COMMODITY SPECIFIC FOOD SAFETY GUIDELINES FOR THE PRODUCTION AND HARVEST OF LETTUCE AND LEAFY GREENS

VERSION 10 - ARIZONA

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Authors Note: This document reflects Commodity Specific Food Safety Guidelines for the Production and Harvest of Leafy Greens for Arizona. It is based on the Commodity Specific Food Safety Guidelines for the Production and Harvest of Leafy Greens accepted for use by the California Leafy Greens Handler Marketing Agreement and contains minor, non-substantive modifications recommended by the Arizona Leafy Greens Marketing Committee. Arizona law supersedes any requirements in this document that may be in conflict.

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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 degrees Celsius (122 degrees 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.
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 by-products, 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 treatments for the purposes of this document.
Agricultural water	Water used in activities covered in these guidelines where water is intended to, or is likely to, contact lettuce/leafy greens or food contact surfaces, including water used in growing activities (including all irrigation water applied using direct water application methods and water used for preparing crop sprays) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested lettuce/leafy greens and water used for preventing dehydration of lettuce/leafy greens).
Animal by-product	Most parts of an animal that do not include muscle meat including organ meat, nervous tissue, cartilage, bone, blood and excrement.
Animal hazard	Feeding, skin, feathers, fecal matter or signs of animal presence in an area to be harvested in sufficient number and quantity to suggest to a reasonable person the crop may be contaminated.
Adenosine Tri-Phosphate (ATP)	A high energy phosphate molecule required to provide energy for cellular function.
Application interval	Means the time between application of an agricultural input (such as a soil amendment) to a growing area and harvest of leafy greens from the growing area where the agricultural input was applied.
ATP test methods	Exploits knowledge of the concentration of ATP as related to viable biomass or metabolic activity; provides an estimate of cleanliness.
Biofertilizers	Fertilizer materials/products that contain microorganisms such

	as bacteria, fungi, and cyanobacteria that shall promote soil biological activities.
Biosolids	Solid, semisolid, or liquid residues generated during primary, secondary, or advanced treatment of domestic sanitary sewage through one or more controlled processes.
Buildings	Any fully- or partially-enclosed building on the farm that is used for storing of food contact surfaces and packaging materials, including minimal structures that have a roof but no walls.
Colony Forming Units (CFU)	Viable micro-organisms (bacteria, yeasts & mold) either consisting of single cells or groups of cells, capable of growth under the prescribed conditions (medium, atmosphere, time and temperature) to develop into visible colonies (colony forming units) which are counted.
Concentrated Animal Feeding Operation (CAFO)	A lot or facility where animals have been, are or will be stabled or confined and fed or maintained for a total of 45 days or more in any 12 month period and crops, vegetation forage growth, or post-harvest residues are not sustained in the normal growing season over any portion of the lot or facility. In addition, there must be more than 1,000 'animal units' (as defined in 40 CFR 122.23) confined at the facility; or more than 300 animal units confined at the facility if either one of the following conditions are met: pollutants are discharged into navigable waters through a man-made ditch, flushing system or other similar man-made device; or pollutants are discharged directly into waters of the United States which originate outside of and pass over, across, or through the facility or otherwise come into direct contact with the animals confined in the operation.
Coliforms	Gram-negative, non-sporeforming, rod-shaped bacteria that ferment lactose to gas. They are frequently used as indicators of process control, but exist broadly in nature.
Co-management	An approach to conserving soil, water, air, wildlife, and other natural resources while simultaneously minimizing microbiological hazards associated with food production.
Composting	Means a process to produce compost in which organic material is decomposed by the actions of microorganisms under thermophilic conditions for a designated period of time (for example, 3 days) at a designated temperature (for example, 131 °F (55 °C)), followed by a curing stage under cooler conditions.
Cross contamination	The transfer of microorganisms, such as bacteria and viruses, from one place to another.
Curing	The final stage of composting, which is conducted after much of the readily metabolized biological material has been decomposed, at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition. Curing may or may not involve insulation, depending on environmental conditions.

Direct water application	Using agricultural water in a manner whereby the water is intended to, or is likely to, contact leafy greens or food contact surfaces during use of the water.
Enterohemorrhagic *E. coli*	Shiga toxin-producing *E. coli* clinically associated with bloody diarrhea.
Escherichia coli (E. coli)	*Escherichia coli* is a common bacteria that lives in the lower intestines of animals (including humans) and is generally not harmful. It is frequently used as an indicator of fecal contamination, but can be found in nature from non-fecal sources.
Fecal coliforms	Coliform bacteria that grow at elevated temperatures and may or may not be of fecal origin. Useful to monitor effectiveness of composting processes. Also called "thermotolerant coliforms."
Flooding	The flowing or overflowing of a field with water outside a producer's control that is reasonably likely to contain microorganisms of significant public health concern and is reasonably likely to cause adulteration of edible portions of fresh produce in that field.
Food contact surface	Those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. ''Food contact surfaces'' includes food contact surfaces of equipment and tools used during harvest, packing and holding.
Food safety assessment	A standardized procedure that predicts the likelihood of harm resulting from exposure to chemical, microbial and physical agents in the diet.
Food safety personnel	Person trained in basic food safety principles and/or working under the auspices of a food safety professional.
Food safety professional	Person entrusted with management level responsibility for conducting food safety assessments before food reaches consumers; requires documented training in scientific principles and a solid understanding of the principles of food safety as applied to agricultural production; in addition this individual must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration See appendix B for more details.
Geometric Mean	Mathematical def.: the n-th root of the product of n numbers, or: Geometric Mean = n-th root of $(X_1)(X_2)...(X_n)$, where X_1, X_2, etc. represent the individual data points, and n is the total number of data points used in the calculation. Practical def.: the average of the logarithmic values of a data set, converted back to a base 10 number.
Green waste	"Green Waste" means any plant material that is separated at the point of generation, contains no greater than 1.0 percent of physical contaminants by weight, and meets the requirements of section 17868.5. Green material includes, but is not limited to, yard

	trimmings ("Yard Trimmings" means any wastes generated from the maintenance or alteration of public, commercial or residential landscapes including, but not limited to, yard clippings, leaves, tree trimmings, prunings, brush, and weeds), untreated wood wastes, natural fiber products, and construction and demolition wood waste. Green material does not include food material, biosolids, mixed solid waste, material processed from commingled collection, wood containing lead-based paint or wood preservative, mixed construction or mixed demolition debris. "Separated At The Point of Generation" includes material separated from the solid waste stream by the generator of that material. It may also include material from a centralized facility as long as that material was kept separate from the waste stream prior to receipt by that facility and the material was not commingled with other materials during handling. [1]
Ground water	The supply of fresh water found beneath the earth's surface, usually in aquifers, which supply wells and springs. Ground water does not include any water that meets the definition of surface water.
Harvesting	Activities that are traditionally performed on farms for the purpose of removing leafy greens from the field and preparing them for use as food; does not include activities that transform a raw agricultural commodity into a processed food. Examples of harvesting include cutting (or otherwise separating) the edible portion of the leafy greens from the crop plant and removing or trimming parts, cooling, field coring, gathering, hulling, removing stems, trimming of outer leaves and washing.
Hazard	Any biological, physical, or chemical agent that has the potential to cause illness or injury in the absence of its control.
Hobby Farm	A small farm, or rural residence with 25 or fewer animals per acre that is operated without expectation of being the primary source of income.
Holding	Storage of leafy greens in warehouses, cold storage, etc. including activities performed incidental to storage (*e.g.*, activities performed for safe or effective leafy green storage) as well as activities performed as a practical necessity for leafy green distribution (such as blending and breaking down pallets), but does not include activities that transform the raw commodity into a processed food.
Hydroponic	The growing of plants in nutrient solutions with or without an inert medium (as soil) to provide mechanical support.
Indicator microorganisms	An organism that when present suggests the possibility of contamination or under processing.
Known or reasonably foreseeable hazard	Known or reasonably foreseeable hazard means a biological, physical, and chemical hazard that is known to be, or has the potential to be, associated with the farm or the food.
Leafy greens	Iceberg lettuce, romaine lettuce, green leaf lettuce, red leaf lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole, endive, spring mix, spinach, cabbage (green, red and savoy), kale, arugula and chard.

Manure	Animal excreta, alone or in combination with litter (such as straw and feathers used for animal bedding) for use as a soil amendment.
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 growers control "monthly" for purposes of water sampling means within 35 days of the previous sample.
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.
Nonsynthetic crop treatments	Any 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.
Oxidation Reduction Potential (ORP)	An intrinsic property that indicates the tendency of a chemical species to acquire electrons and so be reduced; the more positive the ORP, the greater the species' affinity for electrons.
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.
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: (a) 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. (2) "Ready-to-eat food" includes: (b) Raw fruits and vegetables that are washed as specified

	under § 3-302.15; (c) 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;
Risk mitigation	Actions to reduce the severity/impact of a risk
Sanitary facility	Includes both toilet and hand-washing stations.
Sanitize	To adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.
Shipping unit/equipment	Any cargo area used to transport leafy greens on the farm or from the farm to cooling, packing, or processing facilities.
Soil amendment	Elements added to the soil, such as compost, peat moss, or fertilizer, to improve its capacity to support plant life.
Surface water	All water open to the atmosphere (rivers, lakes, reservoirs, streams, impoundments, seas, estuaries, etc.) and all springs, wells, or other collectors that are directly influenced by surface water.
Synthetic crop treatments (chemical fertilizers)	Any crop inputs that may be refined, and/or chemically synthesized and/or transformed through a chemical process (e.g. gypsum, lime, sulfur, potash, ammonium sulfate etc.).
Transporter	The entity responsible for transporting product from the field; LGMA guidelines apply only to shippers and cover production through harvesting.
Ultraviolet Index (UV index)	A measure of the solar ultraviolet intensity at the Earth's surface; indicates the day's exposure to ultraviolet rays. The UV index is measured around noon for a one-hour period and rated on a scale of 0-15.
Validated process	A process that has been demonstrated to be effective through a statistically-based study, literature, or regulatory guidance.
Visitor	Any person (other than personnel) who enters your field/operations with your permission.
Water distribution system	Distribution systems -- consisting of pipes, pumps, valves, storage tanks, reservoirs, meters, fittings, and other hydraulic appurtenances – canals, ditches and rivers -- to carry water from its primary source to a lettuce and leafy green crop.

Acronyms and Abbreviations

AFOs: Animal feeding operations

AOAC: AOAC International (formerly the Association of Official Analytical Chemists)

BAM: Bacteriological Analytical Manual

CAFOs: Concentrated animal feeding operations

CSG2: *Commodity Specific Guidance for Leafy Greens and Lettuce, 2nd Edition*

CFU: colony forming units

cGMP: current good manufacturing practices

COA: Certificate of Analysis

DL: Detection Limit

EHEC: Enterohemorrhagic *E. coli*

FDA: Food and Drug Administration

GAPS: good agricultural practices

GLPs: good laboratory practices

HACCP: hazard analysis critical control point

MPN: most probable number

NGO: nongovernmental organization

NRCS: Natural Resources Conservation Service

ORP: Oxidation reduction potential

PPM: parts per million

RTE: ready-to-eat

SSOPs: Sanitation Standard Operating Procedures

TMECC: Test Methods for the Examination of Composting and Compost USEPA: United States Environmental Protection Agency

UV: ultraviolet

WHO: World Health Organization

LIST OF APPENDICES

INTRODUCTION

In 1998, the U.S. Food and Drug Administration (FDA) issued its "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." The practices outlined in this and other industry documents are collectively known as Good Agricultural Practices or GAPs. GAPs provide general food safety guidance on critical production steps where food safety might be compromised during the growing, harvesting, transportation, cooling, packing and storage of fresh produce. More specifically, GAP guidance alerts fruit and vegetable producers, shippers, packers and processors to the potential microbiological hazards associated with various aspects of the production chain including: land history, adjacent land use, water quality, worker hygiene, pesticide and fertilizer use, equipment sanitation and product transportation. The vast majority of the lettuce/leafy greens industry has adopted GAPs as part of normal production operations. Indeed the majority of lettuce/leafy greens producers undergo either internal or external third-party GAP audits on a regular basis to monitor and verify adherence to their GAPs programs. These audit results are often shared with customers as verification of the producer's commitment to food safety and GAPs.

In 2011, the Food Safety Modernization Act (FSMA) was signed into law. After several years of gathering stakeholder input, the FDA published the final regulations promulgating FSMA requirements including regulation of farming operations for the first time in U.S. history. The *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (the Produce Safety Rule) is the rule that addresses GAPs for farming operations.

While the produce industry has an admirable record of providing the general public with safe, nutritious fruits and vegetables, it remains committed to continuous improvement with regard to food safety. In 2004, the FDA published a food safety action plan that specifically requested produce industry leadership in developing the next generation of food safety guidance for fruit and vegetable production. These new commodity-specific guidelines focus on providing guidance that enhances the safe growing, processing, distribution and handling of commodities from the field to the end user. The 1st Edition of these new voluntary guidelines was published by the industry in April 2006.

In response to continued concerns regarding the microbial safety of fresh produce, this edition of these guidelines (which focuses solely on production and harvest practices) was prepared to provide more specific and quantitative measures of identified best practices for leafy greens production and harvest. In meeting their commitment to keeping the guidelines up-to-date with new scientific and technical advancements, the leafy greens industry has treated the food safety guidelines as a dynamic document by providing routine opportunities for industry members and other stakeholders to recommend revisions and additions. In addition, the guidelines have been updated to reflect the Produce Safety Rule requirements and peer-reviewed research funded by the Center for Produce Safety.

A key focus of this revision was to identify, where possible and practical, metrics and measures that could be used to assist the industry with compliance with the guidelines. In preparing this document, metrics were researched for three primary areas: water quality, soil amendments, and environmental assessments/conditions. A three-tier approach was used to identify these metrics in as rigorous a manner as possible:

1. A comprehensive literature review was conducted to determine if there was a scientifically valid basis for establishing a metric for the identified risk factor or best practice.

2. If the literature research did not identify scientific studies that could support an appropriate metric, standards or metrics from authoritative or regulatory bodies were used to establish a metric.

3. If neither scientific studies nor authoritative bodies had allowed for suitable metrics, consensus among industry representatives and/or other stakeholders was sought to establish metrics.

In the last 10 years, the focus of food safety efforts has been on the farm, initial cooling and distribution points, and value-added processing operations. Fruit and vegetable processing operations have developed sophisticated food safety programs largely centered on current Good Manufacturing Practices (cGMPs) and the principles of Hazard Analysis Critical Control Point (HACCP) programs. As we develop a greater understanding of food safety issues relative to the full spectrum of supply and distribution channels for fruits and vegetables, it has become clear that the next generation of food safety guidance needs to encompass the entire supply chain.

In addition to this document, several supplemental documents have been prepared to explain the rationale for the metrics and assist the producer with activities in the field. These documents include a Technical Basis Document that describes in detail and with appropriate citations the bases for the changes made in this edition of this document, a Sanitary Survey document that describes the processes for assessing the integrity and remediation of water systems, and an example product testing plan. All of these items can be found as Appendices to this document.

SCOPE

The scope of this document pertains only to fresh and fresh-cut lettuce and leafy greens products. It does not include products commingled with non-produce ingredients (e.g. salad kits which may contain meat, cheese, and/or dressings). Examples of "lettuce/leafy greens" include iceberg lettuce, romaine lettuce, green leaf lettuce, red leaf lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole, endive, spring mix, cabbage (green, red and savoy), kale, arugula, chard, radicchio and spinach. These crops are typically considered lettuce and leafy greens by FDA but may not be similarly defined by other state or federal regulatory bodies. This document is also limited to offering food safety guidance practices consistent with the Produce Safety Rule's provisions for crops grown under outdoor field growing practices and may not address food safety issues related to hydroponic and/or soil-less media production techniques for lettuce/leafy greens.

Lettuce/leafy greens may be harvested mechanically or by hand and are almost always consumed uncooked or raw. Because lettuce/leafy greens may be hand-harvested and hand-sorted for quality, there are numerous "touch points" early in the supply chain and a similar number of "touch points" later in the supply chain as the products are used in foodservice or retail operations. Each of these "touch points" represents a potential opportunity for cross-contamination. For purposes of this document, a "touch point" is any occasion when the food is handled by a worker or contacts an equipment food contact surface.

Lettuce/leafy greens present multiple opportunities to employ food safety risk management practices to enhance the safety of lettuce/leafy greens. In the production and harvest of lettuce and leafy greens as raw agricultural commodities, GAPs are commonly employed in order to produce the safest products possible. In a processing operation, the basic principles of cGMPs, HACCP, sanitation and documented operating procedures are commonly employed in order to produce the safest products

possible. Lettuce/leafy greens are highly perishable and it is strongly recommended that they be distributed, stored and displayed under refrigeration.

Safe production, packing, processing, distribution and handling of lettuce/leafy greens depend upon a myriad of factors and the diligent efforts and food safety commitment of many parties throughout the distribution chain. No single resource document can anticipate every food safety issue or provide answers to all food safety questions. These guidelines focus on minimizing only the microbial food safety hazards by providing suggested actions to reduce, control or eliminate microbial contamination of lettuce/leafy greens in the field to fork distribution supply chain.

All companies involved in the lettuce/leafy greens farm to table supply chain shall implement the recommendations contained within these guidelines to provide for the safe production and handling of lettuce/leafy greens products from field to fork. Every effort to provide food safety education to supply chain partners should also be made. Together with the commitment of each party along the supply chain to review and implement these guidelines, the fresh produce industry is doing its part to provide a consistent, safe supply of produce to the market.

These guidelines are intended only to convey the best practices associated with the industry. The Produce Marketing Association, the United Fresh Produce Association, Western Growers, and all other contributors and reviewers make no claims or warranties about any specific actions contained herein. It is the responsibility of any purveyor of food to maintain strict compliance with all local, state and federal laws, rules and regulations. These guidelines are designed to facilitate inquiries and developing information that must be independently evaluated by all parties with regard to compliance with legal and regulatory requirements. The providers of this document do not certify compliance with these guidelines and do not endorse companies or products based upon their use of these guidelines.

Differences between products, production processes, distribution and consumption, and the ever-changing state of knowledge regarding food safety make it impossible for any single document to be comprehensive and absolutely authoritative. Users of these guidelines should be aware that scientific and regulatory authorities are periodically revising information regarding best practices in food handling, as well as information regarding potential food safety management issues. Users of this document must bear in mind that as knowledge regarding food safety changes, measures to address those changes will also change as will the emphasis on particular issues by regulators and the regulations themselves. Neither this document nor the measures food producers and distributors should take to address food safety are set in stone.

Due to the close association between production blocks and environmentally sensitive areas in many locations, it is recommended to review Appendix Z when any mitigation strategies that may impact these areas are employed. Producers should implement strategies that not only protect food safety but also support co-management. All parties involved with implementing the practices outlined in this document should be aware that these metrics are not meant to be in conflict with or discourage co-management practices and principles.

Users are encouraged to utilize the services of their trade associations, the U.S. Food and Drug Administration, the Center for Produce Safety, the U.S. Department of Agriculture, the U.S. Environmental Protection Agency, the Center for Disease Control and Prevention, and state agricultural, environmental, academic, wildlife and natural resources management agencies and/or public health authorities.

The Sanitary Survey and Technical Basis Document prepared as Appendices to these guidelines are considered to be additional resources. They are intended to provide clarification, assist with interpretation and provide additional guidance as users develop food safety programs based on these Guidelines. They are not intended for measurement or verification purposes.

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. ISSUE: 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 which specifically addresses the Best Practices of this document shall be prepared. This plan shall address at least the following areas: water, soil amendments, environmental factors, work practices, and field sanitation.
- Shippers shall have an up to date producers list with contact and location information on file.
- The shipper 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.
- Each producer and shipper shall 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.

3. ISSUE: RECORDS

The best practices below complement, but do not supersede recordkeeping requirements in FDA regulations.

The Best Practices Are:

- All records must include (as applicable to the record):
    - The name (or an identifier e.g., a number that can be linked to the farm/ranch name) and location of the farm
    - Actual values and observations obtained during monitoring

- An adequate description (e.g., commodity name / specific variety / brand name and, when available, any lot number or other identifier) of the leafy green product applicable to the record
- The location of the growing area (e.g., a specific field) applicable to the record
- The date and time of the activity documented

- All records must be:
  - Created at the time an activity is performed or observed
  - Accurate, legible, and indelible
  - 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)

- 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 to comply 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 as true copies (e.g., photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records).
- All required historical records must be readily available and accessible during the retention period for inspection and copying by the LGMA auditor upon oral or written request, except that you have 24 hours to obtain records you keep offsite and make them available and accessible to the auditors for inspection and copying.
- If you use electronic techniques to keep records, or to keep true copies of records, or if you use reduction techniques such as microfilm to keep true copies of records, you must provide the records in a format in which they are accessible and legible.
- Records shall be kept for a minimum of two years following the date of issuance or occurrence.
- Records that relate to the general adequacy of the equipment or processes or records that relate to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations, must be retained at the farm for at least 2 years after the use of such equipment or processes, or records related to analyses, sampling, or action plans, is discontinued.

4. ISSUE: PERSONNEL QUALIFICATIONS AND TRAINING

Adequate training of on-farm and shipper personnel is a critically important element in a successful food safety program. In order to align with federal requirements under the Food Safety Modernization Act (FSMA) and to ensure that all activities prescribed in this

document are effectively and adequately implemented, the following minimum training requirements must be maintained and documented:

The Best Practices Are:

- All personnel (including temporary, part time, seasonal, and contracted personnel) who handle lettuce / leafy greens or who have contact with food-contact surfaces, or who are engaged in the supervision thereof, must:
    - Receive adequate training, as appropriate to the person's duties, upon hiring, and periodically thereafter, at least once annually.
    - Have a combination of education, training, and experience necessary to perform the person's assigned duties in a manner that ensures compliance with these best practices.
- Training must be:
    - Conducted in a manner easily understood by personnel being trained.
    - Repeated as necessary and appropriate based on observations or information indicating that personnel are not meeting standards outlined in these best practices.
- Minimum training requirements must include:
    - For all personnel who handle (contact) lettuce/leafy greens or supervise those who do so must receive training that includes the following:
        - Principles of food hygiene and safety.
        - The importance of health and personal hygiene for all personnel and visitors including recognizing symptoms of a health condition that is reasonably likely to result in contamination of lettuce/leafy greens or food-contact surfaces with microorganisms of public health significance.
        - The standards established in these best practices that are applicable to the employee's job responsibilities.
    - 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 producer 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 after the records are made, by a supervisor or responsible party.

5. ISSUE: 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 land uses, and/or animal hazards that may present a risk to the production block or crop (see Table 5).

The Best Practices Are:

- 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 land uses for possible sources that might contaminate the production field, and evaluating nearby water sources for the potential of past or present flooding.
    - 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."
    - Assessment of Adjacent Land Use
        - Evaluate all land and waterways adjacent to all production fields for possible sources of human pathogen of concern. These sources include, but are not limited to, manure storage, compost storage, CAFO's, grazing/open range areas, surface water, sanitary facilities, and composting operations (see Table 6 for further detail). If any possible uses that might result in produce contamination are present consult with the metrics and refer to Appendix Z.
    - Assessment of Historical Land Use
        - To the degree practical, determine and document the historical land uses for production fields and any potential issues from these uses that might impact food safety (i.e., hazardous waste sites, landfills, etc.).
    - Assessment of Flooding

- Evaluate all produce fields for evidence of flooding. If any evidence is found, follow procedures identified in the "Flooding" section below.

6. ISSUE: WATER

Water used for production and harvest operations may contaminate lettuce and leafy greens if water containing human pathogens comes in direct contact with the edible portions of lettuce/leafy greens. Contamination may also occur by means of water-to-soil followed by soil-to-lettuce/leafy greens contact. Irrigation methods may have varying potential to introduce human pathogens or promote human pathogen growth on lettuce and leafy greens (Stine *et al*., 2005).

There are several different approaches and values that can be utilized to ensure that water is of appropriate quality for its intended use. The metrics applied in this edition of the Commodity Specific Guidance should be considered a starting point in industry efforts to continuously improve the quality of water used in production of these commodities.

The current metrics are intended to provide standards associated with water uses; however, it is known that various water sources have different microbial qualities, and each source should be monitored accordingly. Typical microbial values associated with various sources can be found in the Sanitary Survey document (Appendix A). During the sanitary survey that is performed prior to each growing season expected microbial values and historical monitoring data should be used to evaluate the quality of the water source.

The Best Practices Are:

- A water system description shall be prepared. This description can use maps, photographs, drawings or other means to communicate the location of permanent fixtures and the flow of the water system (including any water captured for re-use.). Permanent fixtures include wells, gates, reservoirs, valves, returns and other above ground features that make up a complete irrigation system should be documented in such a manner as to enable location in the field. Water sources and the production blocks they may serve should be documented.
- Water systems that convey untreated human or animal waste must be separated from conveyances utilized to deliver irrigation water.
- Use irrigation water and water in harvest operations that is of appropriate microbial quality for its intended use; see Table 1 and Decision Trees (1A, 1B and 1C) for specific numerical criteria. Appendix B provides the basis for these water quality metrics.
- Perform a sanitary survey prior to use of water in agricultural operations and if water quality microbial tests are at levels that exceed the numerical values set forth in Table 1. The sanitary survey is described in Appendix A.
- Test water as close to the point-of-use as practical, and if microbial levels are above specific action levels, take appropriate remedial and corrective actions.
- Retain documentation of all test results and/or Certificates of Analysis available for inspection for a period of at least 2 years.

Other Considerations for water

- Evaluate irrigation methods (drip irrigation, overhead sprinkler, furrow, etc.) for their potential to introduce, support or promote the growth of human pathogens on lettuce and leafy greens. Consider such factors as the potential for depositing soil on the crop, presence of pooled or standing water that attracts animals, etc.
- When waters from various sources are combined, consider the potential for pathogen growth in the water.
- For surface water sources, consider the impact of storm events on irrigation practices. Bacterial loads in surface water are generally much higher after a storm than normal, and caution shall be exercised when using these waters for irrigation.
- Use procedures for storing irrigation pipes and drip tape that reduce or eliminate potential pest infestations. Develop procedures to provide for microbiologically safe use of irrigation pipes and drip tape if a pest infestation does occur.
- Reclaimed water shall be subject to applicable state and federal regulations and standards. Use of this water for agricultural purposes must meet the most stringent standard as defined by the following: state and federal regulation or Table 1 of this document. Water sample results and analysis provided by the water district or provider may be utilized as records of water source testing for verification and validation audits.

7. ISSUE: WATER USAGE TO PREVENT PRODUCT DEHYDRATION

Lettuce/leafy greens may be sprayed with small amounts of water during machine harvest or in the field container just after harvest to reduce water loss. Water used in harvest operations may contaminate lettuce and leafy greens if there is direct contact of water containing human pathogens with edible portions of lettuce/leafy greens.

The Best Practices Are:

- Due to the timing of application of water that directly contacts edible portions of lettuce/leafy greens, assure the water is of appropriate microbial quality (e.g., meets U.S. EPA microbial standards for drinking water).
- Test the water source periodically to demonstrate it is of appropriate microbial quality for its intended purpose (e.g., meets U.S. EPA or WHO microbial standards for drinking water) or assure that it has appropriate disinfection potential as described in Table1.

TABLE 1. WATER USE

Use	Metric	Rationale /Remedial Actions
PRE-HARVEST Foliar Applications Whereby Edible Portions of the Crop **ARE** Contacted by Water (*e.g*. overhead sprinkler irrigation, pesticides/fungicide application, etc.)	**Target Organism:** generic *E. coli*. **Sampling Procedure:** 100 mL sample collected aseptically at the point of use; i.e., one sprinkler head per water source for irrigation, water tap for pesticides, etc. Water utilized in preseason irrigation operations may be tested and utilized. **Sampling Frequency:** One sample per water source shall be collected and tested prior to use if >60 days since last test of the water source. Additional samples shall be collected no less than 18 hr apart and at least monthly during use from points within the distribution system. **Municipal & Well Exemption:** For wells and municipal water sources, if generic *E. coli* are below detection limits for five consecutive samples, the sampling frequency may be decreased to no less than once every 180 days and the requirements for 60 and monthly sampling are waived. Closed systems with records to demonstrate that all samples of generic E. coli are below detection limits for the two preceding seasons may decrease sampling to a single sample per season. This exemption is void if there is a significant source or distribution system change.	For any given water source (municipal, well, reclaimed water, reservoir or other surface water), samples for microbial testing shall be taken at a point as close to the point of use as practical (as determined by the sampler, to ensure the integrity of the sample, using sampling methods as prescribed in Table 1) where the water contacts the crop, so as to test both the water source and the water distribution system. In a closed water system (meaning no connection to the outside) water samples may be collected from any point within the system but are still preferred as close to point of use as practical. No less than one sample per month per distribution system is required under these metrics unless a system has qualified for an exemption. If there are multiple potential point-of-use sampling points in a distribution system, then samples shall be taken from different point-of-use locations each subsequent month (randomize or rotate sample locations). Water for pre-harvest, direct edible portion contact shall meet or exceed microbial standards for recreational water, based on a rolling geometric mean of the five most recent samples. However, a rolling geometric mean of five samples is not necessarily required prior to irrigation or harvest. If less than five samples are collected prior to irrigation, the acceptance criteria depends on the number of samples taken. If only one sample has been taken, it must be below 126 CFU/100 mL. Once two samples are taken, a geometric mean can be calculated and the normal acceptance criteria apply. If the acceptance criteria are exceeded during this time period, additional samples may be collected to reach a 5 sample rolling geometric mean (as long as the water has not been used for irrigation). The *rolling* geometric mean calculation starts after 5 samples have been collected. If the water source has not been tested in the past 60 days, the first water sample shall be tested prior to use, to avoid using a contaminated water source. After the first sample is shown to be within acceptance criteria, subsequent samples shall be collected no less frequently than monthly at points of use within the distribution system. Ideally, pre-harvest water should not contain generic *E. coli*, but low levels do not necessarily indicate that the water is unsafe. Investigation and/or remedial action SHOULD be taken when test results are higher than normal, or indicate an upward trend. Investigation and remedial action SHALL be taken when acceptance criteria are exceeded. **Remedial Actions:** If the rolling geometric mean (n=5) or any one sample exceeds the acceptance criteria, then the water shall not be used whereby edible portions of the crop are contacted by water until remedial actions have been completed and generic *E. coli* levels are within acceptance criteria: • Conduct a sanitary survey of water source and distribution system to determine if a contamination source is evident and can be eliminated. Eliminate identified contamination source(s).

	Test Method: FDA BAM method or any U.S. EPA approved or AOAC accredited for quantitative monitoring of water for generic *E. coli.* Presence/absence testing with a similar limit of detection may be used as well. **Acceptance Criteria:** **≤126 MPN (or CFU*)/100 mL** (rolling geometric mean n=5) and **≤235 MPN/100mL** for any single sample. *for the purposes of water testing, MPN and CFU shall be considered equivalent.	• For wells, perform a sanitary survey and/or treat as described in Appendix A Sanitary Survey. • Retest the water after conducting the sanitary survey and/or taking remedial actions to determine if it meets the outlined microbial acceptance criteria for this use. This sample should represent the conditions of the original water system, if feasible this test should be as close as practical to the original sampling point. A more aggressive sampling program (i.e., sampling once per week instead of once per month) shall be instituted if an explanation for the exceedance is not readily apparent. This type of sampling program should also be instituted if an upward trend is noted in normal sampling results. **Crop Testing**: If water testing indicates that a crop has been directly contacted with water exceeding acceptance criteria, product shall be sampled and tested for *E. coli* O157:H7 and *Salmonella* as described in Appendix C, prior to harvest. If crop testing indicates the presence of either pathogen, the crop shall NOT be harvested for human consumption. **Records**: Information requirements: Each water sample and analysis shall record: the type of water (canal, reservoir, well, etc) date, time and location of the sample and the method of analysis and detection limit. Records of the analysis of source water may be provided by municipalities, irrigation districts or other water providers. All test results and remedial actions shall be documented and available for verification from the grower/shipper who is the responsible party for a period of two years.
PRE-HARVEST Non-foliar Applications Whereby Edible Portions of the Crop are **NOT** Contacted by Water (*e.g.*, furrow or drip irrigation, dust abatement water; if water is not used in the vicinity of produce, then testing is not necessary)	**Target Organism, Sampling Procedure, Sampling Frequency. Test Method and Municipal & Well Exemption:** as described for foliar application. **Acceptance Criteria:** **≤126 MPN /100 mL** (rolling geometric mean n=5) and **≤576 MPN /100 mL** for any single sample.	Testing and remedial actions for pre-harvest water that does not come in direct contact with edible portions of the crop are the same as for direct contact water, but acceptance criteria are less stringent because of the reduced risk of contact of the edible portion with contamination from water. Acceptance criteria here are derived from U.S. EPA recreational water standards.

<table>
<tr>
<td rowspan="2">HAND WASH and POSTHARVEST WATER -Direct Product Contact or Food Contact Surfaces</td>
<td><u>Microbial Testing</u>
Target Organism, Sampling Procedure, Test Method and Municipal & Well Exemption: as described for foliar application.

Sampling Frequency: One sample per water source shall be collected and tested prior to use if >60 days since last test of the water source. Additional samples shall be collected at intervals of no less than 18 hr and at least monthly during use.
Municipal & Well Exemption:
For wells and municipal water sources, if generic E. coli are below detection limits for five consecutive samples, the sampling frequency may be decreased to no less than once every 180 days and the requirements for 60 and monthly sampling are waived. Closed systems with records to demonstrate that all samples of generic E. coli are below detection limits for the two preceding seasons may decrease sampling to a single sample per season. This exemption is void if there is a significant source or distribution system change.

Acceptance Criteria:
Negative or below DL for all samples</td>
<td rowspan="2">Water that directly contacts edible portions of harvested crop, water used for hand washing, or is used on food contact surfaces, such as equipment or utensils, shall meet the Maximum Contaminant Level Goal for E. coli as specified by U.S. EPA or contain an approved disinfectant at sufficient concentration to prevent cross contamination. Microbial or physical/chemical testing shall be performed, as appropriate to the specific operation, to demonstrate that acceptance criteria have been met. No less than one sample per month per distribution system is required under these metrics unless a system has qualified for an exemption.

Single Pass vs. Multiple Pass Systems
• Single pass use – Water must have non-detectable levels of E. coli or breakpoint disinfectant present at point of entry
• Multi-pass use – Water must have non-detectable levels of E. coli and/or sufficient disinfectant to ensure returned water has no detectable E. coli (minimally 1 ppm chlorine).

Remedial Actions:
If any one sample exceeds the acceptance criteria, then the water shall not be used for this purpose until remedial actions have been completed and generic E. coli or disinfectant levels are within acceptance criteria:
• Conduct a sanitary survey of water source and distribution system to determine if a contamination source is evident and can be eliminated. Eliminate identified contamination source(s) and/or treat with appropriate disinfectants. For wells, perform a sanitary survey and/or treat as described in Appendix A Sanitary Survey.
• Retest the water at the same sampling point after conducting the sanitary survey and/or taking remedial actions to determine if it meets the outlined microbial acceptance criteria for this use.

For example, if a water sample for water used to clean food contact surfaces has detectable E. coli, STOP using that water system, examine the distribution line and source inlet as described in Appendix A Sanitary Survey, and retest from the same point of use. Continue testing daily for 5 days at the point closest to use, and do not use the water system until it consistently delivers water that is safe, sanitary and of appropriate microbial quality (i.e. Negative result) for the intended use. If any of the five samples taken during the intensive sampling period after corrective actions have been taken have detectable E. coli, repeat remedial actions and DO NOT use that system until the source of contamination can be corrected.</td>
</tr>
<tr>
<td><u>Physical/Chemical Testing</u>
Target Variable:
Water disinfectant (e.g. chlorine or other disinfectant compound, ORP)</td>
</tr>
</table>

	Multi Pass Water Acceptance Criteria: • Chlorine ≥1 ppm free chlorine after application and pH 6.5 – 7.5 OR • ORP ≥ 650 mV, and pH 6.5 – 7.5 • Other approved treatments per product EPA label for human pathogen reduction in water. **Testing Procedure:** • Chemical reaction based colorimetric test, or • Ion specific probe, or • ORP, or • Other as recommended by disinfectant supplier. **Testing Frequency:** Continuous monitoring (preferred) with periodic verification by titration OR Routine monitoring if the system can be shown to have a low degree of variation.	**Records**: All test results and remedial actions shall be documented and available for verification from the user of the water for a period of two years.

Figure 1A. Decision Tree for PRE-HARVEST WATER USE – Foliar Applications whereby edible portions of the crop are contacted by water (e.g. overhead irrigation, pesticide/fungicide applications)

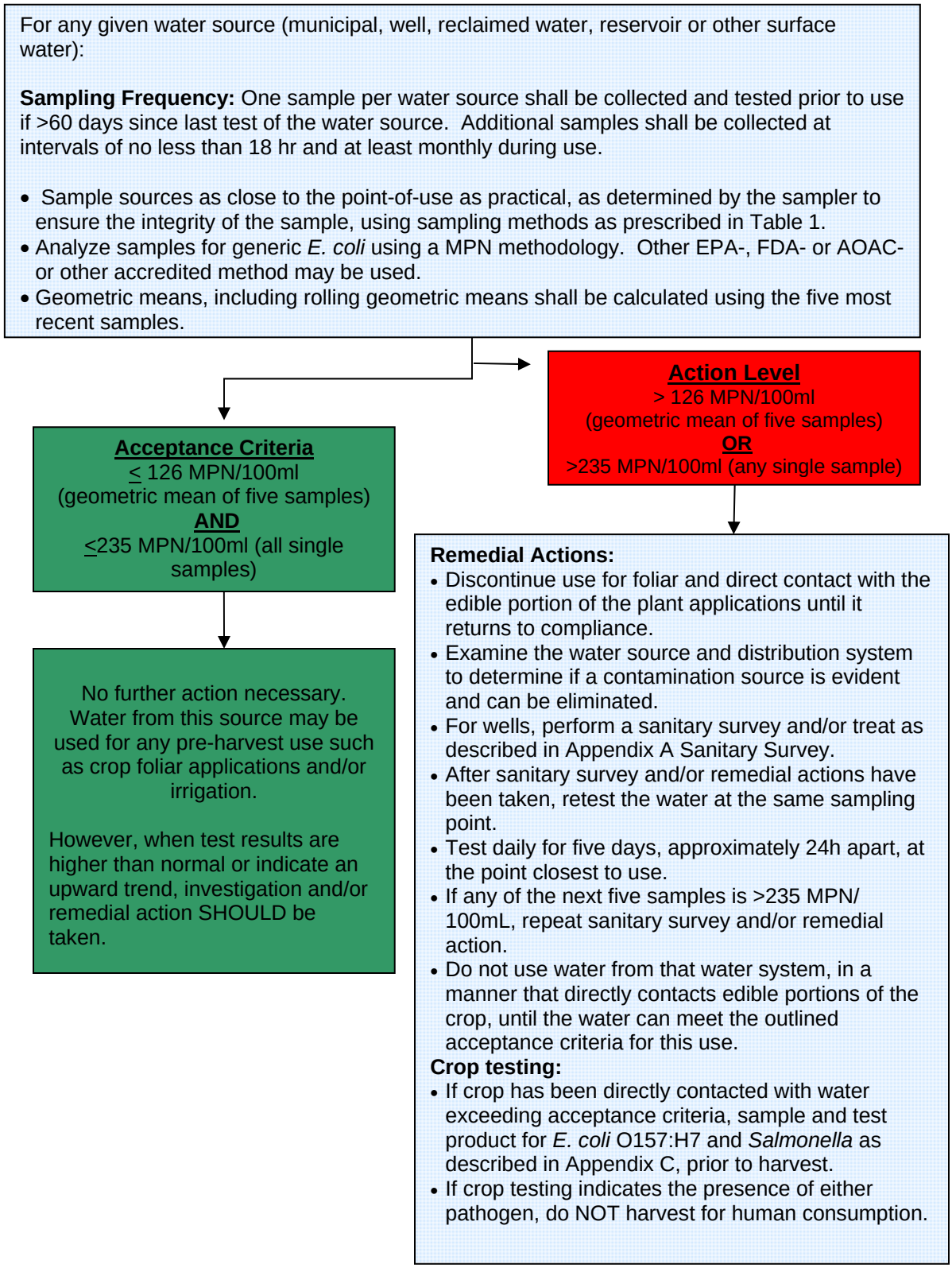


Figure 1B. Decision Tree for PRE-HARVEST WATER USE – Non-Foliar Applications whereby edible portions of the crop are NOT contacted by water (e.g. furrow or drip irrigation, dust abatement water)

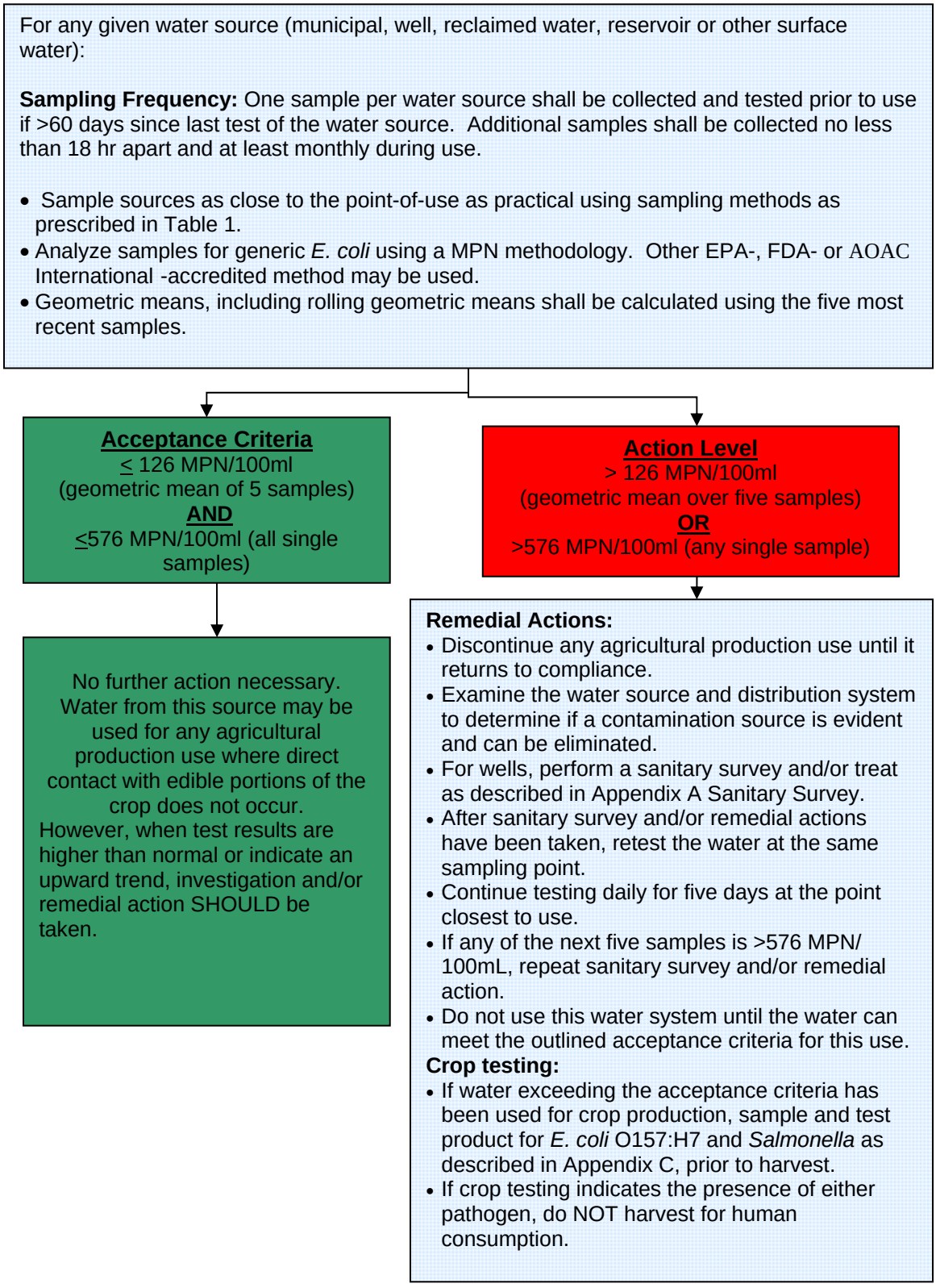
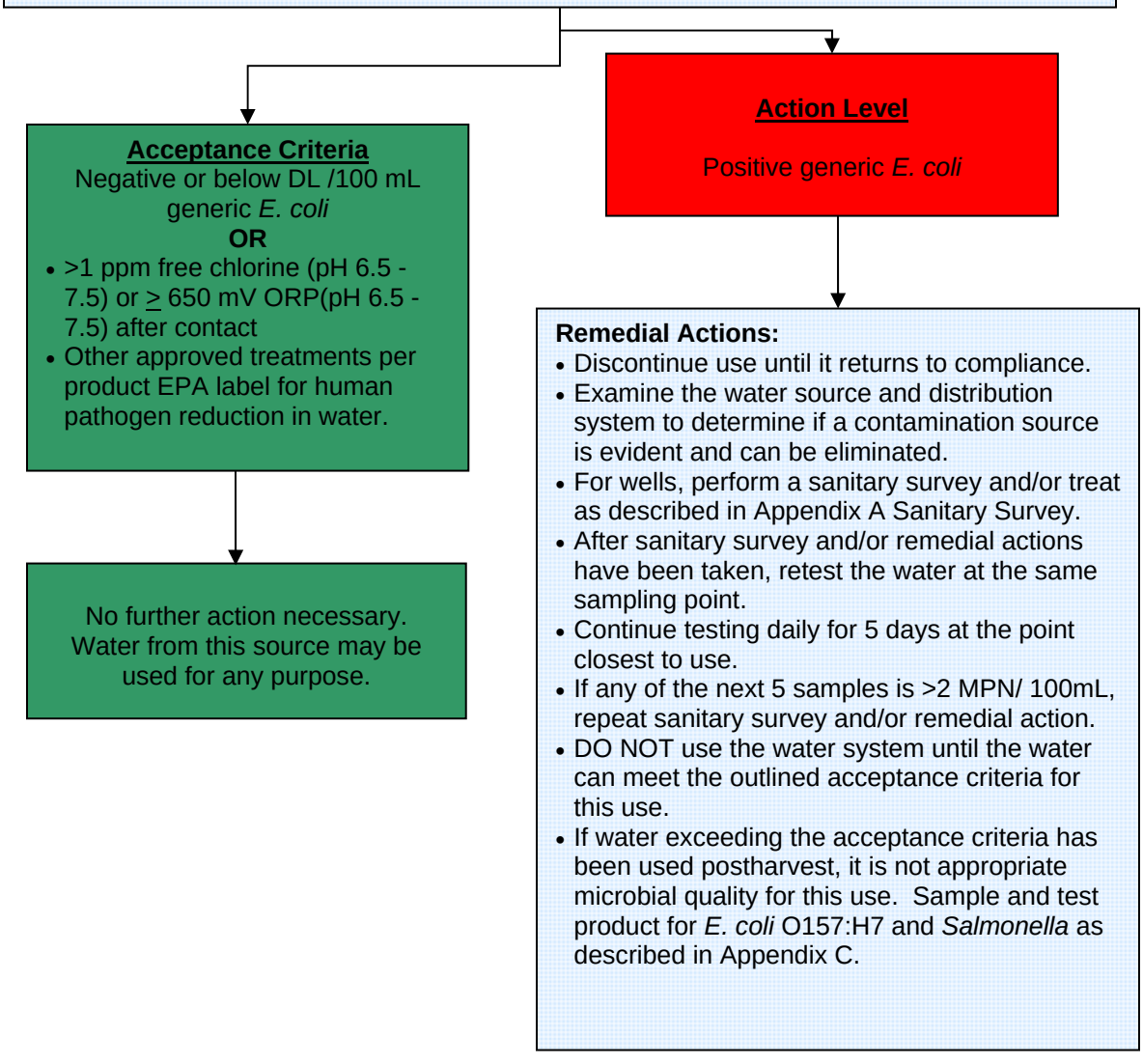


Figure 1C. HAND WASH and POSTHARVEST WATER USE – Direct product contact (e.g. re-hydration, core in field, etc.)

For any given water source (municipal, well, reservoir or other surface water):
Water that directly contacts edible portions of harvested crop, water used for handwashing or is used on food contact surfaces shall meet microbial standards set forth in U.S. EPA National Drinking Water Regulations, and/or contain an approved disinfectant at sufficient concentration to prevent cross contamination.

Sampling Frequency: One sample per water source shall be collected and tested prior to use if >60 days since last test of the water source. Additional samples shall be collected no less than 18 hr apart and a least monthly during use. No less than one sample per month per distribution system is required under these metrics unless a system has qualified for an exemption.

- Sample sources as close to the point-of-use as practical using sampling methods as prescribed in Table 1.
- Analyze samples for generic *E. coli* using a MPN methodology. Other EPA-, FDA- or AOAC



8. ISSUE: SOIL AMENDMENTS

Soil amendments are commonly but not always incorporated prior to planting into agricultural soils used for lettuce/leafy greens production to add organic and inorganic nutrients to the soil as well as intended to improve the physical, chemical, or biological characteristics of soil. Human pathogens may persist in animal manures for weeks or even months (Fukushima *et al.* 1999; Gagliardi and Karns 2000). Proper composting of animal manures via thermal treatment will reduce the risk of potential human pathogen survival. However, the persistence of many human pathogens in agricultural soils depends on many factors (soil type, relative humidity, UV index, etc.) and the effects of these factors is under extensive investigation (Jiang *et al.* 2003; Islam *et al.* 2004).

Field soil contaminated with human pathogens may provide a means of lettuce and leafy greens contamination. Studies of human pathogens conducted in cultivated field vegetable production models point towards a rapid initial die-off from high pathogen populations but a characteristic and prolonged low level survival. Readily detectable survival is typically less than 8 weeks following incorporation, but has been documented to exceed 12 weeks (Jiang et al. 2001; Islam et al. 2005). Recoverable pathogen populations, using highly sensitive techniques, have been reported to persist beyond this period under some test conditions. The detection of introduced pathogens on mature lettuce plants from these low levels of surviving pathogens was not possible, and the risk was concluded to be negligible. Human pathogens do not persist for long periods of time in high UV index and low relative humidity conditions, but may persist for longer periods of time within aged manure or inadequately composted soil amendments. Therefore, establishing suitably conservative pre-plant intervals, appropriate for specific regional and field conditions, is an effective step towards minimizing risk (Suslow et al. 2003).

The Best Practices Are:

- Do not use biosolids as a soil amendment for production of lettuce or leafy greens.
- DO NOT USE raw manure or soil amendment that contain untreated animal by-products, un-composted, incompletely composted animal manure and/or green waste or non-thermally treated animal manure to fields which will be used for lettuce and leafy green production.
- See Table 2 and Decision Trees (Figures 2A and 2B) for numerical criteria and guidance for compost and soil amendments used in lettuce and leafy greens production fields. The Technical Basis Document (Appendix B) describes the process used to develop these metrics.
- Any soil amendment that does not contain animal manure or other animal by-products must have a document (e.g., ingredient list, statement of identity, letter of guaranty, etc.) from the producer or seller demonstrating that it is manure / animal product free. This document must indicate in some way that manure is not an ingredient used in the production of the amendment or provide the ingredients of the product. A statement of identity or product is sufficient for single-chemical amendments (i.e., “calcium carbonate” or “gypsum”). If “inert ingredients” are listed as part of an amendment, then a document from the producer or seller is necessary indicating manure has not been added. The

manure / animal by-product free document must be available for verification before harvest begins and it must be saved and available for inspection for 2 years. A new document is required every two years unless there is a significant process or ingredient change.

- Implement management plans (e.g., timing of applications, storage location, source and quality, transport, etc.) that significantly reduce the likelihood that soil amendments being used contain human pathogens.
- Verify that the time and temperature process used during the composting process reduces, controls, or eliminates the potential for human pathogens being carried in the composted materials, as applicable to regulatory requirements.
- Maximize the time interval between soil amendment application and time to harvest.
- Implement practices that control, reduce or eliminate likely contamination of lettuce/leafy green fields in close proximity to on-farm stacking of manure.
- Use soil amendment application techniques that control, reduce or eliminate likely contamination of surface water and/or edible crops being grown in adjacent fields.
- Segregate equipment used for soil amendment handling, preparation, distribution, applications or use effective means of equipment sanitation before subsequent use that effectively reduce the potential for cross contamination.
- Minimize the proximity of wind-dispersed or aerosolized sources of contamination (e.g., water and manure piles) that may potentially contact growing lettuce/leafy greens or adjacent edible crops. Segregate equipment used for soil amendment applications or use effective means of equipment sanitation before subsequent use.
- Compost suppliers and on-farm composting operations shall have written Standard Operating Procedures to prevent cross-contamination of in-process and finished compost with raw materials through equipment, runoff, or wind, including instructions for handling, conveying and storing in-process or finished compost like it is untreated if it becomes contaminated. Producers shall annually obtain proof that these documents exist.
- Compost operations supplying compost to leafy greens crops shall maintain temperature monitoring and turning records for at least two years. Producers purchasing compost shall annually obtain proof from their supplier that this documentation exists. This applies to composting operations regulated under Title 14 CCR as well as smaller operations that do not fall under Title 14.
- Perform microbiological testing of soil amendments prior to application (Table 2).
- Retain documentation of all processes and test results by lot (at the supplier) and/or Certificates of Analysis available for inspection for a period of at least two years.

TABLE 2. SOIL AMENDMENTS

Amendment	Metric/Rationale
Raw Manure, untreated animal products/by-products or Not Fully Composted green waste and/or Animal Manure Containing Soil Amendments (see composted manure process definition below)	**DO NOT USE OR APPLY** soil amendments that contain un-composted, incompletely composted or non-thermally treated (e.g., heated) animal manure or animal product/by-products to fields which will be used for lettuce and leafy greens production. If these materials have been applied to a field, wait one year prior to producing leafy greens.
Composted Soil Amendments (containing animal manure or animal products/by-products) *Composted soil amendments should not be applied after emergence of plants.	**Please see Figure 2A: Decision Tree for Use of Composted Soil Amendments.** **Composting Process Validation:** Enclosed or within-vessel composting: Active compost must maintain a minimum of 131°F for 3 days Windrow composting: Active compost must maintain aerobic conditions for a minimum of 131°F or higher for 15 days or longer, with a minimum of five turnings during this period followed by adequate curing. Aerated static pile composting: Active compost must be covered with at least 12 inches of insulating materials and maintain a minimum of 131°F for 3 days followed by adequate curing. **Target Organisms:** • *Fecal coliforms* • *Salmonella* spp • *E. coli* O157:H7 **Acceptance Criteria:** • *Fecal coliforms* <1000 MPN/gram • *Salmonella*: Negative or < DL (<1/ 30 grams) • *E. coli* O157:H7: Negative or < DL (<1/ 30 grams)

	Recommended Test Methods: • *Fecal coliforms*: U.S. EPA Method 1680; multiple tube MPN • *Salmonella spp:* U.S. EPA Method 1682 • *E. coli* O157:H7: Any laboratory validated method for compost sampling. • Other U.S. EPA, FDA, AOAC, TMECC or, accredited methods may be used as appropriate. **Sampling Plan:** • A composite sample shall be representative and random and obtained as described in the California state regulations.[1] • Sample may be taken by the supplier if trained by a testing laboratory or state authority. • Laboratory must be certified/accredited for microbial testing by a certification or accreditation body. [2] **Testing Frequency:** • Each lot before application to production fields. A lot is defined as a unit of production equal to or less than 5,000 cubic yards. **Application Interval:** • Must be applied >45 days before harvest **Documentation:** • All test results and/or Certificates of Analysis shall be documented annually and available for verification from the producer (the responsible party) for a period of two years. Records of process control monitoring for on-farm produced soil amendments must be reviewed, dated, and signed, within a week after the records are made by a supervisor or responsible party. **Rationale:** • The microbial metrics and validated processes for compost are based on allowable levels from California state regulations (CCR Title 14 - Chapter 3.1 - Article 7 2007), with the addition of testing for *E. coli* O157:H7 as microbe of particular concern. The 45-day application interval was deemed appropriate due to the specified multiple hurdle risk reduction approach outlined. Raw manure must be composted with an approved process and pass testing requirements before an application.

[1] CCR Title 14 - Chapter-Chapter 3.1 – Article 7 – Section 17868.1
http://www.calrecycle.ca.gov/Laws/Regulations/title14/ch31a5.htm#article7

[2] N/A

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Soil amendments containing animal manure that has been heat treated or processed by other equivalent methods.	**Please see Figure 2B: Decision Tree for Use of Heat Treated Soil Amendments.** **Heat Process Validation** • The heat treatment processes applied to the soil amendment containing animal manure shall be done via a process validated to assure that the process is capable of reducing pathogens of human health significance to acceptable levels. **Target Organism:** • *Fecal coliforms* • *Salmonella* spp • *E. coli* O157:H7 • *Listeria monocytogenes* **Acceptance Criteria:** • *Fecal coliforms* Negative or < DL per gram • *Salmonella*: Negative or < DL (<1/ 30 grams) • *E. coli* O157:H7: Negative or < DL (<1/ 30 grams) • *Listeria monocytogenes*: Negative or <DL (<1 CFU / 5 grams) **Recommended Test Methods:** • *Fecal coliforms*: U.S. EPA Method 1680; multiple tube MPN • *Salmonella spp:* U.S. EPA Method 1682 • *E. coli* O157:H7 *Listeria monocytogenes*: Any laboratory validated method for testing soil amendments. • U.S. EPA, FDA, AOAC, TMECC or, other accredited methods may be used as appropriate **Sampling Plan:** • Extract at least 12 equivolume samples (identify 12 separate locations from which to collect the sub-sample, in case of bagged product 12 individual bags). • Sample may be taken by the supplier if trained by a testing laboratory or state authority. • Laboratory must be certified/accredited by annual review of laboratory protocols based on GLPs by a certification or accreditation body. **Testing Frequency:** • Each lot before application to production fields. • In lieu of the above analysis requirement a Certificate of Process Validity Issued by a recognized *Process Authority* can be substituted. This certificate will attest to the process

	validity as determined by either a documented (included w/Certificate)) inoculated pack study of the standard process or microbial inactivation calculations of organisms of significant risk (included w/Certificate) as outlined in FDA CFSAN publication "**Kinetics of Microbial Inactivation for Alternative Food Processing Technologies. Overarching Principles: Kinetics and Pathogens of Concern for All Technologies"** (Incorporated for reference in Appendix E Thermal Process Overview) **Application Interval:** • If the heat treatment process used to inactivate human pathogens of significant public health concern that may be found in animal manure containing soil amendments, is validated and meets the microbial acceptance criteria outlined below, then no time interval is needed between application and harvest. • If the heat treatment process used to inactivate human pathogens of significant public health concern that may be found in animal manure containing soil amendments is not validated but will likely significantly reduce microbial populations of human pathogens and meets microbial acceptance criteria outlined above, then a 45 day interval between application and harvest is required. **Documentation:** • All test results and/or Certificates of Analysis and/or Certificates of Process Validation shall be documented and available for verification from the producer who is the responsible party for a period of two years. The suppliers operation should be validated by a process authority and a record maintained by the producer for a period of two years. **Rationale:** • The microbial metrics and validated processes for compost are based on allowable levels from California state regulations (CCR Title 14 - Chapter 3.1 - Article 7 2007), with the addition of testing for *E. coli* O157:H7 as the microbe of particular concern. A more stringent level of fecal coliform was also included to address the much more controlled nature of soil amendments produced in this manner. The above suggested application interval was deemed appropriate due to the specified multiple hurdle risk reduction approach outlined. Raw manure must be composted with an approved process and pass testing requirements before application. • FDA has established the validity of D-values and Z-values for key pathogens of concern in foods. This method of process validation is currently acceptable to US regulators. Alternatively, results of an inoculated test pack utilizing the specific process is also an acceptable validation of the lethality of the process.

Soil Amendments Not Containing Animal Manure	• Any soil amendment that DOES NOT contain animal manure must have documentation that it is manure-free. • The documentation must be available for verification before harvest begins. • If there is documentation that the amendment does not contain manure or animal products/by-products then no additional testing is required, and there is no application interval necessary • Any test results and/or documentation shall be available for verification from the producer who is the responsible party for a period of two years.

Figure 2A. Decision Tree for Composted Soil Amendments (SA)

If raw manure has been directly applied to the field in the past, a 1 year waiting period shall be observed before planting any variety of leafy green crops.

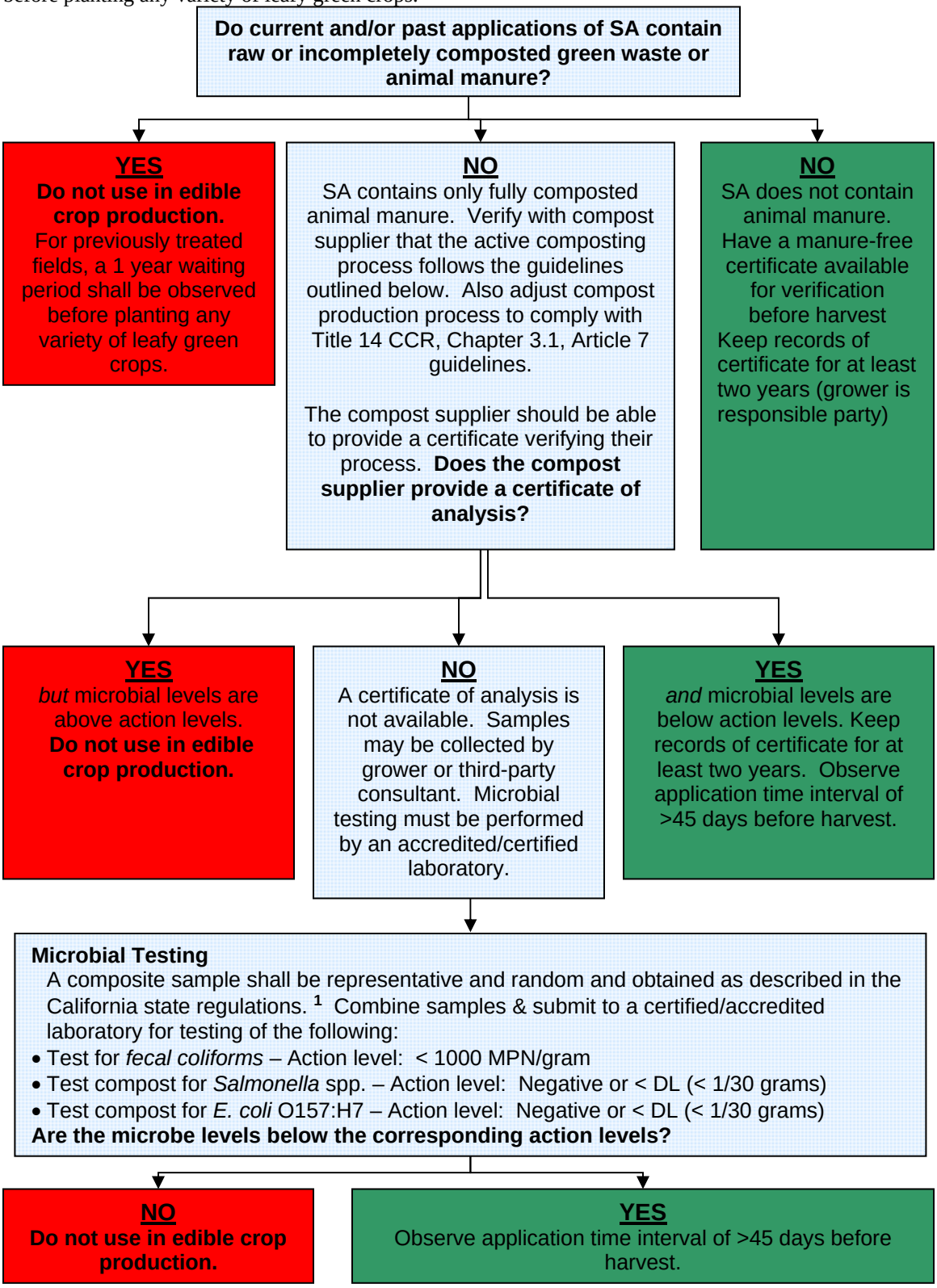
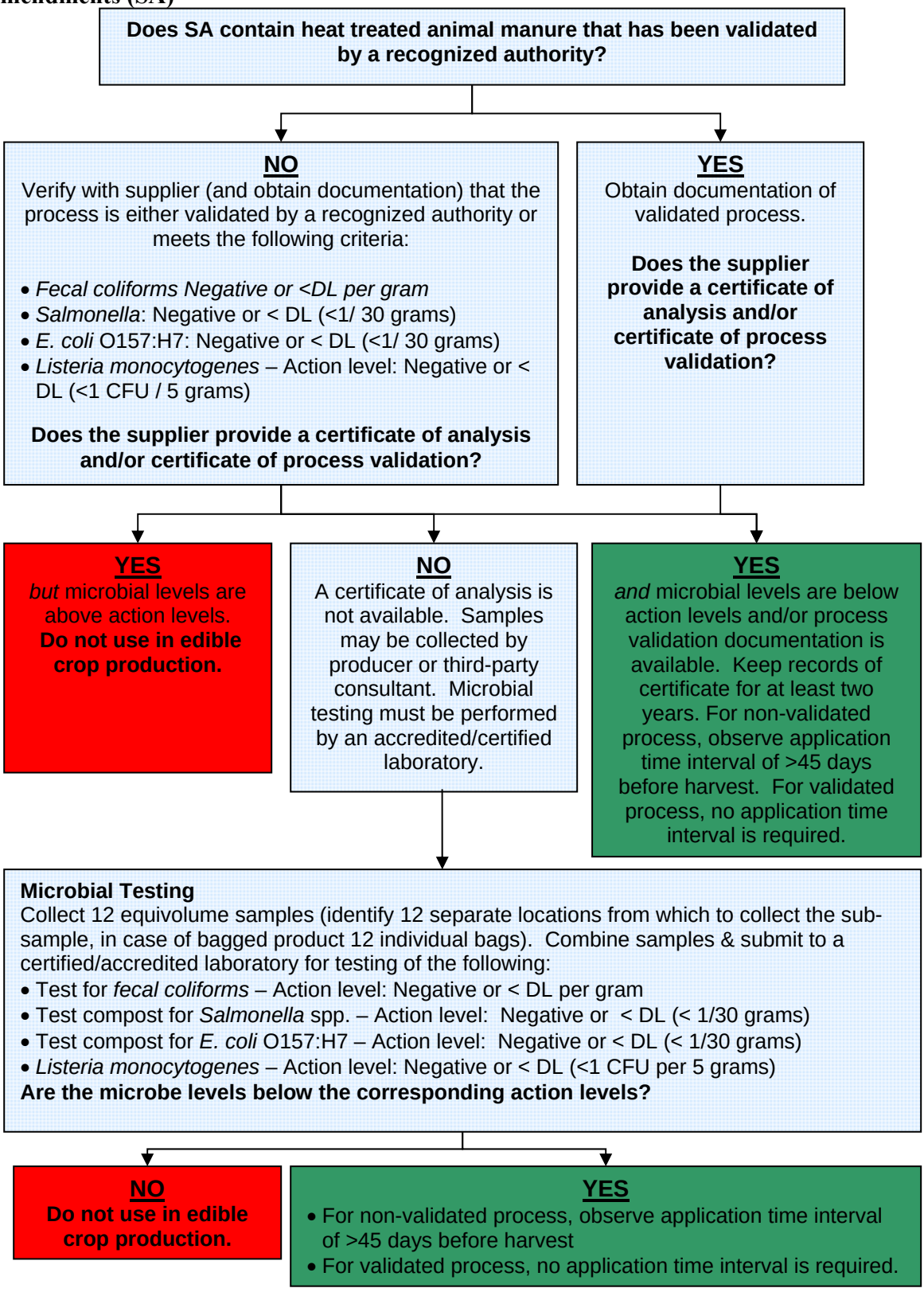


Figure 2B. Decision Tree for Heat Treated Animal Manure Containing Soil Amendments (SA)



9. ISSUE: NONSYNTHETIC CROP TREATMENTS

Nonsynthetic crop treatments are commonly applied post-emergence for pest and disease control, greening, and to provide organic and inorganic nutrients to the plant during the growth cycle. For the purposes of this document, they are defined as any crop input that contains animal manure, an animal product, and/or an animal by-product that is reasonably likely to contain human pathogens. Due to the potential for human pathogen contamination, these treatments should only be used under conditions that minimize the risk for crop contamination.

The Best Practices Are:

- Do not use crop treatments that contain raw manure or other untreated animal products or by-products for lettuce or leafy green produce.
- Do not apply untreated agricultural or compost teas containing added nutrients (e.g., molasses, yeast extract, algal powder, etc.) intended to increase microbial biomass directly to lettuce/leafy greens.
- Water used to make agricultural teas must meet the water quality requirement for post-harvest water use in Table 1. Liquid crop treatments such as agricultural or compost teas may be used in water distribution systems provided all other requirements herein are met.
- Retain documentation of all test results available for inspection for a period of at least two years.
- Implement management plans (e.g. timing of applications, storage location, source and quality, transport, etc.) that assure to the greatest degree practicable that the use of crop treatments does not pose a significant pathogen contamination hazard.
- Verify that the time and temperature process used during crop treatment manufacture reduces, controls, or eliminates the potential for human pathogens being carried in the nonsynthetic crop treatment materials, as applicable to regulatory requirements.
- Maximize the time interval between the crop treatment application and time to harvest.
- Implement practices that control, reduce or eliminate likely contamination of lettuce/leafy green fields that may be in close proximity to on-farm storage of crop treatments (see Table 6 for additional metrics).
- Use crop treatment application techniques that control, reduce or eliminate the likely contamination of surface water and/or edible crops being grown in adjacent fields.
- Segregate equipment used for crop treatment applications or use effective means of equipment sanitation before subsequent use.
- See Table 3 and Decision Tree (Figure 3) for numerical criteria and guidance for nonsynthetic crop treatments used in lettuce and leafy greens production fields. The Technical Basis Document (Appendix B) describes the process used to develop these metrics.

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Treatment	Metric/Rationale
Any crop input that contains animal manure, an animal product, and/or an animal by-product that is reasonably likely to contain human pathogens. Examples include but are not limited to: • Agricultural / Compost teas, • Fish emulsions • Fish meal • Blood meal • "Bio-fertilizers" commonly used for pest control, greening, disease control, fertilizing. Suppliers of these products shall disclose on labels, certificates of analysis, or other companion paperwork whether the product contains any animal manure or products.	**Non synthetic crop treatments that contain animal products/by-products or animal manure that have not been physically heat treated or processed by other equivalent methods shall NOT be directly applied to the edible portions of lettuce and leafy greens.** **Please see Figure 3: Decision Tree for Use of Nonsynthetic Crop Treatments.** **Process Validation** • The physical, chemical and/or biological treatment process(es) used to render the crop input safe for application to edible crops must be validated. **Target Organism:** • *Fecal coliforms* • *Salmonella* spp • *E. coli* O157:H7 • *Listeria monocytogenes* **Acceptance Criteria (at point of use):** • *Fecal coliforms*: Negative or < DL (<1/ 30 grams or mL) • *Salmonella*: Negative or < DL (<1/ 30 grams or mL) • *E. coli* O157:H7: Negative or < DL (<1/ 30 grams or mL) • *Listeria monocytogenes*: Negative or < DL (< 1 CFU / 5 grams or mL) • Other pathogens appropriate for the source material **Recommended Test Methods:** • *Fecal coliforms*: U.S. EPA Method 1680; multiple tube MPN • *Salmonella spp:* U.S. EPA Method 1682 • *E. coli* O157:H7 and *Listeria monocytogenes*: Any laboratory validated method for the non synthetic material to be tested. • Other U.S. EPA, FDA, AOAC, TMECC or, accredited methods may be used as appropriate **Sampling Plan:** • 12 point sampling plan composite sample (if solid), one sample per batch if liquid (if liquid-based, then water quality acceptance levels as described in Table 1 should be used) • Sample may be taken by the supplier if trained by the testing laboratory

Treatment	Metric/Rationale
	• Laboratory must be certified/accredited by annual review of laboratory protocols based on GLPs by a certification or accreditation body. **Testing Frequency:** • Each lot before application to production fields. **Application Interval:** o If the physical, chemical and/or biological treatment process used to render the crop input safe for application to edible crops is validated and meets that microbial acceptance criteria outlined above, no time interval is needed between application and harvest. o If the physical, chemical and/or biological treatment process used to render the crop input safe for application to edible crops is not validated yet meets the microbial acceptance criteria outlined above, a 45 day time interval between application and harvest is required. **Documentation:** • All test results and/or Certificates of Analysis shall be documented and available from the producer for verification for a period of 2 years. The producer the party responsible party for maintaining the appropriate records. **Rationale:** • The microbial metrics and validated processes for compost are based on allowable levels from California state regulations (CCR Title 14 - Chapter 3.1 - Article 5 2007), with the addition of testing for *E. coli* O157:H7 as the microbe of particular concern. The above suggested application interval was deemed appropriate due to the specified multiple hurdle risk reduction approach outlined. Any non synthetic crop treatment that contains animal manure must use only fully composted manure in addition to a validated process and pass testing requirements before a application to soils or directly to edible portions of lettuce and leafy greens.

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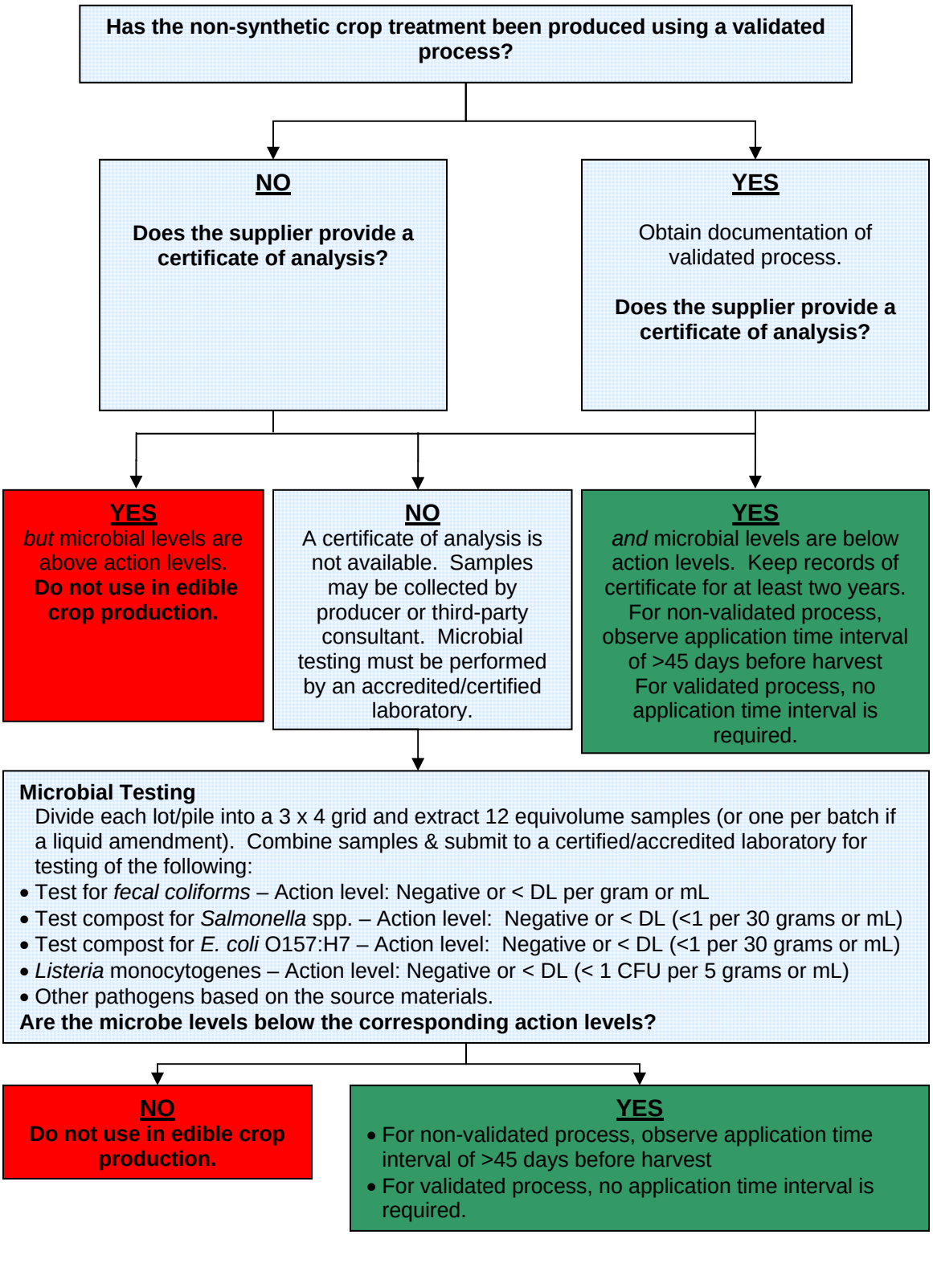
Figure 3. Decision Tree for Nonsynthetic Crop Treatments That Contain Animal Products/by-products



Note: Mixtures of soil amendment materials
For soil amendments that contain mixtures of materials each component must meet the requirements of its respective class of materials. The usages allowed will conform to that of the most stringent class of materials utilized in the mixture.

For example; Soil amendments containing animal manure that has been heat treated or processed by other equivalent methods mixed with soil amendments not containing animal manure would require a process certification for the heat treated or processed by other equivalent methods materials and the components from non-animal manure would require documentation attesting to its manure free status. The resulting mixture could then be applied in accordance with the guidelines associated with the heated treated class of materials (most stringent limits).

10. ISSUE: HARVEST EQUIPMENT, PACKAGING MATERIALS, AND BUILDINGS (FIELD SANITATION)

This section addresses harvest and harvest aid equipment and packaging materials used for lettuce/leafy greens as well as any fully or partially enclosed buildings used to store food contact surfaces and packaging materials. Mechanical or machine harvest has become increasingly prevalent and provides opportunity for increased surface contact exposure. This includes field cored lettuce operations that use various harvest equipment and aids.

The Best Practices Are:

- Use equipment such as pallets, forklifts, tractors, and vehicles that may have contact with leafy greens in a manner that minimizes the potential for product or food contact surface contamination.
- Prepare an SOP for harvest equipment and containers that addresses the following:
    - Sanitation verification
    - Daily inspection
    - Proper cleaning, sanitation and storage of hand harvest equipment (knives, scythes, etc.)
    - Control procedures when equipment is not in use, including policy for removal of equipment from the work area or site and the use of scabbards, sheathes or other storage equipment.
- Prepare an SOP for handling and storage of product containers that addresses the following:
    - Overnight storage
    - Contact with the ground
    - Container assembly (RPC, fiber bin, plastic bin, etc)
    - Damaged containers
    - Use of containers only as intended
- Prepare an SOP for sanitary operation of equipment which addresses.

- Spills and leaks
- Inoperative water sprays
- Exclusion of foreign objects (including glass, plastic, metal and other debris)
- Establish and implement cleaning and sanitation schedules for containers and equipment that will be used in hydration.
- Maintain logs documenting cleaning and sanitation, and retain these records for at least two years.
- Establish and implement procedures for the storage and control of water tanks and equipment used for hydration operations when not in use.

- Establish and implement appropriate measures that reduce and control the potential introduction of human pathogens at the cut surface during and after mechanical harvest operations. Due to the cut surface being more vulnerable to microbial contamination, this best practice is extremely important and all practical means should be taken to reduce the possibility of introduction of contamination at this process step.
- If re-circulated rinse or antioxidant solutions are used on the cut surface, take all practicable precautions to prevent them from becoming a source of contamination.
- Instruments or controls used to measure, regulate, or record temperatures, hydrogen ion concentration (pH), sanitizer efficacy, or other conditions must be:
  - Accurate and precise as necessary and appropriate for their intended use
  - Adequately maintained; and
  - Adequate in number for their designated uses.
- Convey, store, and dispose of trash, litter, and waste to:
  - Minimize the potential to attract and harbor pests.
  - Protect lettuce/leafy greens, food-contact surfaces, production areas, and agricultural water sources and distribution systems from contamination.
- Design equipment to facilitate cleaning by using materials and construction that facilitate cleaning of non-food contact surfaces and cleaning and sanitation of equipment food contact surfaces (e.g., transportation tarps, conveyor belts, etc.).
  - Seams on food-contact surfaces on equipment and tools must be smoothly bonded or maintained to minimize accumulation of dirt, filth, food particles, and organic materials and the opportunity for harborage or growth of microorganisms.
- Establish sanitation and/or cleaning frequency of food contact and non-food contact surfaces of equipment, tools, and containers by developing and implementing Sanitation Standard Operating Procedures (SSOPs) and a sanitation schedule for machine harvest operations.

- Evaluate the use of cleaning verification methods for harvesting equipment (e.g., ATP test methods).
- Document the date and method of cleaning and sanitizing. A supervisor or responsible party must review, date, and sign these records within a week after the records are made.
- Establish and implement equipment and tool storage and control procedures to minimize the potential for contamination and to prevent it from attracting and harboring pests when not in use.
- Establish policies and implement sanitary design principles that facilitate frequent and thorough cleaning of non-food contact surfaces and cleaning and sanitizing of food contact surfaces.
- Develop and implement appropriate cleaning, sanitizing, storage and handling procedures of all equipment and food contact surfaces to reduce and control the potential for microbial cross contamination.
    - Locate equipment, tool and container cleaning and sanitizing operations away from product and other equipment to reduce the potential for cross contamination.
    - If equipment and tool food contact surfaces have contact with produce that is not covered by the Produce Safety Rule, adequately clean and sanitize before using this equipment to harvest lettuce/leafy greens.
- Allow adequate distance for the turning and manipulation of harvest equipment to prevent cross contamination from areas or adjacent land that may pose a risk.
- Use packaging material that are cleanable or designed for single use and unlikely to support the growth or transfer of bacteria.
- If packaging materials are reused, take steps to ensure food contact surfaces are clean or covered with a clean liner.
- Buildings must be suitable in size, construction and design to facilitate building maintenance and sanitary operations to reduce the potential for contamination of food contact surfaces with known or reasonably foreseeable hazards. Buildings must:
    - Provide sufficient space for placement of equipment and storage of packaging materials.
    - Take proper precautions to reduce potential for contamination of food contact surfaces or packaging materials. Reduce the potential for contamination by effective building design including the separations of operations in which contamination is likely to occur by location, time, partition, enclosed systems, or other effective means.
    - Provide adequate drainage in all areas where water or other liquid waste is discharged on the ground or floor of the building.
    - Prevent contamination of food-contact surfaces and packaging materials by protecting them from drips or condensate and excluding pests and animals.

11. ISSUE: HARVEST PERSONNEL - DIRECT CONTACT WITH SOIL AND CONTAMINANTS DURING HARVEST (FIELD SANITATION)

After manual harvest of lettuce/leafy greens, placing or stacking product on soil before the product is placed into a container may expose the product to human pathogens if the soil is contaminated. Research has demonstrated that microbes, including human pathogens, can readily attach to cut lettuce/leafy green surfaces (Takeuchi *et al.* 2001).

The Best Practices Are:

- Evaluate appropriate measures that reduce and control the potential introduction of human pathogens through soil contact at the cut surface after harvest (e.g. frequency of knife sanitation, no placement of cut surfaces of harvested product on the soil, container sanitation, single use container lining, etc.).
- Discard and do not pack any lettuce/leafy greens dropped on the ground during harvest.
- Do not stack soiled bins on top of each other if the bottom of one bin has had direct contact with soil unless a protective barrier (*i.e.*, liner, cover, *etc.*) is used to separate the containers.
- Establish and implement an SOP for handling in-field trash and other debris including transporting it out of the field in a manner that does not pose a contamination risk.

12. ISSUE: FIELD AND HARVEST PERSONNEL - TRANSFER OF HUMAN PATHOGENS BY WORKERS (FIELD SANITATION)

It is possible for persons in the field to transfer microorganisms of significant public health concern to produce during pre-harvest and harvest activities. Establish and implement preventive measures to minimize potential contamination of leafy greens especially during harvest activities when each lettuce/leafy greens plant is touched/handled by harvest crews.

The Best Practices Are:

- Use appropriate preventive measures outlined in GAPs such as training in appropriate and effective hand washing, glove use and replacement, and mandatory use of sanitary facilities to reduce and control potential contamination.
- Establish and implement a written worker hygiene/practices program (i.e., an SOP) that can be used to verify employee compliance with company food safety policy. This program shall establish the following practices for field and harvest employees as well as visitors.
    - During growing and harvesting operations, there must be at least one individual designated as responsible for food safety in compliance with these best practices.
    - Use, storage, record keeping, and proper labeling of chemicals
    - Follow and be trained in proper sanitation and hygiene practices and policies including:
        - Requirements for workers to wash their hands with soap and running water before beginning or returning to work, before putting on gloves,

after using the toilet, as soon as practical after touching animals or any waste of animal origin and at any other time when hands may have become contaminated.

- Requirement for workers' clothing to be clean at the start of the day and appropriate for the operation.
- If gloves are used in handling or harvesting lettuce/leafy greens, maintain gloves in an intact and sanitary condition and replace them when no longer able to do so.
- Avoiding contact with any animals.
- Confinement of smoking, eating and drinking of beverages other than water to designated areas.
- Prohibitions on spitting, urinating or defecating in the field.

- Make visitors aware of policies and procedures to protect lettuce/leafy greens and food contact surfaces from contamination by people and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures.

- Develop and implement a written physical hazard prevention program for leafy green products that are intended for further processing. The program must address the following:
  - Employee clothing and jewelry (head and hair restraints, aprons, gloves, visible jewelry, etc.) Removing or covering hand jewelry (if allowed) that cannot be adequately cleaned and sanitized during periods in which leafy greens are manipulated by hand.
  - Removal of all objects from upper pockets.
  - Designated storage for personal items.
- Establish and implement a worker health practices program (i.e., an SOP) that address the following issues:
  - Workers with diarrhea disease or symptoms of other infectious disease are prohibited from being in the field and handling fresh produce and food contact surfaces.
  - Workers with open cuts or lesions are prohibited from handling fresh produce and food contact surfaces without specific measures to prevent cross contamination.
  - Actions for employee to take in the event of injury or illness (i.e. notifying a supervisor or other responsible party).
  - A policy describing procedures for handling/disposition of produce or food contact surfaces that have come into contact with blood or other body fluids.
- A field sanitary facility program (i.e., an SOP) shall be implemented, and it should address the following issues: the number, condition, and placement of field sanitation units according to federal, state or local regulations, the accessibility of the units to the work area, facility maintenance, facility supplies [i.e., hand soap, water (use of

antiseptic/sanitizer or wipes, as a substitute for soap and water, is not permitted), single-use paper towels, toilet paper, etc.], facility signage, facility cleaning and servicing, and a response plan for major leaks or spills.

- During harvest, packing, and holding activities, hand-washing facilities must be furnished with microbial potable running water.
- Sanitary facilities should be placed such that the location minimizes the impact from potential leaks and/or spills while allowing access for cleaning and service.
- The location and sanitary design of toilets and hand wash facilities should be optimized to facilitate the control, reduction and elimination of human pathogens from employee hands. Evaluate the location of sanitary facilities to maximize accessibility and use, while minimizing the potential for the facility to serve as a source of contamination.
- Establish and implement the frequency of sanitary facilities maintenance/sanitation and the appropriate disposal of waste
- Establish and implement equipment and supply storage and control procedures when not in use.
- Maintain documentation of maintenance and sanitation schedules and any remedial practices for a period of two years.

13. ISSUE: EQUIPMENT FACILITATED CROSS CONTAMINATION (FIELD SANITATION)

When farm equipment has had direct contact with raw untreated manure, untreated compost, waters of unknown quality, animals, or other potential human pathogen reservoirs it may be a source of cross contamination. Such equipment should not be used in proximity to or in areas where it may contact edible portions of lettuce and or leafy greens without proper sanitation.

The Best Practices Are:

- Identify any field operations that may pose a risk for cross-contamination. These include management personnel in the fields, vehicles used to transport workers, as well as many other possibilities.
- Segregate equipment used in high-risk operations or potentially exposed to high levels of contamination.
- Use effective means of equipment cleaning and sanitation before subsequent equipment use in lettuce/leafy greens production, if it was previously used in a high-risk operation.
- Develop and implement appropriate means of reducing and controlling the possible transfer of human pathogens to soil and water that may directly contact edible lettuce/leafy green tissues through use of equipment.
- Maintain appropriate records related to equipment cleaning and possible cross-contamination issues for a period of two years.

14. ISSUE: FLOODING

Flooding for purposes of this document is defined as the flowing or overflowing of a field with water outside of a producer's control, that is reasonably likely to contain microorganisms of significant public health concern and is reasonably likely to cause adulteration of the edible portions of fresh produce in that field. Pooled water (e.g., rainfall) that is not reasonably likely to contain microorganisms of significant public health concern and is not reasonably likely to cause adulteration of the edible portion of fresh produce should not be considered flooding.

If flood waters contain microorganisms of significant public health concern, crops in close proximity to soil such as lettuce/leafy greens may be contaminated if there is direct contact between flood water or contaminated soil and the edible portions of lettuce/leafy greens (Wachtel *et al.* 2002a;2002b).

In the November 4, 2005 FDA "Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce/leafy greens" the agency stated that it "considers ready to eat crops (such as lettuce/leafy greens) that have been in contact with flood waters to be adulterated due to potential exposure to sewage, animal waste, heavy metals, pathogenic microorganisms, or other contaminants. FDA is not aware of any method of reconditioning these crops that will provide a reasonable assurance of safety for human food use or otherwise bring them into compliance with the law. Therefore, FDA recommends that such crops be excluded from the human food supply and disposed of in a manner that ensures they do not contaminate unaffected crops during harvesting, storage or distribution.

"Adulterated food may be subject to seizure under the Federal Food, Drug, and Cosmetic Act, and those responsible for its introduction or delivery for introduction into interstate commerce may be enjoined from continuing to do so or prosecuted for having done so. Food produced under unsanitary conditions whereby it may be rendered injurious to health is adulterated under § 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(4); (US FDA 2004).

Areas that have been flooded can be separated into three groups: 1) product that has come into contact with flood water, 2) product that is in proximity to a flooded field but has not been contacted by flood water, and 3) production ground that was partially or completely flooded in the past before a crop was planted. The considerations for each situation are described below and presented in Table 4.

The Best Practices For Product That Has Come Into Contact With Flood Water Are:

- See Table 4 for numerical criteria for lettuce and leafy greens production fields that have possibly come into contact with flood waters. The Technical Basis Document (Appendix B) describes the process used to develop these metrics.
- FDA considers any crop that has come into contact with floodwater to be an "adulterated" commodity that cannot be sold for human consumption.

- To reduce the potential for cross contamination do not drive harvest equipment through flooded areas reasonably likely to contain microorganisms of public health significance (see previous section).

TABLE 4. FLOODING

When evidence of flooding in a production block occurs.

Practice	Metric/Rationale
Flooding Defined	The flowing or overflowing of a field with water outside a producer's control that is reasonably likely to contain microorganisms of significant public health concern and is reasonably likely to cause adulteration of edible portions of fresh produce in that field. Additional discussion of this definition and implications for production is provided in the text portion of this document.
Allowable Harvest Distance from Flooding	• Buffer and do not harvest any product within 30 ft of the flooding. • Required buffer distance may be greater than 30 ft based on risk analysis by food safety professional. • If there is evidence of flooding, the production block must undergo a detailed food safety assessment by appropriately trained food safety personnel (see Glossary) prior to harvest, as defined in the text of this document.
Verification	• Documentation must be archived for a period of two years following the flooding event. Documentation may include photographs, sketched maps, or other means of delineating affected portions of production fields.
Time Interval Before Planting Can Commence Following the Receding of Floodwaters	• 60 days prior to planting provided that the soil has sufficient time to dry out. • Appropriate soil testing can be used to shorten this period to 30 days prior to planting. This testing must be performed in a manner that accurately represents the production field and indicates soil levels of microorganisms lower than the recommended standards for processed compost. Suitable representative samples should be collected for the entire area suspected to have been exposed to flooding. For additional guidance on appropriate soil sampling techniques, use the *Soil Screening Guidance: Technical Background Document* (US EPA 1996). Specifically, Part 4 provides guidance for site investigations. Reputable third-party environmental consultants or laboratories provide sampling services consistent with this guidance. • Appropriate mitigation and mitigation strategies are included in the text portion of the document.
Rationale	• The basis for the 30 foot distance is the turnaround distance for production equipment to prevent cross-contamination of non-flooded ground or produce.

The Best Practices for Product in Proximity to a Flooded Area but Not Contacted By Flood Water Are:

- Prevent cross contamination between flooded and non-flooded areas (e.g. cleaning equipment, eliminating contact of any farming or harvesting equipment or personnel with the flooded area during growth and harvest of non-flooded areas).
- To facilitate avoiding contaminated/adulterated produce, place markers identifying both the high-water line of the flooding and an interval 30 feet beyond this line. If 30 feet is not sufficient to prevent cross contamination while turning harvesting or other farm equipment in the field, use a greater appropriate interval. Take photographs of the area for documentation. Do not harvest product within the 30 foot buffer zone.

The Best Practices For Formerly Flooded Production Ground Are:

- Prior to replanting or soil testing, the designated food safety professional for the producer shall perform a detailed food safety assessment of the production field. This designated professional will be responsible for assessing the relative merits of testing versus observing the appropriate time interval for planting, and also will coordinate any soil testing plan with appropriate third-party consultants and/or laboratories that have experience in this type of testing.
- Evaluate the source of flood waters (e.g., drainage canal, river, irrigation canal, etc.) for potential significant upstream contributors of human pathogens at levels that pose a significant threat to human health.
- Allow soils to dry sufficiently and be reworked prior to planting subsequent crops on formerly flooded production ground.
- Do not replant formerly flooded production ground for at least 60 days following the receding of floodwaters. This period or longer and active tillage of the soil provide additional protection against the survival of pathogenic organisms.
- If flooding has occurred in the past on the property, soil clearance testing may be conducted prior to planting leafy greens. Soil testing may be used to shorten the clearance period to 30 days. If performed, testing must indicate soil levels of microorganisms lower than the standards for processed compost. Suitable representative samples should be collected for the entire area suspected to have been exposed to flooding.
- Sample previously flooded soil for the presence of microorganisms of significant public health concern or appropriate indicator microorganisms. Microbial soil sampling can provide valuable information regarding relative risks; however, sampling by itself does not guarantee that crops grown within the formerly flooded production area will be free of the presence of human pathogens.
- Evaluate the field history and crop selection on formerly flooded production ground.
- Assess the time interval between the flooding event, crop planting, and crop harvest. Comparative soil samples may be utilized to assess relative risk if

significant reductions in indicator microorganisms have occurred within this time interval.

- Prevent cross-contamination by cleaning or sanitizing any equipment that may have contacted previously flooded soil (also see the section on Equipment Facilitated Cross Contamination above).

15. ISSUE: PRODUCTION LOCATIONS - CLIMATIC CONDITIONS AND ENVIRONMENT

Lettuce/leafy greens are grown in varying regions but generally in moderate weather conditions. Cool, humid conditions favor human pathogen persistence (Takeuchi and Frank 2000; Takeuchi *et al.* 2000) while drier climates may present other problems such as requirements for additional water that may increase the potential for introduction of human pathogens. Heavy rains in certain areas may also cause lettuce/leafy greens to be exposed to contaminated soil due to rain splashing. It is important to tailor practices and procedures designed to promote food safety to the unique environment in which each crop may be produced

The Best Practices Are:

- Consider harvest practices such as removing soiled leaves, not harvesting soiled heads, etc., when excessive soil or mud builds up on lettuce/leafy greens.
- Take care to reduce the potential for windborne soil, including soil from roads adjacent to fields, water, or other media that may be a source of contamination to come into direct contact with the edible portions of lettuce and leafy greens. Do not allow runoff from adjacent properties to come into contact with produce.
- Evaluate and implement practices to reduce the potential for the introduction of pathogens into production blocks by wind or runoff. Such practices may include but are not limited to berms, windbreaks, diversions ditches and vegetated filter strips.
- When soil has accumulated on plants, remove soil during the harvest or further processing.

16. ISSUE: PRODUCTION LOCATIONS - ENCROACHMENT BY ANIMALS AND URBAN SETTINGS

Lettuce/leafy greens are generally grown in rural areas that may have adjacent wetlands, wildlands, parks and/or other areas where animals may be present. Some animal species are known to be potential carriers of various human pathogens (Fenlon 1985; Gorski et al. 2011; jay et al. 2007; keene et al. 1997; LeJeune et al. 2008; perz et al. 2001). In addition, extensive development in certain farming communities has also created situations with urban encroachment and unintentional access by domestic animals and/or livestock which may also pose varying degrees of risk. Finally, it is possible that some land uses may be of greater concern than others when located near production fields. Table 6 provides a list of these uses and recommended buffer distances.

The Best Practices Are:

- See Tables 5 and 6 and Decision Tree (Figure 5) for numerical criteria and guidance applicable to animal encroachment and adjacent land uses. The Technical Basis Document (Appendix B) describes the process used to develop these metrics.
- During the Environmental Assessments discussed in Section 3, the location of any adjacent land uses that are likely to present a food safety risk should be documented. In addition, as specified in Table 6, any deviations from the recommended buffer distances due to mitigation factors or increased risk should be documented.
- Evaluate and monitor animal activity in and proximate to lettuce/leafy greens fields and production environments. Conduct and document periodic monitoring, and pre-season, pre-harvest, and harvest assessments. If animals present a probable risk (medium/high hazard), make particular efforts to reduce their access to lettuce and leafy green produce.
- Fencing, vegetation removal, and destruction of habitat may result in adverse impacts to the environment. Potential adverse impacts include loss of habitat to beneficial insects and pollinators; wildlife loss; increased discharges of sediment and other pollutants resulting from the loss of vegetative filtering; and increased air quality impacts if bare soil is exposed to wind. It is recommended that producers check for local, state, and federal laws and regulations that protect riparian habitat and wetland areas, restrict removal of vegetation or habitat, or regulate wildlife deterrence measures, including hazing, harassment, lethal and non-lethal removal, etc.
- Evaluate the risk to subsequent crop production or production acreage that has experienced recent postharvest grazing with or by domesticated animals that used field culls as a source of animal feed.
- Document any probable risk (medium/high hazard) during production and/or harvest periods and take appropriate corrective action per Table 5 in LGMA metrics.
- Locate production blocks to minimize potential access by animals and maximize distances to possible sources of microbial contamination. For example, consider the proximity to water (i.e., riparian areas), animal harborage, open range lands, non-contiguous blocks, urban centers, etc. Periodically monitor these factors and assess during pre-season and pre-harvest assessments as outlined in Tables 5 and 6. If the designated food safety professional deems that there is the potential for microbial contamination from adjacent areas, a risk assessment shall be performed to determine the risk level as well as to evaluate potential strategies to control or reduce the introduction of human pathogens.
- DO NOT harvest areas of fields where unusually heavy activity by animals has occurred (see Figure 5 Decision Tree).
- If animal intrusions are common on a particular production field, consider fencing, barriers, noisemakers, and other practices that may reduce intrusions.

- Train harvest employees to recognize and report evidence (e.g., feces) of animal activity.
- Pooled water (e.g., a seasonal lake) from rainfall may attract animals and should be considered as part of any land use evaluation.
- Consider controlling risks associated with encroachment by urban development. Risks may include, but are not limited to, domestic animal fecal contamination of production fields and harvest equipment and septic tank leaching.
- After a significant event (such as flooding or an earthquake) that could negatively impact a sewage or septic system, take appropriate steps to ensure that sewage and septic systems continue to operate in a manner that does not contaminate produce, food contact surfaces, areas used for produce handling, water sources, or water distribution systems.
- Producers are encouraged 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. In addition, producers may wish to consult with local NRCS to evaluate the food safety risks associated with wildlife, livestock, domestic animals and other adjacent land uses and to develop and document strategies to control or reduce the introduction of human pathogens for each production block.

1153 Figure 5. PRE-HARVEST and HARVEST Assessment – Animal Hazard/Fecal Matter Decision
1154 Tree

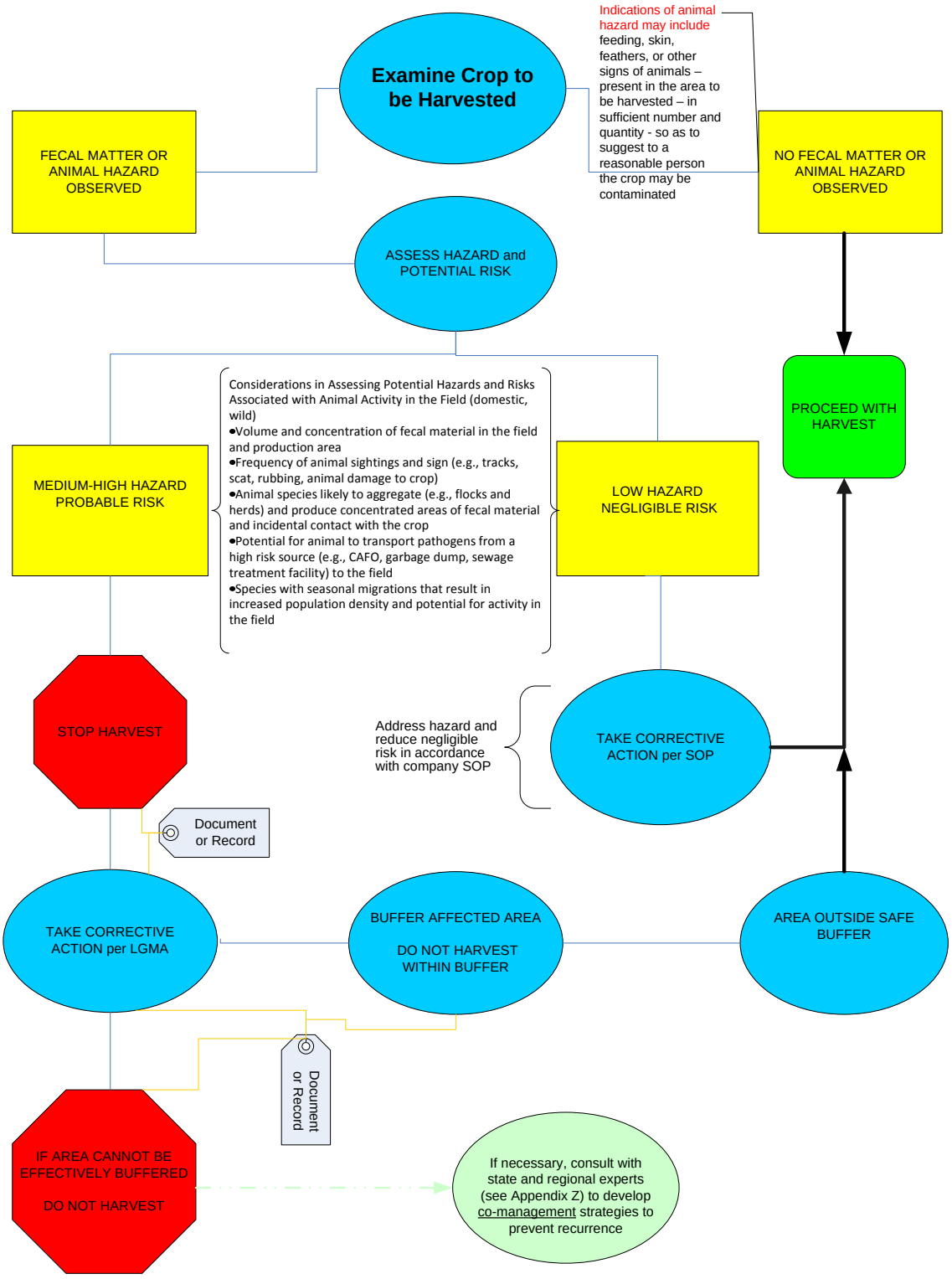


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TABLE 5. ANIMAL HAZARD IN FIELD (WILD OR DOMESTIC)

When evidence of animal intrusion in a production block occurs.

Issue	Metric	Remedial Actions
Evidence of Intrusion	Frequency • There shall be a periodic monitoring plan in place for production fields. • There shall be Pre-Season, Pre-Harvest, and Harvest Assessments Variables • Physical observation of animals in the field • Downed fences • Animal tracks in production block • Animal feces or urine in production block • Damaged or eaten plants in production block	• If there is evidence of intrusion by animals, the production block must undergo a detailed food safety assessment by appropriately trained food safety personnel (see Glossary) prior to harvest, as defined in the text of this document. • Animal intrusion events shall be categorized as low or medium/high hazard. An example of a low hazard might be a sign of animal intrusion into the leafy green production area by a single animal or solitary bird with minimal to no fecal deposition. • Corrective actions for "Low hazard" animal intrusion shall be carried out according to company SOP. • Corrective actions for "medium/high hazard" animal intrusion shall be carried out per the accepted LGMA metrics and must include food safety buffers and do not harvest areas. • In developing preventive remedial and corrective actions, consider consulting with wildlife and/or domestic animal experts as appropriate. • If remedial actions, such as appropriate no harvest buffers, cannot be formulated to control or eliminate the identified risk, do not harvest and instead destroy the contaminated crop. • Equipment used to destroy crop must be cleaned and sanitized upon exiting the field. • Formulate effective corrective actions. Prior to taking action that may affect natural resources, producers should check local, state and federal laws and regulations that protect riparian habitat and wetland areas, restrict removal of vegetation or habitat, or restrict construction of wildlife deterrent fences in riparian areas or wildlife corridors. • Food safety assessments and corrective actions shall be documented and available for verification for a period of two years.

Issue	Metric	Remedial Actions
Allowable Harvest Distance from Evidence of Intrusion	**Please see Figure 5. Decision Tree for Conducting Pre-Harvest and Harvest Assessments.** *Monitoring* Conduct periodic monitoring and, pre-season, pre-harvest and harvest assessments. Evaluate and monitor animal activity in and proximate to lettuce/leafy greens fields and production environments. *Pre-Harvest Assessment and Daily Harvest Assessment* • Conduct the pre-harvest assessment not more than one week prior to harvest. • Conduct the daily harvest assessment on each day of harvest. **Fecal Material** • Do not harvest any produce that has come into direct contact with fecal material. • If evidence of fecal material is found, conduct a food safety assessment using qualified personnel. Do not harvest any crop found within a minimum 5 foot radius buffer distance from the spot of the contamination unless remedial action can be found that adequately control the risk. The food safety professional can increase this buffer distance if deemed appropriate. **Intrusion** • If evidence of animal intrusion is found in a production field, conduct a visual food safety assessment to determine whether the intrusion is a probable (medium/high hazard) or negligible (low hazard) risk. Low hazard (negligible risk) can be corrected by following a company SOP. Medium/high hazard (probable risk) intrusion should include a three foot buffer radius where the impacted crop has been isolated. *Daily Harvest Assessment ONLY* If evidence of medium/high hazard risk animal intrusion into the production block is not discovered until harvest operations: • Stop harvest operations. • Initiate an intensified block assessment for evidence of further contamination and take appropriate actions per the aforementioned actions. • If evidence of intrusion is discovered during production block harvest operations and the harvest rig has been potentially contaminated by contaminated product or feces, clean and sanitize the equipment before resuming harvest operations. • Require all employees to wash and sanitize their hands/gloves before resuming harvest operations. • If contamination is discovered in harvest containers such as bins/totes, discard the product, and clean and sanitize the container before reuse.	
Verification	• Archive documentation for a period of two years following the intrusion event. Documentation may include photographs, sketched maps, or other means of delineating affected portions of production fields.	
Rationale	• The basis of these metrics is qualitative assessment of the relative risk from a variety of intrusions. Some animal feces and some signs of intrusion (feces vs. tracks) are considered to be of more concern than others. Because it is difficult to develop quantitative metrics for these types of risks, a food safety assessment is considered appropriate for this issue. • Individual companies need to make the determination as to the level of hazard after considering the following risk factors: the concentration and volume of fecal matter, frequency of animals (observed or indicators) in the field, density of animal population and surrounding area risk – all identified during a risk assessment. A trained food safety professional should be involved in decisions related to animal intrusion. See Appendix B for more details on the qualifications for this person. • Appendix B describes in detail the process used to develop these metrics	

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1161 **TABLE 6. CROP LAND AND WATER SOURCE ADJACENT LAND USE**

Land Use/Water Source	Metric (This distance may be either increased or decreased depending on risk and mitigation factors.)	Considerations for Risk Analysis*		
		Risk/Mitigation Factors	Increase Distance	Decrease Distance
Composting Operations (manure or animal products)	Due to the lack of science at this time, an interim guidance distance of 400 ft from the edge of crop is proposed. This number is subject to change as science becomes available. The proximate safe distance depends on the risk/mitigation factors listed to the right. Evaluate risk and document consideration of these factors. Research is being proposed to study appropriate distance.	Distance from active compost operation	--	--
		Topography: Uphill from crop	√	
		Topography: Downhill from crop		√
		Opportunity for water run off through or from composting operations	√	
		Opportunity for soil leaching	√	
		Presence of physical barriers such as windbreaks, diversion ditches, vegetative strips		√
Concentrated Animal Feeding Operations (as defined in 40 CFR 122.23)	Due to the lack of science at this time, an interim guidance distance of 400 ft from the edge of crop is proposed. This number is subject to change as science becomes available. The proximate safe distance depends on the risk/mitigation factors listed to the right. Evaluate risk and document consideration of these factors. Research is being proposed to study appropriate distance.	Fencing and other physical barriers such as berms, diversion ditches and vegetated strips can be employed to prevent intrusion of domestic animals, control runoff, etc.		√
		Topography: Uphill from crop	√	
		Topography: Downhill from crop		√
		Opportunity for water run off through or from CAFOs	√	
		Opportunity for soil leaching	√	
		Manure Management Program utilized		√
Non-synthetic Soil Amendment Pile (containing manure or animal products)	Due to the lack of science at this time, an interim guidance distance of 400 ft from the edge of crop is proposed. This number is subject to change as science becomes available. The proximate safe distance depends on the risk/mitigation factors listed to the right. Evaluate risk and document consideration of these factors. Research is being proposed to study appropriate distance.	Access and review COA for materials in question.		√
		Topography: Uphill from crop	√	
		Topography: Downhill from crop		√
		Opportunity for water run off through or from non-synthetic soil amendment storage areas	√	
		Opportunity for soil leaching	√	

Land Use/Water Source	Metric (This distance may be either increased or decreased depending on risk and mitigation factors.)	Considerations for Risk Analysis*		
		Risk/Mitigation Factors	Increase Distance	Decrease Distance
	For non-synthetic crop treatments that have been heat treated using a validated process an interim guidance distance of 30 feet from the edge of the crop is proposed	Covering on pile to prevent wind dispersion		√
Grazing Lands/Domestic Animals (includes homes with hobby farms, and non commercial livestock)	30 ft from the edge of crop.	Fencing and other physical barriers such as berms, diversion ditches and vegetated strips can be employed to prevent intrusion of domestic animals, control runoff, etc.		√
		Topography: Uphill from crop	√	
		Topography: Downhill from crop		√
		Opportunity for water run off through or from grazing lands	√	
		Opportunity for soil leaching	√	
Homes or other building with a septic leach field.	30 ft from the edge of crop to the leach field.	Active leach field: < 10 yrs old		√
		Active leach field: > 25 yrs old	√	
		Inactive leach field		√
		Topography: Uphill from crop	√	
		Topography: Downhill from crop		√
		Physical barriers		√
Well Head Distance from Untreated Manure	200 ft separation of untreated manure from wells, although less distance may be sufficient.	Topography: Uphill from manure		√
		Topography: Downhill from manure	√	
		Opportunity for water runoff from or through untreated manure to well head	√	
		Opportunity for soil leaching	√	
		Presence of physical barriers such as windbreaks, diversion ditches, vegetative strips		√
Surface Water Distance from	At least 100 feet separation for sandy soil and 200 feet	Topography: Uphill from manure		√

Land Use/Water Source	Metric (This distance may be either increased or decreased depending on risk and mitigation factors.)	Considerations for Risk Analysis*		
		Risk/Mitigation Factors	Increase Distance	Decrease Distance
Untreated Manure	separation for loamy or clay soil (slope less than 6%; increase distance to 300 feet if slope greater than 6%) is recommended.	Topography: Downhill from manure	√	
		Opportunity for water runoff from or through untreated manure to surface waters.	√	
		Opportunity for soil leaching	√	
		Presence of physical barriers such as windbreaks, diversion ditches, vegetative strips		√
Rationale	• The bases for these distances above is best professional judgment of authors, contributors, and expert reviewers to prevent potential cross-contamination from adjacent land uses, taking into consideration the 200 foot distance cited in FDA (US FDA 2001) for separation of manure from wellheads and the 30 foot turn-around distance for production equipment. Because of the numerous factors that must be taken into account to determine appropriate distances, a qualitative assessment of the relative risk from various types of land use and surface waters was used to determine appropriate distances.			

*Producers 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. Producers 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.

17. TRANSPORTATION

When transporting lettuce/leafy greens on the farm or from the farm to a cooling, packing, or processing facility, manage transportation conditions to minimize the risk of contamination. Food contact surfaces on transportation equipment and in transporter vehicle cargo areas that are not properly maintained are potential sources of contamination.

The Best Practices Are:

- Visually inspect all shipping units and equipment used to transport leafy greens on the farm or from the farm to a cooling, packing, or processing facility to ensure they are:
  - In good, working condition; and
  - Clean before use in transporting lettuce/leafy greens.

18. DETAILED BACKGROUND GUIDANCE INFORMATION

Required Reference Documents

1. FDA Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (www.foodsafety.gov/~dms/prodguid.html)
2. UFFVA Food Safety Auditing Guidelines: Core Elements of Good Agricultural Practices for Fresh Fruits and Vegetables
3. UFFVA Food Safety Questionnaire for Fresh Fruits and Vegetables
4. National GAPs Program Cornell University: Food Safety Begins on the Farm: A Grower Self-Assessment of Food Safety Risks

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