 400 feet | Distance, timing of production, production process, volume of production, topography, water runoff, wind direction, history | Preventive barriers, pre-harvest pathogen testing, knowledge of process, water treatment |
| **Non-synthetic Soil Amendment Pile**  (not containing manure or animal products) | 400 feet | Distance, timing of production, production process, volume of production, topography, water runoff, wind direction, history | Preventive barriers, pre-harvest pathogen testing, knowledge of process |
| **Biosolids** | 400 Feet | Distance, timing of production, production process, volume of production, topography, water runoff, wind direction, history | Preventive barriers, pre-harvest pathogen testing, knowledge of process |

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| **Non-leafy green crops** | **Cannabis/hemp, cover crops, dates, flowers, grapes, other** | The approximate safe distance depends on risk and mitigation factors | History of risk identification, distance from adjacent operation, topography, crop production timeline, foreign object, animal/bird attractant, grazing animals, harvest practices. | Physical barriers, pre-harvest pathogen testing, increased monitoring, knowledge of process |
| **Water Source and Systems** | **Well Head distance from Untreated Manure** | 200 feet | History of risk identification, distance from adjacent operation, topography, opportunity for water run off through or from untreated manure, or composting operations, soil  leaching | Adjacent operation management practices, Increased monitoring, preventive barriers, type of system (closed vs open), water treatment |
| **Surface Water Distance from Untreated Manure** | 100-300 feet | History of risk identification, distance from adjacent operation, topography, opportunity for water run off through or from untreated manure or composting operations, flooding, soil leaching | Adjacent operation management practices, increased monitoring, preventive barriers, water treatment |
| **Water Storage and Conveyance systems** | 30--300 feet | History of risk identification, distance from adjacent operation, topography, flooding, animal Intrusion, trash and debris, excessive vegetation, integrity of water storage, conveyance and distribution | Adjacent operation management practices, increased monitoring, type of system (closed vs open), water treatment |
| **Urban Settings** | **Homes or other building with a septic leach field** | 30 feet | History of risk identification, distance,  topography, leach field status (active vs inactive), runoff | Preventive barriers, knowledge of septic field |
| **Other Environmental Considerations** | **Habitat/Riparian Area** | The approximate safe distance depends on risk and mitigation factors. | History of risk identification, distance from potential risk, topography, potential for animal intrusion, physical hazards | Preventive barriers, increased monitoring |

* Growers should check for local, state, and federal laws and regulations that protect riparian habitat, restrict removal of vegetation or habitat, or
* restrict construction of wildlife deterrent fences in riparian areas or wildlife corridors. Growers may want to contact the relevant agencies (e.g., the
* Regional Water Quality Control Board and state and federal fish and wildlife agencies) to confirm the details of these requirements.

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| 649 1281 | 17. DETAILED BACKGROUND GUIDANCE INFORMATION |
| 1282 | **Required Reference Documents** |
| 1283 | 1. FDA Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables |
| 1284 | ([www.foodsafety.gov/~dms/prodguid.html](http://www.foodsafety.gov/%7Edms/prodguid.html)) |
| 1285 | 2. UFFVA Food Safety Auditing Guidelines: Core Elements of Good Agricultural Practices for Fresh Fruits and |
| 1286 | Vegetables |
| 1287 | 3. UFFVA Food Safety Questionnaire for Fresh Fruits and Vegetables |
| 1288 | 4. National GAPs Program Cornell University: Food Safety Begins on the Farm: A Grower Self-Assessment of |
| 1289 | Food Safety Risks |







1. Issue: Pre-Harvest Product Testing Pilot Program for Romaine

Pre-harvest product testing is one of many tools that can assist in developing a long-term view of food safety system performance. Analysis of product testing data can provide valuable insights to demonstrate if implemented preventive measures are effective and to help enhance food safety system performance and inform a broader industry understanding of risk potential and prevention efforts. Industry standardized and aggregated data can be applied to predictive trend analysis for improved risk assessments and refine pre-harvest product testing parameters and sampling plan designs over time. For this reason, a two-year pilot program will sample and test monoculture whole head romaine lettuce for select pathogens. Thepre-harvest testing program’s objective is to increase the understanding of how practices may affect contamination, contamination prevalence over time, risk factors, and to inform the continual improvement of industry prevention efforts.

**The Best Practices Are:**

* Develop a written pre-harvest product sampling and testing program (two-year pilot program) for monoculture whole head romaine lettuce (including romaine hearts) that provides 90% confidence in detecting 1 CFU/lb of randomly distributed contamination in a lot.[[1]](#footnote-1) When designing your testing program use the following minimum parameters:
* **Sampling timeline** – Prior to scheduled harvest (7 days or closer to harvest is better).
* **Target organisms** – Screen for STEC [[2]](#footnote-2) (including specific *E. coli* O157: H7) and *Salmonella*.
* **Sampling lot size** – Lot definition may vary depending on the ranch/farm, but should not be more than 30 contiguous acres
* **Sample size** – Total sample mass per lot must equal at least 1,025 grams (3 composites of 350 − 375 g) weighed and recorded by the third-party service laboratory.
* **Sampling method** – Stratified randomized sampling within a designated lot. Consider stratifying by the number of composite samples collected to reach the 1,025 g total mass. For example, collecting 3 composites of 350 − 375 g from roughly 1/3 of each defined lot area.
* **Number of grabs** – A minimum of 60 grabs per composite. More individual grabs per lot improve the probability of contamination detection. When deciding on sampling plans, see Appendix L for sampling plan options.
* Samples must be taken by a trained sampler. Implement mandatory training on the sampling protocol for personnel conducting the preharvest product testing.
* Analyze the data collected thru your program periodically. Data analysis can provide valuable insights to help you enhance your food safety system performance and inform a broader industry understanding of risk potential and prevention efforts.
* If a positive test result is reported, do not harvest the sampling lot. Determine if further investigation and root cause analysis (RCA) is of value based on observations and elective follow-up sampling. Utilize industry guidance[[3]](#footnote-3) on how to evaluate the value of and conduct RCA activities.
* Shippers/Handlers shall retain documentation for two years of all test results, mitigation (s) taken, and whether a root cause analysis was performed for positive test results. Pilot program aggregated data will be reviewed in collaboration with the CA LGMA.

Appendix L. Sampling plans **by median power to detect a pathogen in a field with a product density of 10,000 lb/acre, at a given pathogen hazard level, covering a given portion of the field.**

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| **Overall Parameters** | | | **Distribution of grabs by size, subsample, and location** | | | | | **Power to detect at least 1**  **1 CFU/lb**\*  widespread contamination  covering 100%  of lot | **Power to take at least 1 sample within a** | | |
| **Sampling Lot size** (acre) | **Total sample size** (grams) per lot | **Total sample grabs** (number) per lot | Required # of grab specimen per subsample | Approximate grab specimen size (grams) | Required # of sub-samples | Sub-sample size (grams) | Sampling location | **Cluster covering 1%\*** of lot | **Cluster covering 0.1%\*** of lot | **Cluster covering 400 lb** of lot \*\*\* |
| 1 | 1,025 | 60 | 20 | 18 | 3 | 350-375 | Random, stratified by 1 subsample per 1/3 acre# | 90% | 45% | 6% | 91% |
| 1 | 1,025 | 180 | 60 | 6 | 3 | 350-375 | 90% | 84% | 16% | 100% |
| 1 | 1,025 | 600 | 200 | 1.7 | 3 | 350-375 | 90% | 100%\*\* | 45% | 100% |
| 3 | 1,025 | 60 | 20 | 18 | 3 | 350-375 | Random, stratified by 1 subsample per 1 acre# | 90% | 45% | 6% | 55% |
| 3 | 1,025 | 180 | 60 | 6 | 3 | 350-375 | 90% | 84% | 16% | 91% |
| 3 | 1,025 | 600 | 200 | 1.7 | 3 | 350-375 | 90% | 100%\*\* | 45% | 100% |
| 30 | 1,025 | 60 | 20 | 18 | 3 | 350-375 | Random, stratified by 1 subsample per 10 acres# | 90% | 45% | 6% | 8% |
| 30 | 1,025 | 180 | 60 | 6 | 3 | 350-375 | 90% | 84% | 16% | 21% |
| 30 | 1,025 | 600 | 200 | 1.7 | 3 | 350-375 | 90% | 100%\*\* | 45% | 55% |

\*To have the same number of pathogens in the cluster, a 1% cluster contains 100 CFU/lb covering between 100 to 4,000 lb of product (for 1 acre to 40 acres, respectively). The 0.1% cluster contains 1,000 CFU/lb over 10 to 400 lb of product.

\*\* This 100% power is just about if a sample is taken from the contaminated zone. That is true regardless of the pathogen level in zone. The overall power may be overstated if the individual grab sample mass is too small to be confident once would always recover a pathogen. Under the assumptions in this table the 1% cluster contains pathogens 100 CFU / lb, which is 0.22 CFU / g or about 1 pathogen in 4.5 g. Therefore, one would need a grab sample mass of at least 4.5 g to be very confident a single grab from the cluster would recover the pathogen.

\*\*\* A 400 lb lot covers 4% of the 1-acre field, 1.3% of the 3-acre field, and 0.13% of the 30-acre field.

#Take the 3-acre sampling lot as an example. This would mean dividing the lot into three 1-acre sublots. Within each 1-acre sublot, take one composite sample of 350-375 grams. To gather the composite, take the desired number of grabs per subsample at random locations within the sublot.

1. The total mass number is based on the United Fresh outbreak thought experiment, geared to detect a low level of lot distributed contamination calculated to result in a greater risk of a multistate outbreak (1 CFU/lb.). [↑](#footnote-ref-1)
2. Shiga toxin-producing *E. coli* (STEC) is comprised of a diverse bacterial group genetically capable of synthesizing these potent biological toxins. For this reason, this required ‘target’ may be considered as an **endpoint** whenever positive but is more reasonably viewed as an **action point** and therefore a screening tool rather than a definitive test. Two commonly encountered toxins are STX1 and STX 2. The presence of genes to produce these or related shiga toxins is essential but not sufficient for a bacterial cell, such as a cell population lineage of *E. coli*, to be a serious human pathogen. The *stx* genes, a combined molecular target in most certified commercial platforms, are also known to be present in environmental bacteria related to but distinct from *E. coli*. *E. coli* can have the stx gene(s) but no other virulence traits and, therefore, is not a serious pathogen but will give a positive outcome for STEC. Even if the program defines STEC screening as any sample positive for both stx and eae (one type of attachment factor necessary for virulence to humans), each of these genetic traits may be contributed by independent cells, neither being a human pathogen, and neither necessarily an *E.coli*.  In screening for the broad STEC group, a handler has several decisions and options to consider if a screening result is positive for STEC.  As a specific test for one type of STEC, *E. coli* O157:H7, is required by the program, a preharvest product test result for this ‘target’ is a clear **endpoint**.  There are many platforms and rapid kits which take varying approaches to first screening and then, secondarily, testing for other virulence markers, or testing for specific STEC pathogens of serious long-term health and lethality concerns (*E. coli* O26, O45, O103, O111, O121: O145) which cause the majority of human illnesses in North America. However, there are other less common but similarly serious foodborne pathogens which have been detected environmentally or on fresh produce. So, these considerations taken together would indicate that a Best Practice for having adopted a broad screen for STEC, given any outcome with a negative test result for *E. coli* O157:H7 and *Salmonella*, would be to request a set of secondary tests for other target markers indicating the higher risk potential for foodborne pathogen presence. Growers and handlers should work with the commercial laboratory of their choosing to understand the available options and what each does and does not provide in support of a firm’s decision-tree policies regarding positive detection test results. Handlers may choose to seek outside expert assistance. [↑](#footnote-ref-2)
3. How to Conduct a Root Cause Analysis at [RCA Guidance for the Produce Industry How to do RCA.pdf (wga.com)](https://www.wga.com/sites/default/files/resource/files/RCA%20Guidance%20for%20the%20Produce%20Industry_How%20to%20do%20RCA.pdf) [↑](#footnote-ref-3)