ARIZONA LGMA

September 16, 2022

COMMODITY SPECIFIC FOOD SAFETY GUIDELINES

FOR THE PRODUCTION AND HARVEST OF LETTUCE AND LEAFY GREENS

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Accepted by the Arizona Leafy Greens Food Safety Committee on ~~September 16, 2022~~August 31st, 2023

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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GLOSSARY

Disclaimer: Please note the definitions presented here are simplified, functional definitions that have been derived from various resources for specific use in this document and may differ from definitions used in relevant federal, state, and local regulations.

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.
ADJACENT / NEARBY LAND	Land within a proximity that could potentially affect safe production of leafy greens.
AERATED STATIC PILE	Composting process where active ingredients are covered with an insulating material and air is forced through the product. The product is maintained at a minimum of 131 degrees Fahrenheit for 3 days.
AERIAL APPLICATION	Any application administered from above leafy greens where water may come in contact with the edible portion of the crop; may be delivered via aircraft, sprayer, sprinkler, etc.
AEROSOLIZED	The dispersion or discharge of a substance under pressure that generates a suspension of fine particles in air or other gas.
ANIMAL FEEDING OPERATION (AFO)	Animal Feeding Operation (AFO)- are agricultural operations where animals are kept and raised in confined situations. An AFO is a lot or facility (other than an aquatic animal production facility) where the following conditions are met: *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.Less than 1000 animal units does not meet the requirements of a CAFO.
AGRICULTURAL / COMPOST TEA	A water extract of biological materials (such as compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, table waste, or yard trimmings), excluding any form of human waste, produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase. Agricultural / Compost teas are held for longer than one hour before application and are considered non-synthetic crop inputs for the purposes of this document.

AGRICULTURAL MATERIAL	*Agricultural Material* means waste material of plant or animal origin, which results directly from the conduct of agriculture, animal husbandry, horticulture, aquaculture, silviculture, vermiculture, viticulture and similar activities undertaken for the production of food or fiber for human or animal consumption or use, which is separated at the point of generation, and which contains no other solid waste. With the exception of grape pomace or material generated during nut or grain hulling, shelling, and processing, agricultural material has not been processed except at its point of generation and has not been processed in a way that alters its essential character as a waste resulting from the production of food or fiber for human or animal consumption or use. Agricultural material includes, but is not limited to, manures, orchard and vineyard prunings, grape pomace, and crop residues.
AGRICULTURAL TAILWATER	Excess run off water which is generated and collected during the process of irrigation.
ANCILLARY EQUIPMENT	Temporary storage equipment for fertilizers such as third-party storage tanks, pony tanks, etc.
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 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).
AGRICULTURAL WATER SYSTEM	Each distinct, separate combination of water source, conveyance, storage used to carry water from its primary source to its point of use; includes wells, irrigation canals, pumps, valves, storage tanks, reservoirs, meters, pipes, fittings, and sprinklers.
AGRICULTURAL WATER TREATMENT SYSTEM	An add-on to an agricultural water system that improves the quality (safety) of the water to make it more acceptable for a specific end- use. The agricultural water treatment system may treat multiple ranches, water sources or batches of water as defined by the water system description.
ANIMAL BY-PRODUCT/PRODUCT	Parts of an animal that do not include muscle meat including organ meat, nervous tissue, cartilage, bone, blood and excrement. This also include worm castings, guano, and other animal-based products and excrements.
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.
ANIMAL UNIT	There are three approaches to defining an animal unit: cow-calf unit, 1,000 pounds of live weight of any species, and on an energy basis.
ANTIMICROBIAL WATER TREATMENT	A physical, energetic, or chemical agent, applied alone, in combination, or as a sequential process, to achieve and maintain a defined microbiological water quality standard.

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.
BIOLOGICALS	Biologicals are products that contain beneficial, naturally occurring microorganisms or microbial derivatives as active ingredients.
BIORATIONALS	Biorationals are non-synthetic input materials in agriculture that are derived from natural sources such as microorganisms, biochemicals, minerals, organic materials, and plant extracts
BIOSOLIDS	Solid, semisolid, or liquid residues generated during primary, secondary, or advanced treatment of domestic sanitary sewage through one or more controlled processes. **Class A:** Class A biosolids undergo a "Process to Further Reduce Pathogens (PFRP)." Pathogens are reduced to a level similar to the native soil and environment. Class A biosolids products can be used on hand golf courses, and other places where public contact is likely. Class A biosolids products include composted biosolids, lime pasteurized biosolids, and fertilizer pellets. Class A biosolids products are soil amendments, potting soils, and slow-release fertilizers. **Class B:** Class B biosolids undergo a "Process to Significantly Reduce Pathogens (PSRP)." This means that while pathogens are significantly reduced to levels which are often below those found in animal manure, management practices (BMPs) are required at the site where they are used. Class B biosolids are used in bulk as fertilizers in agriculture and forestry and to reclaim barren lands. Site permits are required.
BLUE VALVE	Pipes which are used as a closed conveyance system for moving agricultural surface water from water source to irrigation systems or reservoirs for agricultural use.
BREAKPOINT	The point at which the disinfection demand has been met.
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.
CARBOHYDRATE	Ingredient for soil amendments and crop inputs that could improve growth of bacteria.

CLOSED DELIVERY SYSTEM	A water storage or conveyance system which is fully enclosed and protected such that water is not exposed to the environment from the water source to the point of use.
COLONY FORMING UNITS (CFU)	Viable microorganisms (bacteria, yeasts and 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-spore-forming, 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.
COMPOST/MATURE COMPOST	C*ompost* is the product manufactured through the controlled aerobic, biological decomposition of biodegradable materials. The product has undergone mesophilic and thermophilic temperatures, which significantly reduces the viability of pathogens and weed seeds and stabilizes the carbon such that it is beneficial to plant growth. Compost is typically used as a soil amendment but may also contribute plant nutrients.
COMPOST FEEDSTOCK	“Feedstock” means any compostable material used in the production of compost or chipped and ground material including, but not limited to, agricultural material, green material, vegetative food material, food material, biosolids, digestate, and mixed material. Feedstocks shall not be considered as either additives or amendments.
COMPOSTING	Means a process to produce compost in which organic material is decomposed by the actions of microorganisms under thermophilic conditions for a designated time period (for example, 3 days) at a designated temperature (for example, 131 °F (55 °C)), followed by a curing stage under cooler conditions.
COVERED PRODUCE	Commodities that FDA has identified as typically consumed raw. For our purposes this is for lettuce and leafy greens.
CROSS-CONTAMINATION	The transfer of microorganisms, such as bacteria and viruses, from one place to another.

CROP INPUT	Crop inputs are materials that 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.
CURING	The secondary phase of the composting process. As the active phase slows down and the temperature drops, mesophilic microorganisms recolonize and continue to breakdown the remaining organic matter. This process is also known as or referred to as the maturation step.
DETECTION LIMIIT	A detection limit is the lowest quantity of a substance or measurable target that can be distinguished from the absence of that substance or measurable target.
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* (EHEC)	Shiga toxin-producing *E. coli* clinically associated with bloody diarrhea.
***ESCHERICHIA COLI* (*E. COLI*)**	*Escherichia coli* are common bacteria that live in the lower intestines of animals (including humans) and are generally not harmful. *E. coli* are 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."
FIELD EQUIPMENT	Equipment used to: prepare the production area and plant, cultivate, fertilize, treat or any other pre-harvest in-field activities.
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 MATERIAL	*Food Material* means a waste material of plant or animal origin that results from the preparation or processing of food for animal or human consumption and that is separated from the municipal solid waste stream. Food material includes, but is not limited to, food waste from food facilities, food processing establishments, grocery stores, institutional cafeterias (such as prisons, schools and hospitals), and residential food scrap collection. Material that is defined as "food material" is not agricultural material.
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 principals 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.
GRAZING LANDS	Grazing Lands include grasslands, savannas, and shrub lands that are grazed by livestock.
GREEN WASTE	Any plant material that is separated at the point of generation contains no greater than 1.0 percent of physical contaminants by weight. 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/SOIL	Ground – solid surface of the Earth. Soil – upper layer of the Earth in which plants grow. [growing media] These two words are considered synonymous throughout and for the purpose of the document.
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.
HABITAT	The natural home or environment of an animal, plant, or other organism.
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 of, and washing.
HARVEST EQUIPMENT	Any kind of equipment which is used during or to assist with the harvesting process including but not limited to harvesting machines, food-contact tables, belts, knives, etc.
HAZARD	Any biological, physical, or chemical agent that has the potential to cause illness or injury in the absence of its control.
HEAT TREATED SOIL AMENDMENTS AND CROP INPUTS	Soil amendments and crop inputs that have been physically heat treated and dried in accordance to standards issued by the USDA.
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.
INCOMPLETELY COMPOSTED MANURE /IMMATURE COMPOST	Any form of compost that has not gone through a complete, validated, composting process approved by the LGMA and does not have tests showing that Fecal Coliforms, *E. coli*, *E.coli O157:H7,* Listeria, and Salmonella have been eliminated.
INDICATOR MICROORGANISMS	An organism that when present suggests the possibility of contamination or under processing.
IRRIGATION WATER TREATMENT	Any system used to treat agricultural water so it makes the quality adequate for its intended use
KNOWN OR REASONABLY FORESEEABLE HAZARD	Known or reasonably foreseeable hazard means a biological, chemical, and physical hazard that is known to be, or has the potential to be, associated with the farm or the food.
LETTUCE AND 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.
LISTERIA	Any of a genus (*Listeria*) of small, gram-positive, rod-shaped bacteria that do not form spores and have a tendency to grow in chains and that include one (*Listeria monocytogenes*) that causes listeriosis.
LOT (PERTAINING TO SOIL AMENDMENTS AND CROP INPURTS OTHER THAN COMPOST)	Lot means a specific quantity of a finished product or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

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 producer's control "monthly" for purposes of water sampling means within 35 days of the previous sample.
MORTALITY COMPOST	*Mortality Compost* is compost created through a process to manage livestock mortalities. The use of crop inputs, made from mortality composting processes, shall follow all local, state and federal regulations
MOST PROBABLE NUMBER (MPN)	Estimated values that are statistical in nature; a method for enumeration of microbes in a sample, particularly when present in small numbers.
MUNICIPAL WATER	Water that is processed and treated by a municipality to meet USEPA drinking water standards.
NON-DETECT	Non-detect means not present but consideration should be given to the limit of detection of the approved laboratory method used for biological or chemical analysis.
NON-SYNTHETIC SOIL AMENDMENTS AND CROP INPUTS OF ANIMAL ORIGIN	Any soil amendment and/or crop input that contains animal manure, an animal product, and/or an animal by-product that is reasonably likely to contain human pathogens. Includes agricultural or compost teas for the purposes of these guidelines.
OPEN DELIVERY SYSTEM	A water storage or conveyance system which is partially or fully open and unprotected such that water is exposed to the environment at any point from the water source to the point of use.
PACKING	Placing leafy greens into a container other than packaging them and also includes activities performed incidental to packing (*e.g.,* activities performed for the safe or effective packing of leafy greens (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)).
PARTS PER MILLION (PPM)	Usually describes the concentration of something in water or soil; one particle of a given substance for every 999,999 other particles.
PATHOGEN	A disease-causing agent such as a virus, parasite, or bacteria.
PEST	Any objectionable animals or insects, including birds, rodents, flies, and larvae.
POOLED WATER	An accumulation of standing water; not free-flowing.
POST-CONSUMER WASTE	*Post-consumer waste* is a waste type produced by the end consumer of a material stream. Generally, this is discarded materials after something has been used. Post-consumer waste can include items such as packaging and unconsumed food.

POTABLE WATER	Water that is safe to drink or to use for food preparation without risk of health problems.
PRE-CONSUMER WASTE	A food item that was produced for consumption but that was never purchased, consumed or used.
PROCESS AUTHORITY	A regulatory body, person, or organization that has specific responsibility and knowledge regarding a particular process or method; these authorities publish standards, metrics, or guidance for these processes and/or methods.
READY-TO-EAT (RTE) FOOD ***(EXCERPTED FROM USFDA 2005 MODEL FOOD CODE)***	(1) "Ready-to-eat food" means FOOD that: (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.
RECONDITIONED/RE-PROCESSED	Finished product that is added to a new production lot and goes through the entire validated production process. The old, finished product is now part of the new lot and testing of the new lot must follow all current requirements for LGMA testing before the product is used.
RESPONSIBLE PARTY	The signatory is deemed to be the responsible party for purposes of the Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens. The signatory must assign or identify personnel to supervise or otherwise be responsible for food safety SOPs requiring responsible party oversight.
RIPARIAN AREA	A vegetated ecosystem along a waterbody through which energy, materials, and water pass. Riparian areas characteristically have a high water table and are subject to periodic flooding and influence from the adjacent waterbody. These systems encompass wetlands, uplands, or some combination of those two landforms. They will sometimes, but not in all cases, have all the characteristics necessary for them to be also classified as wetlands (USEPA 2005).
RISK	A function of the likelihood (high, medium, low) of occurrence of an adverse health effect and the severity of that effect, consequential to a hazard(s).
RISK MITIGATION	Actions to reduce the severity/impact of a risk.
ROOT CAUSE ANALYSIS	A process for systematic investigation where incident-specific information is assembled, and problem-solving techniques are used to analyze and evaluate why an incident or event happened.
SALMONELLA	*Salmonella* is a Gram-negative facultative rod-shaped bacterium in the same proteobacterial family as Escherichia coli, the family Enterobacteriaceae, trivially

	known as "enteric" bacteria. Salmonellae live in the intestinal tracts of warm, and cold blooded, animals. In humans, Salmonella is the cause of two diseases called salmonellosis: enteric fever (typhoid), resulting from bacterial invasion of the bloodstream, and acute gastroenteritis, resulting from a foodborne infection/intoxication.
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.
SEDIMENT	Undissolved organic and inorganic material transported or deposited by water.
SHIGA-TOXIN PRODUCING E. COLI (STEC)	Bacteria found in the environment, foods, and animal and human intestines that produce a potent disease-causing toxin. The serogroup most commonly identified and associated with severe illness and hospitalization in the United States is *E. coli* O157; however, there are over 50 other serogroups that can also cause illness.
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	Water either stored or conveyed on the surface and open to the environment. (e.g. rivers, lakes, streams, reservoirs, etc.)
SYNTHETIC SOIL AMENDMENTS AND CROP INPUTS (CHEMICAL FERTILIZERS)	Any soil amendments and/or 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.).
TOTAL COLIFORMS	Total coliforms are a group of related bacteria that are (with few exceptions) not harmful to humans. This family of bacteria are found in soil and water. The EPA considers total coliforms to be a useful indicator of the possible presence of other pathogens for drinking water. Total coliforms are used to determine the adequacy of water treatment and the integrity of a water distribution system.
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 though a statistically based study, literature, or regulatory guidance.
VALIDATION	The act of determining whether products or services conform to meet specific requirements.

VEGETATIVE MATERIAL	*Vegetative material* means food material resulting from the production or processing of food for animal or human consumption, but is no longer intended for such consumption, that is derived solely from plants and is separated from the municipal solid waste stream.
VERIFICATION	The act of confirming a product or service meets the requirements for which it was intended.
VESSEL COMPOST PROCESS	Enclosed composting process where ingredients are maintained at a minimum of 131 degrees Fahrenheit for at least 3 days.
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 - to carry water from its primary source to a lettuce and leafy green crop.
WATER SOURCE	The location from which water originates; water sources can be municipal, well or surface water such as rivers, lakes or streams.
WATER TREATMENT	Any process that improves the quality (safety) of the water to make it more acceptable for a specific end-use.
WATER USE	The method by which water is being used in the agricultural process.
WELL	An artificial excavation put down by any method for the purposes of withdrawing water from the underground aquifers. A bored, drilled, or driven shaft, or a dug hole whose depth is greater than the largest surface dimension and whose purpose is to reach underground water supplies

ACRONYMS AND ABBREVIATIONS

AFO	Animal feeding operation
AOAC	AOAC International (formerly the Association of Official Analytical Chemists)
AU	Animal units
CAFOs	Concentrated animal feeding operations
CFU	Colony Forming Units
cGMP	Current Good Manufacturing Practices
COA	Certificate of Analysis
DL	Detection Limit
FDA	Food and Drug Administration
FSMA	Food Safety Modernization Act
GAPs	*Good Agricultural Practices*
GLPs	Good laboratory practices
HACCP	Hazard Analysis Critical Control Point
ISO	International Organization for Standardization
mL	Milliliter
MPN	Most Probable Number
NRCS	Natural Resources Conservation Service
PPM	Parts per million
SOP	Standard Operating Procedure
SSOPs	Sanitation Standard Operating Procedures
STEC	Shiga-toxin producing *E. coli*
TMECC	Test Methods for the Examination of Composting and Compost US EPA
USDA	United States Department of Agriculture
US EPA	United States Environmental Protection Agency
UV	Ultraviolet
WHO	World Health Organization

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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 the FDA's guidance 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 and nearby land use, water quality, worker hygiene, pesticide and fertilizer use, equipment sanitation and product transportation.

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.

The vast majority of the lettuce/leafy greens industry have 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.

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 the continued concerns regarding the microbial safety of fresh produce, these guidelines were 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 revisions is to identify, where possible and practical, metrics and measures that can be used to assist the industry in complying with these industry guidelines.

In preparing the original 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, an *Agricultural Water System Assessment* document that describes the processes for assessing the integrity and remediation of agricultural 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 that 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 the FDA but may not be similarly defined by other state or federal regulatory bodies. This document is also limited to offering food safety best 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 primarily on minimizing 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 should 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 leafy greens 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 that Appendix Z be reviewed when any mitigation strategies could potentially impact these areas. 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 FDA, the Center for Produce Safety, the U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (U.S. EPA), the Centers for Disease Control and Prevention (CDC), and state agricultural, environmental, academic, wildlife and natural resources management agencies and/or public health authorities.

The Agricultural Water System Assessment and Technical Basis Document prepared as Appendices to these guidelines 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 OPERATIONS

1. PURPOSE

The issues identified in this document are based on the core elements of Good Agricultural Practices. The specific recommendations contained herein are intended for lettuce and leafy greens only. If these specific recommendations are effectively implemented this would constitute the best practices for a GAP program for the production and harvest unit operations of lettuce and leafy greens.

2. GENERAL REQUIREMENTS

In addition to the area-specific requirements discussed in latter sections, there are several general requirements that are part of an effective best practices program. These requirements are outlined below.

THE BEST PRACTICES ARE:

- A written Leafy Greens Compliance Plan shall be prepared that specifically addresses the Best Practices listed in this document. This plan shall address as a minimum the following areas: water, soil amendments, crop inputs, 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. RECORDS

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

THE BEST PRACTICES ARE:

- ~~Signatory must assign or identify personnel to supervise (or otherwise be responsible for) your operations to ensure compliance with the requirements of this part. This must be documented.~~
- All records must include (as applicable to the record):
  - 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 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:

Commented [KVH1]: Remove requirement to have Signatory assign or identify personnel that sign off on records as voted on by TSC 7.11.23

- 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)
- Reviewed, dated, and signed after the records are made ~~by a supervisor or responsible party~~ within the timeframes specified in the leafy greens compliance plan (e.g., harvesting records, soil amendments/crop inputs, training, water).

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- All records and documents of policies, procedures, and activities to fulfill requirements related to the Leafy Greens Compliance Plan shall be maintained on-site, at an off-site location, or accessible electronically and shall be available for inspection by the end of the day the audit is conducted.
- Existing records (e.g., records that are kept in compliance with other federal, state, or local regulations or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements herein. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this section. Records must be kept in the original, electronically, or 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. 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.
  - For personnel conducting environmental hazard and risk assessments, training must be completed, and the training program must address the following minimum requirements:
    - When an environmental hazard or risk assessment should be completed
    - How to conduct an environmental hazard or risk assessment
    - Potential hazard and risk identification
    - Recognizing product that may be contaminated with known or reasonably foreseeable hazards
    - Mitigations and corrective actions
    - When an environmental hazard or risk assessment deems pre-harvest product testing is necessary
- 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 reasonable time per company's SOP after the records are made, by a supervisor or responsible party.

5. Environmental Assessments

This section addresses assessments that shall be completed and documented prior to the first seasonal planting, within one week prior to harvesting and during harvest operations. These environmental assessments are intended

to identify any issues related to the produce field, adjacent and nearby land uses, and/or animal hazards that may present a risk to the production block or crop (see Table 6 and Table 0).

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 and nearby land uses for possible sources that might contaminate the production field, and evaluating nearby water sources for the potential of past or present flooding.
- The pre-season environmental assessment at a minimum must address crop land and water source adjacent and nearby land uses listed in Table 0:
  - **Assessment of Produce Field**
    - Evaluate all produce fields for evidence of animal hazards and/or feces prior to the first seasonal planting, within one week prior to harvesting, and during harvest operations. If any evidence is found, follow procedures identified in Issue 15 "Production Locations - Encroachment by Animals and Urban Settings."
    - Evaluate potential environmental sources of contaminants in or near production locations after a change in weather conditions or weather events that could impact the original risk assessment, pre-harvest, or daily harvest of the field or block and follow procedures identified in Issue 14 "Production Locations - Climatic Conditions and Environment".
  - **Assessment of Adjacent and Nearby Land Use**
    - Prior to the first seasonal planting, conduct and document a detailed pre-season environmental risk assessment that evaluates food safety hazards and risk level of all land and water sources adjacent and nearby to all production fields for possible sources of human pathogens of concern. These sources include, but are not limited to manure storage, compost storage and operation, biosolids, CAFO's, AFO's, grazing lands, domestic animals/hobby farms, water storage and conveyance, habitat/riparian area, sanitary facilities, septic systems, and non-leafy green crops (see Table 0 and Appendix H: Risk Assessment Tool-Reserved for further detail). If any possible sources on adjacent or nearby lands that might result in produce contamination are present, consult with the metrics and refer to Appendix Z.
    - At any time prior to planting, during the growing of the crop, or during the period when harvest operations are occurring, if on farm or adjacent and nearby land activities result in a possible higher risk situation, conduct additional environmental risk assessments and perform additional mitigations as necessary.

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  - **Assessment of CAFOs**
    - ~~At any time prior to planting, during the growing of the crop, or during the period when harvest operations are occurring, if on farm or adjacent and nearby land activities result in a possible~~
    - Conduct and document a rigorous pre-season environmental assessment of any Concentrated Animal Feeding Operation that may impact your operation. Include, to the degree possible, communication with the CAFO operator and/or third-party operator to document Best Management Practices (BMPs) within the facility, examination of the CAFO for locations and risk associated with composting, storage, sick pens, dead piles and other internal operations, examination of traffic routes associated with the CAFO and examine settling and manure ponds for any signs of leakage. Note if the CAFO drainage or discharge is a possible source of

contamination. Record the approximate number of animals within the CAFO and the method used to determine.

- Conduct and document a pre-harvest assessment that confirms no changes in pre-season conditions. Note if any discharge events that may impact your crop or operations; changes in weather condition or weather events occurred during the production period.
- Water sources that are proximate to a CAFO may pose additional risk and should be closely evaluated. Refer to Appendix A: Agricultural Water System Assessment.

- **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 Issue 13 “Flooding”.

TABLE 0. CROP LAND AND WATER SOURCE ADJACENT AND NEARBY LAND USE

Adjacent and Nearby Land Uses Hazards		Current Metric	Considerations for Risk Analysis	
			Factors to consider when assessing severity and likelihood of a hazard	Risk Mitigating Factors
Animal operations	**AFOs**	30 feet (no composting) 400 feet (with composting)	Distance, topography, water runoff, number of animal units, wind direction, history	Pre-harvest pathogen testing, water treatment, vegetative buffers, barriers, increased buffers, animal and insect monitoring
	CAFO	1200 feet (1,000 - 80,000 animals)	Distance, topography, water runoff, number of animal units, wind direction, history	Pre-harvest pathogen testing, water treatment, vegetative buffers, barriers, increased buffers, animal and insect monitoring
	CAFO	1 mile (80,000+ animals)	Distance, topography, water runoff, number of animal units, wind direction, history	Pre-harvest pathogen testing, water treatment, vegetative buffers, barriers, increased buffers, animal and insect monitoring
	Grazing Lands	30 feet	Distance, topography, water runoff, number of animal units, wind direction, history	Pre-harvest pathogen testing, water treatment, vegetative buffers, barriers, increased buffers, animal and insect monitoring
	Domestic Animals/Hobby Farms	30 feet	Distance, topography, water runoff, number of animal units, wind direction, history	Pre-harvest pathogen testing, water treatment, vegetative buffers, barriers, increased buffers, animal and insect monitoring
Compost/Soil Amendment Operations	**Compost Operations** (Manure or Animal Products)	400 feet	Distance, Timing of production, Production Process, Volume of production, Topography, Water runoff, Wind direction, History	Preventive barriers, Pre-harvest pathogen testing, Knowledge of process, Water Treatment
	Non-synthetic Soil Amendment Pile (containing manure or animal products)	400 feet	Distance, Timing of production, Production Process, Volume of production, Topography, Water runoff, Wind direction, History	Preventive barriers, Pre-harvest pathogen testing, Knowledge of process, Water Treatment
	Non-synthetic Soil Amendment Pile (not containing manure or animal products)	400 feet	Distance, Timing of production, Production Process, Volume of production, Topography, Water runoff, Wind direction, History	Preventive barriers, Pre-harvest pathogen testing, Knowledge of process
	Biosolids	400 Feet	Distance, Timing of production, Production Process, Volume of production, Topography, Water runoff, Wind direction, History	Preventive barriers, Pre-harvest pathogen testing, Knowledge of process

TABLE 0. CROP LAND AND WATER SOURCE ADJACENT AND NEARBY LAND USE

Non-leafy green crops	**Cannabis/hemp, cover crops, dates, flowers, grapes, other non-leafy green crops**	The approximate safe distance depends on risk and mitigation factors	History of risk identification, Distance from adjacent operation, Topography, Crop production timeline, Foreign object, Animal/Bird attractant, Grazing animals, Harvest practices.	Physical barriers, Pre-harvest pathogen testing, Increased monitoring, Knowledge of process
Water Source and Systems	**Well Head distance from Untreated Manure**	200 feet	History of risk identification, Distance from adjacent operation, Topography, Opportunity for water run off through or from untreated manure, or composting operations, Soil leaching	Adjacent operation management practices, Increased monitoring, Preventive barriers, Type of system (Closed vs Open), Water treatment
	Surface Water Distance from Untreated Manure	100-300 feet	History of risk identification, Distance from adjacent operation, Topography, Opportunity for water run off through or from untreated manure or composting operations, Flooding, Soil Leaching	Adjacent operation management practices, Increased monitoring, Preventive Barriers, Water Treatment
	Water Storage and Conveyance systems	30-300 feet	History of risk identification, Distance from adjacent operation of concern, Topography, Flooding, Animal Intrusion, Trash and debris, Excessive vegetation, Integrity of water storage, Conveyance and distribution History of risk identification, Distance from adjacent operation of concern, Topography, Flooding, Animal Intrusion, Trash and debris, Excessive vegetation, Integrity of water storage, Conveyance and distribution system	Adjacent operation management practices, Increased monitoring, Type of System (Closed vs Open), Water Treatment
Urban Settings	**Homes or other building with a septic leach field**	30 feet	History of risk identification, Distance, Topography, Leach field status (active vs inactive), Runoff	Preventive barriers, Knowledge of septic field
Other Environmental Considerations	**Habitat/Riparian Area**	The approximate safe distance depends on risk and mitigation factors.	History of risk identification, Distance from potential risk, Topography, Potential for animal intrusion, Physical hazards	Preventive barriers, Increased Monitoring

Producers should check for local, state, and federal laws and regulations that protect riparian habitat and wildlife, restrict removal of vegetation or habitat, or restrict the use of wildlife deterrents or construction of wildlife deterrent fences in riparian areas or wildlife corridors. Producers may want to contact the relevant agencies (e.g., Game & Fish Department, USDA APHIS Wildlife Services – Arizona Division, U.S. Fish and Wildlife Services) to confirm the details of these requirements.

PRE-HARVEST PRODUCT TESTING

Pre-harvest product testing is one of many tools that can help assess the potential for lot-specific product contamination and assist in developing a long-term view of food safety system performance. The FDA's Food Safety Modernization Act - Produce Safety Rule requires the fresh produce industry take all measures reasonably necessary to identify and not harvest covered produce that is reasonably likely to be contaminated with known or reasonably foreseeable hazards. Standard operating procedures ensure consistency for routine and non-routine sampling events and should address voluntary and or routine sampling, instances when environmental risk assessments deem pre-harvest testing is necessary, water criteria failure, unusual occurrences, and for-cause incidents.

THE BEST PRACTICES ARE:

- Pre-harvest product testing is required when environmental risk assessments deem it is necessary.
- Develop a pre-harvest testing SOP. When deciding on sampling plans, see Appendix C for sampling plan options and recommendations. The SOP must address the following minimum requirements:
    - All lettuce and leafy green commodities. If testing programs differ by commodity, outline in the SOP.
    - Sampling timeline. An interval closer to estimated harvest date is considered a best practice.
    - Target organisms. Test for E. coli O157:H7, STEC/EHEC, and Salmonella.
    - Sampling lot size. Sampling lot size may decrease when risk is elevated.
    - Sample size.
    - Number of grabs. More individual grabs per lot improves the probability of contamination detection.
    - Sampling method. Laboratories used for analytical parameters must be certified and/or accredited by recognized State, Federal, or international bodies (ISO) for the analytical methods being reported and the matrices being analyzed.
    - Risk considerations, including when a sampling plan should be more stringent based on the identified risk.
    - Develop a test and hold policy.
    - Corrective measures to be taken when positive samples are detected.
    - Records review and documentation
- Samples must be taken by a trained sampler. If utilizing in-house samplers, implement mandatory training on the sampling protocol for personnel conducting pre-harvest product testing.
- If a positive test result is reported, **do not** harvest the sampling lot. Determine if further investigation and root cause analysis (RCA) is of value based on observations and elective follow-up sampling. Utilize industry guidance[1] on how to evaluate the value of and conduct RCA activities.

How to Conduct a Root Cause Analysis at RCA Guidance for the Produce Industry How to do RCA.pdf (wga.com)

6. ISSUE: WATER

The safety of whole fresh and fresh-cut (e.g., bagged salad) leafy greens is a longstanding issue. Leafy greens are mostly consumed raw without cooking or processing steps to eliminate microbial hazards. Therefore, the way they are grown, harvested, packed, held, processed, and distributed is crucial to ensuring that the risk of human pathogen contamination is minimized. These metrics are intended to prioritize risk by classifying agricultural water systems for specific uses within leafy greens operations. Remedial actions follow a "find and fix" structure to identify and correct both system nonconformities and more serious failures. These metrics should be considered the minimum controls necessary to assess agricultural water systems for fitness of use.

GENERAL AGRICULTURAL WATER MANAGEMENT - THE BEST PRACTICES ARE:

- Agricultural water systems are a function of the source, storage, and conveyance. Each component of an agricultural water system that is within your control must be evaluated to ensure that the quality of agricultural water used in leafy green operations is known (i.e., the required parameters are measured and conform to the prescribed standards) and adequate for its intended use.
- It's prudent to evaluate and make a good faith effort to address the food safety hazards proximate to your agricultural water systems that may not be under your control.
- NEVER use water from any water source that has not been microbially characterized.
- Perform an Agricultural Water Assessment, as described in Appendix A, prior to use of water in agricultural operations. An agricultural 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 or other natural or managed features which prevent environmental runoff from entering the water system). Permanent fixtures include wells, gates, reservoirs, valves, returns and other permanent above ground fixtures 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. All components of your agricultural water system that are within your control including the water source and the on-ranch (farm) distribution /conveyance system(s) must be managed and maintained in a manner that minimizes human pathogen contamination. Testing water at the end of the delivery system (e.g., the last sprinkler head) or the point-of-use is essential for ensuring water that contacts the crop is of adequate microbial quality. 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.
- Water systems that convey untreated human or animal waste are never suitable for use in leafy greens operations in any manner and must be separated from conveyances utilized to deliver agricultural water.
- Water records must be reviewed, dated, and signed, within a week after the records are made, by a supervisor or responsible party.

HAZARD ANALYSIS - STEP 1: ASSESSMENT OF AGRICULTURAL WATER SYSTEMS

Evaluating food safety hazards from agricultural water applications in leafy green operations must take into account the quality of the agricultural water system, how the agricultural water will be applied, and when it will be applied. Prior to using water in any leafy green operation, conduct an agricultural water system assessment (including source, storage, and conveyance as described in Appendix A) and determine the agricultural water system type.

There are two types of agricultural water systems used in leafy green operations:

- **Type A:** Agricultural water that is unlikely to contain indicators of fecal contamination either due to natural hydrogeologic filtration or through controlled USEPA and state regulated treatment regime as demonstrated by an agricultural water system assessment as outlined in Appendix A, microbial testing, and when applicable, treatment verification.
- **Type B:** All other agricultural water systems.

1) **Source**: Evaluate each agricultural water source used in your leafy green operations and determine its type.
    a) Some agricultural water sources are supplied by a third-party provider that certifies the water is of adequate microbial quality (i.e., unlikely to contain indicators of fecal contamination). Example of these sources are:
        - Public (e.g., municipal) or private providers that deliver certified potable water achieved through treatment or some other process
    b) Some agricultural water sources deliver water of appropriate microbial quality due to natural physical, chemical, and biological processes that filter water as it passes through the soil. Examples of these sources for Type A agricultural water systems are:
        - Wells constructed in a manner such that contamination from outside sources (e.g., surface water or other surface chemical or biological influences / effects) is unlikely (e.g., well heads are protected, maintained, and monitored; see Appendix A for additional guidance), and water is tested to conform to standards.
        - Regulated recycled water (e.g., tertiary treated, purple pipe, etc.) providers that treat, test, and deliver water that is suitable for use in agricultural applications.[1]
    c) Some agricultural water sources are part of a Type A system due to on-ranch treatment that, when operating under validated and verifiable parameters, turns Type B water into Type A. An example of a water source used in a Type B → A agricultural water system is:
        - Treated surface water (verified to conform to standards)
    d) Some agricultural water sources are considered part of a Type B system because they are vulnerable to contamination and have not been treated to achieve adequate microbial reduction and shall be used in a manner that minimizes contamination of the crop. Examples of water sources in a Type B agriculture water system are:
        - Wells that may be vulnerable to contamination by outside sources including surface waters or by other surface chemical or biological influences / effects)
        - Untreated surface water
2) **Storage and conveyance**: Agricultural water source is only one component of an agricultural water system. An agriculture water system that starts out with water of appropriate microbial quality at the source may change quality as it progresses through the delivery system. Microbial water quality depends on the properties of the agricultural water system's components and how they are maintained (for more on system maintenance, see the section below on *Best Practice for Managing Storage and Conveyance*

[1] State regulations vary for recycled water. In some states recycled water for produce production allows a certain level of generic *E. coli*, total coliforms, and/or fecal coliforms.

Systems). Agricultural water systems are typically opened or closed. For the purposes of this document, these systems are defined as follows:

- Closed delivery systems store or convey agricultural water in a manner that does not expose it to the outside environment and where water maintains the initial source type. Water from closed delivery systems must be tested at the end of the system to verify water quality is unchanged as it moves through the system. Additional details about testing requirements for a closed delivery system is provided in Tables 2B and 2C, and guidance is provided in Appendix A.
- Open delivery systems, at some point in the system, store or convey agricultural water in a manner that exposes it to the outside environment (i.e., a reservoir / pond, canal, lateral, uncovered water tank, etc.). Water in open delivery systems (e.g., reservoirs and ponds) may be used in overhead applications within 21 days to the scheduled harvest if it is treated (as described in Table 2D) at the time it is applied to crops. Additional details about testing requirements for an open delivery system is provided in Table 2F pertaining to Type B agricultural water systems, and guidance is provided in Appendix A.

3) **System**: Each component of an agricultural water system must be evaluated to ensure that the quality of agricultural water used in leafy green operations is known (i.e., the required parameters are measured and conform to the prescribed standards) and adequate for its intended use. Agricultural water use will vary depending on the type of system.
    - When determining whether a system is Type A or B, each component (source, storage, conveyance, etc.) must be individually evaluated in typing an entire system.
    - When Type A and B waters are combined, categorize water as Type B.

HAZARD ANALYSIS - STEP 2: HOW IS YOUR AGRICULTURAL WATER SYSTEM BEING USED?

Use/Application method: Risk of leafy green contamination is closely related to *how* water is used in the production and harvest environment as well as in post-harvest applications (Rock *et al*., 2019). For this reason, agricultural water requirements vary depending on *how* it is applied. In leafy green operations, agricultural water is typically used in aerial (e.g., sprayers, overhead sprinklers, aircraft), ground (e.g., furrow and drip irrigation), and post-harvest applications. Agricultural water is also used for cleaning and, when appropriate, sanitizing equipment used during production, harvest, and post-harvest activities. Type A, Type B water that is treated to become Type A (B→A), and Type B agricultural water systems are suitable for specific uses as described in Table 1.

HAZARD ANALYSIS - STEP 3: WHEN IS YOUR AGRICULTURAL WATER SYSTEM BEING USED?

Timing of use: Risk of leafy green contamination is closely related to *when* agricultural water is applied in the production environment. For this reason, requirements for agriculture water that is aerially applied to leafy green crops vary depending on *when* the water is applied (Fonseca *et al*., 2010; Gutierrez-Rodriquez *et al*., 2012, 2019; Koike *et al*., 2009; 2010; Moyne *et* al., 2011; Suslow *et al*., 2010; Wood *et al.*, 2010).

A number of environmental factors, including location of the operation, and the climatic conditions of UV, relative humidity, precipitation, and temperature, may alter the appropriateness of these time-based requirements. Based on the most appropriate, currently available research addressing the risks related to the timing of aerial agricultural water application in leafy green operations, time-based requirements are generally divided as follows:

- Within (≤) 21 days of the scheduled harvest date
- Greater than (>) 21 days until the scheduled harvest date

- Agricultural water from a Type A agricultural water system used in overhead irrigation within (≤) 21 days of the scheduled harvest must meet the performance requirements for Type A agricultural water systems as outlined in Tables 2B and 2C.

- Untreated agricultural water that meets Type A requirements for irrigation water or Type B system that meets the performance requirements outlined in Table 2E may be used in aerial applications prior (>) 21 days before the scheduled harvest.
- To use agricultural water from a Type B agricultural water system in overhead irrigation within (≤) 21 days of the scheduled harvest date, the water must be treated to become Type A water (B→A) and demonstrated to meet the performance requirements as outlined in Table 2D.

TABLE 1. AGRICULTURAL WATER SYSTEM USES BY APPLICATION METHOD – SEE TABLE 2A-2G

Application	Agricultural water systems (possible sources)	Treatment methods for use in direct contact with crop	Microbial indicator
• **Overhead irrigation and chemical application prior to (>) 21 days before scheduled harvest date** • **Germination** • **Ground chemigation** • **Drip irrigation** • **Furrow irrigation** • **Dust abatement** • **Non-food-contact farm equipment cleaning**	Type A and B agricultural water systems	No treatment necessary if it can be demonstrated to meet the microbial standards.	generic *E. coli*
• **Overhead applications (including irrigation, pesticide spray, aerial chemigation) applied within (≤) 21 days of scheduled harvest date**	Type A agricultural water systems (closed systems including water from wells, municipalities, tertiary treated and disinfected recycled water e.g., purple valve)	No treatment necessary if it can be demonstrated to meet the microbial standards.	generic *E. coli*
	Treated Type B→A agricultural water systems with open components such as reservoirs, ponds, canals, laterals, ditches, etc.	Must be treated and tested to demonstrate treatment efficacy and compliance with microbial standards.	generic *E. coli* and total coliforms
• **Food-contact (harvest) equipment cleaning & sanitizing** • **Hand wash water**	Water that directly contacts edible portions of harvested crop or is used on food-contact surfaces such as equipment or utensils, must meet the Maximum Contaminant Level Goal for E. coli as specified by U.S. EPA or contain an approved antimicrobial treatment at a concentration sufficient 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.		

IRRIGATION WATER SAMPLING PLANS AND REMEDIAL ACTIONS

Testing agricultural water systems is one method of gathering evidence that your system is of adequate quality for its intended use. Along with visual monitoring of agricultural water systems, a water quality testing program is a vital best practice for protecting leafy green crops from contamination. To be most effective as a food safety tool, water samples must reflect, to the extent possible, the water at the point of use.

- As irrigation system equipment may change locations throughout the season, but water sources are generally at a fixed location, a robust overhead irrigation water quality testing program must include assessments of both the irrigation water source and the irrigation system. Assessing water quality at the end of the delivery system ensures source water quality does not degrade as it moves through the system.
- For the purposes of this document, sampling of agricultural water systems occurs for the following three reasons and Tables 2B-2C follow this framework providing specific details for each assessment's requirements:
    - **Baseline microbial assessments:** To "type" your agriculture water *source* and establish its "known" quality.
    - **Initial microbial water quality assessment:** To test your agricultural water *system* prior to use to ensure water is not degraded as it moves through the system.
    - **Routine system assessments:** To monitor the microbial quality of your agricultural water *system* throughout the season to ensure it continues to meet the microbial water quality standards.
        - If you are applying water from a Type A agricultural water system greater than (>) 21 days to the scheduled harvest date, you may choose to sample and test your water according to Type B criteria rather than according to Type A criteria; however, Type A baseline (when required) and initial microbial water quality assessments must be conducted before the 21 days-before-harvest window closes and routine verification / monitoring begins (per requirements outlined in Tables 2B and 2C).
        - Routine sampling is a part of building a dataset useful for evaluating individual data points and evaluating trends to gain a better understanding of your agricultural water system.
            - Non-routine sampling when food safety risks are deemed higher due to specific circumstances (i.e., weather, animal and human activities, discharge, etc.) should also be part of a robust food safety program. In the event that additional risk factors that could affect water quality are observed or measured such as weather, manure application in a nearby field, or animal-related activity, consider conducting additional water testing.
            - If you are irrigating with Type B→A agricultural water systems, collecting and analyzing water system data is essential for understanding of how the treatment functions in your irrigation system and can optimize its effectiveness.
- All agricultural water systems used in overhead irrigation prior to (>) 21 days before the scheduled harvest date must meet the water quality requirements outlined in Table 2E for Type B agricultural water systems.
- If a Type A or B agricultural water system fails the respective acceptance criteria, follow remedial action steps as outlined in Table 2F (also included in Figures 2B, 3A and 3C). Consider performing root cause analysis to determine if additional preventive measures can be incorporated in the agricultural water system operation.
- Retain documentation of all test results and/or Certificates of Analysis/Quality Assurance for a period of at least two (2) years.

BEST PRACTICES FOR MANAGING STORAGE AND CONVEYANCE SYSTEMS:

- Develop a SOP for the maintenance of ancillary equipment and water storage and conveyance components of each agricultural water system used in your operations. The SOP must address:
  - Regularly scheduled visual inspections, including ancillary equipment connected to your storage and conveyance system, to ensure it is in good working order and does not pose a contamination risk to your system.
  - Measures to maintain water quality by removing debris and controlling the presence of weeds, algae, tule, trash, and when appropriate, sediment within the producer's control.
  - Procedures to control pest access to the storage and conveyance systems (examples may include avian deterrents, fencing, and rodent monitoring).
  - Corrective actions to ensure irrigation pipes and drip tape are microbiologically safe to use if a pest infestation does occur.
  - Berms, slopes and diversion ditches for prevention of run-off (i.e., from irrigation or rain) into water storage and conveyance systems.
  - Procedures to ensure standing and/or stagnant water does not pose a contamination risk.
  - Management of agricultural water system components used to prepare crop inputs (e.g., pesticides and fertilizers) to ensure these activities and equipment are not a contamination source.
  - Water used in aerial applications (e.g., pesticide and fertilizer, etc.) within the 21-days-to-harvest window must be from Type A or B→A agricultural water systems. Implement practices to ensure:
  - Holding tanks and equipment-mounted application tanks, manifold and boom lines, and nozzles are to be properly maintained and cleaned.
  - Water treatment chemistry or approach is compatible with the agricultural chemicals being applied.
  - Establish corrective action procedures for non-compliance scenarios, including:
  - Contaminated source water
  - Animal intrusion
  - Contaminating run-off
  - Uncontrolled flooding
- Document all corrective measures, cleaning activities, and maintenance.

BEST PRACTICES FOR FURROW IRRIGATION SYSTEM MANAGEMENT

- Agricultural practices, such as irrigation methods, bed configuration, etc., should be implemented in a manner to avoid water from breaching the top of the bed.
- Agricultural practices, such as equipment movement, irrigation practices, etc., should be monitored at headland and tail ditch locations for damaged beds which may allow water to contact the edible portion of the crop.
- Coordinate irrigation events with harvest, to the degree possible, to avoid saturation of the field soil to prevent excessive dirt and mud from getting on the edible portion of the crop, harvest tools (e.g., knives, gloves, etc.), and harvest equipment (e.g., machines, belts, trailers, etc.).

BEST PRACTICES FOR DRIP TAPE IRRIGATION SYSTEMS MANAGEMENT

- Drip tape should be handled, stored, used, and re-used in a manner that prevents damage and contamination to the drip tape.

- While in use, repairs to drip tape should be completed in a timely manner to prevent water contact with the edible portion of the crop.

BEST PRACTICES FOR MANAGING IRRIGATION WATER TREATMENT SYSTEMS

- The minimum best practices for managing irrigation water treatment are outlined below and must be completed. For greater detail refer to Appendix A.
- Prior to 21 days-to-scheduled harvest conduct an initial irrigation water treatment assessment to establish treatment process parameters that will be monitored to ensure consistent treatment delivery and to demonstrate its effectiveness as described in Appendix A.
  - Repeat this assessment if a material change (e.g., change in equipment or type of water treatment) to your system occurs.
- Before using treated water to irrigate crops within the ≤ 21 days-to-scheduled harvest timeframe producers must first establish SOP's outlining irrigation treatment and process parameters for all irrigation treatment systems unless duplicated systems are in use.
- Confirm that water microbial quality is not being degraded as it passes through each of your water treatment systems (i.e., due to equipment conditions) by performing a microbial water quality assessment during an irrigation event before entering the ≤ 21 days-to-scheduled harvest timeframe.
  - Collect three (3) 100 mL samples from 3 different sprinkler heads with at least one sample from the farthest/last sprinkler head. Acceptance Criteria and Data Monitoring Criteria as outlined in Table 2D-Routine Monitoring of Microbial Water Quality must be met.

BEST PRACTICES FOR WATER USED FOR OVERHEAD CHEMICAL APPLICATIONS WITHIN 21 DAYS OF SCHEDULED HARVEST (THIS SECTION DOES NOT APPLY TO CHEMICAL APPLICATIONS MADE THROUGH THE DISTRIBUTION SYSTEM I.E. SPRINKLER)

Type B water used for overhead applications within 21 days of scheduled harvest must be treated. With the start-up of any new treatment process, it is important to evaluate all conditions that may affect water treatment efficacy and performance. Examples of parameters that provide valuable information about treatment efficacy in relationship to water quality are: Turbidity, pH, antimicrobial dose, historical microbial monitoring data, etc. (See Appendix A for additional guidance).

- Develop a SOP for all of the parts of the agricultural water system used in overhead chemical application. The SOP must address:
  - Water used in overhead applications (e.g., pesticide and fertilizer, etc.) within the 21 days-to-harvest window must meet Type A and or B→A water quality requirements.
  - Holding tanks and equipment-mounted application tanks, manifold and boom lines, and nozzles MUST be regularly inspected and properly maintained and cleaned so they do not pose a contamination risk.
  - Water treatment chemistry or approach shall be compatible with the agricultural chemicals being applied.
  - Procedures to control pest access to the equipment during storage and staging (examples may include: avian deterrents, fencing, and rodent monitoring) must be in place (validation can include: Pest Control Applicator (PCA) records, label requirements, letter of guarantee).
  - Establish corrective action procedures for non-compliance scenarios including:
    - Treatment failure
    - Contaminated source water
    - Pest concerns

- Chemical incompatibility
- Equipment sanitation concerns

- Document all corrective measures, cleaning activities and maintenance.
- Develop a SOP for each unique application process to treat water that will be used in an overhead application within 21 days of a scheduled harvest. Prior to the 21 days-to-scheduled harvest conduct an initial water treatment assessment to establish treatment process parameters that will be monitored to ensure consistent treatment delivery and to demonstrate effectiveness. Repeat this assessment if a material change to your system occurs. Incorporate this assessment's findings into your water treatment SOP. The SOP must address:
  - Step-by-step instructions to ensure the water treatment is correctly implemented
  - Location of water sources
  - Name, and suggested supplies needed
  - Sanitizer used and quantity used
  - Critical limits and operational limits
  - Water sampling location
  - Corrective actions if critical limits are not met
  - Required records
- Develop a baseline for water treatment:
  - Prior to the 21 days-to-scheduled harvest a minimum of three (3)-100 mL samples must be taken for each overhead application process (distinct water quality source, different sanitizer, different size water holding tank, etc.). The three (3) samples must be taken from different treated water batches.
  - All three (3) samples must be non-detect for generic *E. coli.*
  - Total coliforms sampling not included here.
- Routine Testing:
  - A minimum of one (1) microbiological sample must be taken each month from a representative routinely treated water batch or at the next application event
  - This 100 mL sample must have no detectable generic *E. coli*.
  - Total coliforms sampling not included here.
- Corrective action:
  - If microbiological testing shows that the water did not meet generic *E. coli* acceptance criterion within 21 days of a scheduled harvest, perform a root cause analysis and correct the concern. Notify the grower/producer.
  - The product must be tested for pathogens before harvest if this water was used in overhead application. Follow the product testing requirements outlined in Table 2F.
- Ongoing monitoring:
  - Between microbiological routine testing events, records must be kept that verify that each application event is conducted following the parameters established during the initial setup.
  - If monitoring shows that the water treatment parameters are not being met, *do not use the water*.
    - Perform a corrective action to assure the water treatment is effective before using the

Commented [KVH4]: TSC voted on 8.1.23 to add TC not included here; not clear based on Overhead applications requirement in Table 1.

water.

- Take a microbiological sample to verify that the treatment was effective and have that result as part of the corrective action documentation.
- If the verification microbiological sample does not meet acceptance criteria, perform a root cause analysis and correct the treatment process. Product must be tested for pathogens before harvesting. Follow Table 2F for product testing requirements.

- Maintain records that demonstrate the water used for chemical applications meets Type A source water requirements. See Tables 2B and 2C for historical and/or baseline water quality requirements for source water that will be used for overhead applications.

OTHER CONSIDERATIONS FOR WATER

- Treat water only with antimicrobial treatments approved by the USEPA for use in agricultural applications in accordance with label specifications, guidelines for use, and consideration of environmental impacts.
- Antimicrobial treatments must be used and managed in a manner that meets all federal, state, and local regulations.
- Do not store raw manure or any type of compost near irrigation water sources or conveyance systems (see Table ∅).

BEST PRACTICES FOR IRRIGATION WATER FROM TYPE B AGRICULTURAL WATER

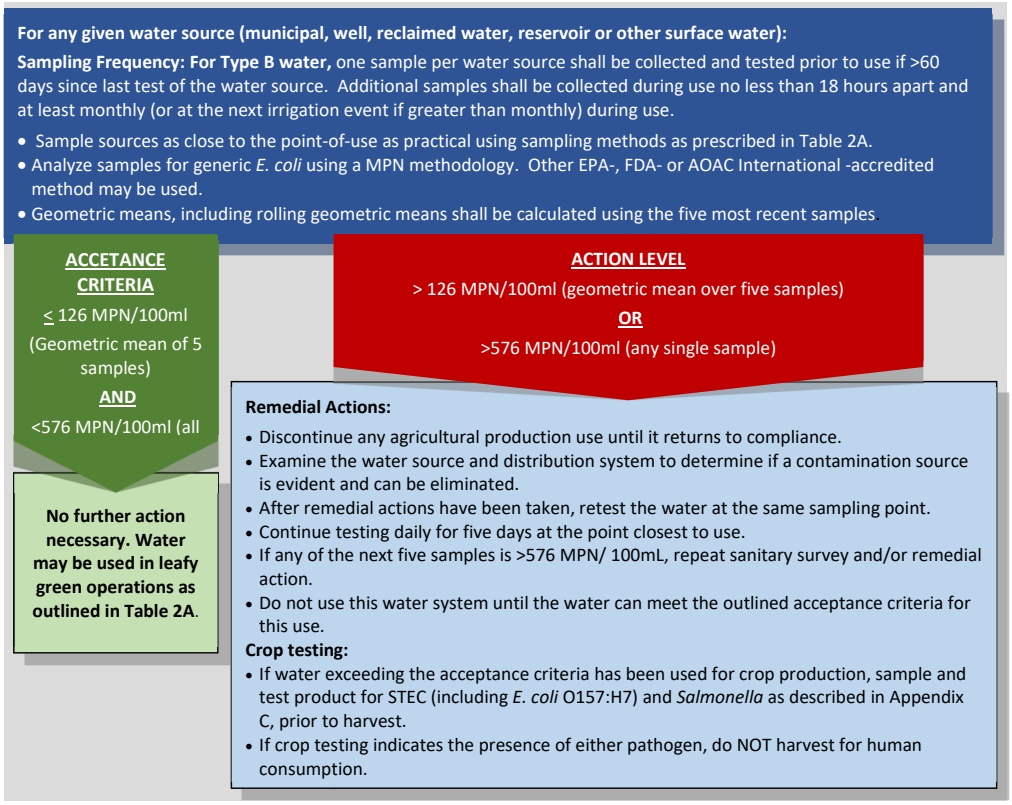
The following table (2A) outlines the metrics for agricultural water conveyance systems whereby edible portions of the crop are not likely to be contacted (e.g. germination, ground chemigation, furrow, drip irrigation, dust abatement water; if water is used in the vicinity of produce, then testing is necessary. For any of these uses, the agricultural water system must be assessed and monitored to demonstrate that the water meets the microbial standards for water that is likely to contain indicators of fecal contamination. Routine monitoring of microbial quality is required for all water types and remedial actions are required if water testing shows a conveyance system has failed to deliver water that meets the microbial standard. Efforts should always be made, when using Type B water, to avoid contact with the edible portion of the crop within 21 days of a scheduled harvest. When performing remedial actions, it is the intent that all remedial steps outlined in the tables below are followed and that they are followed in the order of sequence as written.

651 **TABLE 2A. IRRIGATION WATER FROM TYPE B AGRICULTURAL WATER– SEE FIGURE 1**

Metric	Rationale /Remedial Actions
Examples of water from Type B agricultural water systems: • **Ground chemigation** • **Drip irrigation** • **Furrow irrigation** • **Dust abatement**	Water for Type B use throughout the production of the crop shall meet or exceed microbial standards 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 depend on the number of samples taken. If only one sample has been taken, it must be below 126MPN/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 (or at the next irrigation event if longer than monthly) at points of use within the distribution system. Ideally, irrigation 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 indicated an upward trend. Investigation and remedial action SHALL be taken when acceptance criteria are exceeded.
Target Organisms: Generic *E. coli*	
Sampling Procedure: 100 mL sample collected aseptically as close as practical to the point of use. **Sampling Frequency:** One sample per agricultural 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 hours apart and at least monthly (or at the next irrigation event if greater than monthly) during use from points within the delivery system. **Acceptance Criteria**:	If the rolling geometric mean (n=5) or any one sample exceeds the acceptance criteria, then the water shall not be used until remedial actions have been completed and generic E. coli levels are within acceptance criteria: • Conduct an agricultural water assessment (Appendix A) of water source and conveyance system to determine if a contamination source is evident and can be eliminated. Eliminate identified contamination sources. • Retest the agricultural water after taking remedial actions to determine if it meets the outlined microbial water quality 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. • If follow-up agricultural water testing indicates that a crop has been directly contacted with water exceeding acceptance criteria, product shall be sampled and tested for STEC (including E. coli O157:H7) and Salmonella as described in Appendix C, prior to harvest. If crop testing

≤ 126 MPN/100 mL (rolling geometric mean n=5) and ≤576 MPN/100 mL for any single sample	indicates the presence of either pathogen, the crop shall NOT be harvested for the fresh market.
Test Method: Any FDA-allowed method[2]	
Records: Each water sample and analysis shall record the water source, date, time, and location of the sample, the method of analysis, and, if quantitative, the detection limit. All test results and remedial actions shall be documented and available for verification from the producer/shipper who is the responsible party for a period of two years.	

FIGURE 1. IRRIGATION WATER FROM TYPE B AGRICULTURAL WATER– SEE TABLE 2A



[2] Equivalent testing methodology for agricultural water
https://www.fda.gov/food/foodscienceresearch/laboratorymethods/ucm575251.htm

BEST PRACTICES FOR IRRIGATION WATER FROM TYPE A AGRICULTURAL WATER USES

The following tables (2B – 2F) refer to agricultural water distribution systems and not to specific ranches, lots, fields, etc. The tables outline the metrics for overhead applications of agricultural water sourced from public/private supplies (2B), regulated recycled water and private wells (2C), treated water supplies (2D), and untreated water that is likely to contain indicators of fecal contamination (2E). Each type of agricultural water system must be assessed to demonstrate that the water from the source and the distribution system meet the microbial standards. Treated water must be assessed and monitored to demonstrate that the water treatment is working as intended and that the treated water meets the microbial standard. Routine monitoring of microbial quality is required for all water system types, and remedial actions are required if water testing shows a system has failed to deliver water that meets the microbial standard. When performing remedial actions, it is the intent that all remedial steps outlined in the tables below are followed and that they are followed in the order of sequence as written.

TABLE 2B. IRRIGATION WATER FROM TYPE A AGRICULTURAL WATER SYSTEMS SOURCED FROM PUBLIC OR PRIVATE PROVIDERS – SEE FIGURE 2A-2B

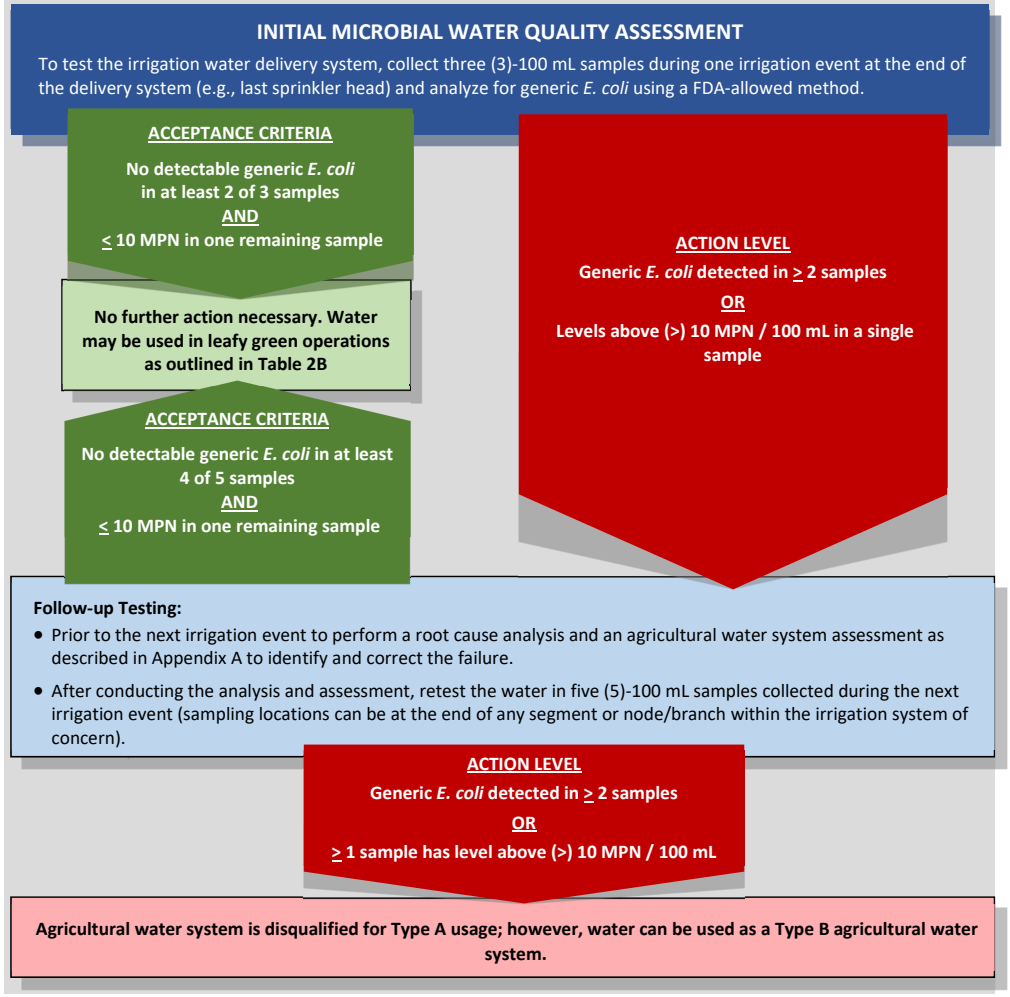
Metric	Rationale /Remedial Actions
Examples of these types of Type A agricultural water systems: Water may come from public and private providers and are stored and conveyed in closed delivery systems.	Irrigation water from Type A agricultural water systems sourced from regulated public or private providers would not be expected to contain generic *E. coli* due to treatment or some other filtering-type process. Water sourced from a public/private Type A agricultural water provider must be stored and conveyed in well-maintained, closed systems and tested for generic *E. coli*.
B1. Baseline Microbial Assessment	
A baseline microbial assessment of the water source is not necessary for a Type A system using source water from a public/private provider. In lieu of a baseline microbial assessment, acquire and maintain the supplier's most current COA on file.	
Records: Records of the analysis of source water may be provided by municipalities, irrigation districts, or other water providers and must be available for verification from the producer/shipper who is the responsible party for a period of two years	
B2. Initial Microbial Water Quality Assessment	
Target Organisms: Generic *E. coli*	

Initial Assessment Sampling Procedure: Aseptically collect at least three (3)-100 mL samples during one irrigation event with at least one sample at the end of the delivery system (e.g., last sprinkler head). **Initial Assessment Sampling Frequency:** This is a one-time seasonal sampling event for each system with samples collected during one irrigation event occurring before the 21-day-to-scheduled-harvest-period begins. (Also conduct this assessment after any material modifications to Type A overhead irrigation systems.) **Initial Assessment Acceptance Criteria**: Non-detectable in two (2) of three (3)-100 mL samples and 10 MPN as the single sample maximum for one (1) sample. **Follow-up Testing Acceptance Criteria :** Non-detectable in four (4) of five (5)-100 mL samples and 10 MPN as the single sample maximum for one (1) sample. **Note**: For the purposes of water testing, MPN and CFU are considered equivalent.	The purpose of this assessment is to confirm that the water's microbial quality is not being degraded as it passes through your system (i.e., due to equipment conditions). The assessment is performed to verify that your irrigation water delivery system is able to maintain and deliver water of the same microbial quality (e.g., Type A) as the source water. Unless there is a material change to your system (e.g., change in equipment or type of water treatment), this is a one-time assessment for each irrigation system, and it is not necessary to repeat system evaluations for each irrigation event. To test your water delivery systems, sample and test irrigation water during an irrigation event. All discrete systems are to be tested before entering the 21-days-to-scheduled-harvest timeframe. To assess the water delivery system, water samples are taken throughout the system with at least one sample at the end of the line where water contacts the crop. Initial Assessment Testing If at least two (2) in three (3) samples do not have detectable levels of generic *E. coli*, and the level in the one remaining sample is no greater than (≤) 10 MPN, then the water system maintains its Type A status. If water samples do not meet the acceptance criteria (i.e., if two (2) or more of the samples have detectable levels of generic *E. coli* or the level in at least one sample is greater than (>) 10 MPN), then conduct the following follow-up testing: Follow-up Testing 1) Prior to the next irrigation event perform a root cause analysis and an agricultural water system assessment as described in Appendix A to identify and correct the failure. 2) After assessing the system, retest the system for generic *E. coli* in five (5)-100 mL samples collected during the next irrigation event using the sampling procedure and frequency (described in the left column). Water samples can be pulled from the end of any system nodes/branches in the irrigation system of concern. Of the five (5) follow-up samples, four (4) must have no detectable generic *E. coli* and the one (1) remaining sample must have levels no greater than (≤) 10 MPN / 100 mL. 3) If test results meet the acceptance criterion for generic *E. coli*, the water system can be used as a Type A system. Testing Failure: When one sample has more than (>) 10 MPN / 100 mL or more than one sample have detectable generic *E. coli*, the agricultural water system is disqualified for Type A usage. Perform a root cause analysis to identify and correct the failure (see Appendix A for mitigation measures). In the interim, the water can be used as a Type B agricultural water system.

Test Method: Any FDA-allowed method[2]	
Records: Each water sample and analysis shall record the water source, date, time, and location of the sample, the method of analysis, and, if quantitative, the detection limit. All test results and remedial actions shall be documented and available for verification from the producer/shipper who is the responsible party for a period of two years.	
B3. Routine Verification of Microbial Water Quality	
Routine Verification Sampling Procedure: Aseptically collect at least three (3)-100 mL samples during one irrigation event with at least one sample at the end of the delivery system (e.g., last sprinkler head). **Routine Verification Sampling Frequency:** Sample and test each distinct irrigation system for generic *E. coli* at least once during the season. **Routine Verification Acceptance Criteria:** Non-detectable generic *E. coli* in 100 mL water samples and ≤ 10 MPN as the single sample maximum for one (1) in three (3) samples **Note**: For the purposes of water testing, MPN and CFU are considered equivalent.	To verify irrigation water continues to meet the acceptance criteria throughout the season, design your sampling plan so each distinct irrigation system that is in use is sampled and tested at least once during the season. If two (2) or more of the samples have detectable levels of generic *E. coli* or the level in at least one sample is greater than (>) 10 MPN, prior to the next irrigation event and perform a **Level 1 Assessment** as outlined in Table 2F.
Test Method: Any FDA-allowed method[2~~2~~]	
Records: Each water sample and analysis shall record the water source, date, time, and location of the sample, the method of analysis, and, if quantitative, the detection limit. All test results and remedial actions shall be documented and available for verification from the producer/shipper who is the responsible party for a period of two years.	

[2] Equivalent testing methodology for agricultural water
https://www.fda.gov/food/foodscienceresearch/laboratorymethods/ucm575251.htm

672 **FIGURE 2A. IRRIGATION WATER FROM TYPE A AGRICULTURAL WATER SYSTEMS SOURCED FROM PUBLIC / PRIVATE**
673 **PROVIDERS – SEE TABLE 2B**



674

675 **FIGURE 2B. IRRIGATION WATER FROM TYPE A AGRICULTURAL WATER SYSTEMS SOURCED FROM PUBLIC / PRIVATE**
676 **PROVIDERS – SEE TABLE 2B**

ROUTINE MONITORING of MICROBIAL WATER QUALITY

- For Type A agricultural water from public/private sources for overhead applications when used **within (<) 21 days** of the scheduled harvest date. When using Type A agricultural water from these sources for overhead applications **up to (>) 21 days** of the scheduled harvest date follow water metrics in Table 2E/Figure 5 for Type B agricultural water systems.
- Collect three (3) samples at the end of the delivery system (e.g., last sprinkler head), and test at least once seasonally during use; each distinct irrigation system must be tested at least once during the season.
- Test for generic *E. coli* using a FDA-allowed method.
- Assess microbial quality using the three (3) collected samples.

ACCEPTANCE CRITERIA

No detectable generic *E. coli* in at least 2 of 3 consecutive samples
AND
< 10 MPN in one remaining sample

No further action necessary. Water may be used in leafy green operations as outlined in Table 2B.

ACTION LEVEL

Generic *E. coli* detected in > 2 samples

OR

One sample has levels above (>) 10 MPN / 100 mL

CONDUCT A LEVEL 1 ASSESSMENT:

1) If generic *E. coli* levels in your water exceed the acceptance criteria, prior to the next irrigation event conduct an agricultural water system assessment as described in Appendix A and retest water (as described in step #2 below) until it is shown to be back in compliance with the acceptance criteria.
2) During the next irrigation event, collect 5 - 100 mL samples from the irrigation system and test for generic *E. coli*. Water can be pulled from the end of any system nodes/branches in the irrigation system of concern. If these water samples also fail to meet the acceptance criteria, discontinue use of this water for overhead applications while continuing to evaluate your water system to identify and correct any failures and continuing to test as described in this step until the water is back in compliance (see Appendix A for guidance on troubleshooting irrigation system failures).
3) If this water (i.e., the water from the initial sampling to the last of the follow-up sampling) has been applied to leafy greens, either consider the crop unsuitable for the fresh market or test the crop from all affected lots (i.e., lots that have been irrigated with this water within the <21 days-to-scheduled-harvest window) for STEC (including *E. coli* O157:H7) and *Salmonella.* Product needs to be tested prior to harvesting and after your last irrigation event. Sample crop per the protocol described in Appendix C. If any individual sample tests positive for any of these human pathogens, the crop within that lot shall NOT be harvested for the fresh market and human consumption.

677

678 **TABLE 2C. IRRIGATION WATER FROM TYPE A AGRICULTURAL WATER SYSTEMS SOURCED FROM PRIVATE WELLS OR**
679 **REGULATED TERTIARY TREATED RECYCLED WATER SUPPLIES – SEE FIGURE 3A-3C**

Metric	Rationale /Remedial Actions
Examples of water from Type A agricultural water systems: • Regulated recycled waste water • Water sourced from a well – well water is conveyed to the field in a closed delivery system and applied to the crop via overhead sprinklers.	Irrigation water from Type A agricultural water systems with well source water would not be expected to contain generic *E. coli* due to natural filtration as the water passes through the soil. Water from regulated tertiary treated recycled water supplies may have low levels of generic *E. coli* due to regulatory allowable limits. Type A agricultural water systems must be stored and conveyed in well-maintained, closed systems and tested for generic *E. coli*. Remedial actions vary depending on when the water is being used in relation to harvest.
C1. Baseline Microbial Assessment	
Target Organisms: Generic *E. coli*	
Baseline Assessment Sampling Procedure: If historical water test data is not available, aseptically collect at least three (3)-100 mL sample at the source. **Baseline Assessment Sampling Frequency:** Sample and test the water two times (with sampling events separated by no less than 7 days) before using the water within the 21 days-to-scheduled-harvest-window. **Baseline Assessment Acceptance Criteria**: Non-detectable generic *E. coli* in five (5) of six (6) 100 mL samples and ≤ 10 MPN as the single sample maximum for one (1) sample. **Note**: For the purposes of water testing, MPN and CFU are considered equivalent.	The purpose of a baseline assessment is to ensure your water source (e.g., a well or regulated tertiary treated recycled water) meets the microbial standards for generic *E. coli*. This baseline microbial assessment must be conducted before these Type A water sources can be used for overhead irrigation within 21 days to scheduled harvest. For agricultural water systems with multiple wells, each well must be tested prior to use in order to validate the integrity of the agricultural water system. Self-certification with historical water test data: If at least four (4) of the last five (5) consecutive historical water tests (80%) have no detectable generic *E. coli*, the remaining one (1) sample does not exceed (≤) 10 MPN in 100 mL, and one (1) of those tests was taken within the last 6 months, then the well/regulated tertiary treated recycled water supply is self-certified as a Type A agricultural water source. Self-certification process when no historical data is available: If historical data is unavailable, test each well or regulated recycled water twice (separated by no less than seven days) prior to use as the source water for a Type A agricultural water system. If at least five (5) of the six (6) total samples have no detectable generic *E. coli* and the remaining sample has ≤ 10 MPN in 100 mL, then the water/well is self-certified as a Type A agricultural water source. Testing Failure: If test results do not meet the acceptance criteria, then the water/well cannot be considered a Type A agricultural water source. Perform a root cause analysis and an agricultural water system assessment as described in Appendix A to identify and correct the failure. In the interim, the water can be treated or used as a source for a Type B agricultural water system.

Test Method: Any FDA-allowed method[22]

Records: Each water sample and analysis shall record the water source, date, time, and location of the sample, the method of analysis, and, if quantitative, the detection limit. All test results and remedial actions shall be documented and available for verification from the producer/shipper who is the responsible party for a period of two years.

C2. Initial Microbial Water Quality Assessment

Target Organism: Generic *E. coli*

Initial Assessment Sampling Procedure:

Aseptically collect at least three (3)-100 mL during one irrigation event at the end of the delivery system (e.g., last sprinkler head).

Initial Assessment Sampling Frequency:

This is a one-time seasonal sampling event for each system with samples collected during one irrigation event occurring before the 21-day-to-scheduled-harvest-period begins. (Also conduct this assessment after any material modifications to Type A overhead irrigation systems.)

Initial Assessment Acceptance Criteria:

Non-detectable generic *E. coli* in two (2) of three (3)-100 mL samples and ≤ 10 MPN as the single sample maximum for one (1) sample.

Follow-up Testing Acceptance Criteria:

Non-detectable in four (4) of five (5)-100 mL samples and ≤ 10 MPN as the single sample maximum for one (1) sample.

Note: For the purposes of water testing, MPN and CFU are considered equivalent.

The purpose of this assessment is to confirm that the water's microbial quality is not being degraded as it passes through your system (i.e., due to equipment conditions). The assessment is performed to verify that your irrigation water delivery system is able to maintain and deliver water of the same microbial quality (e.g., Type A) as the source water. Unless there is a material change to your system (e.g., change in equipment or type of water treatment), this is a one-time assessment for each irrigation system, and it is not necessary to repeat system evaluations for each irrigation event.

To test your water delivery systems, sample and test irrigation water during an irrigation event. All discrete systems are to be tested before entering the 21-days-to-scheduled-harvest timeframe. To assess the water delivery system, water samples are taken at the end of the line where water contacts the crop.

Initial Assessment Testing

If at least two (2) in three (3) samples do not have detectable levels of generic *E. coli*, and the level in the one remaining sample is no greater than (≤) 10 MPN, then the water system maintains its Type A status.

If water samples do not meet the acceptance criteria (i.e., if two (2) or more of the samples have detectable levels of generic *E. coli* or the level in at least one sample is greater than (>) 10 MPN), then conduct the following follow-up testing:

Follow-up Testing

1) Prior to the next irrigation event perform a root cause analysis and an agricultural water system assessment as described in Appendix A to identify and correct the failure.
2) After assessing the system, retest the system for generic *E. coli* in five (5)-100 mL samples collected during the next irrigation event using the sampling procedure and frequency (described in the left column). Water samples can be pulled from the end of any system nodes/branches in the irrigation system of

	concern. Of the five (5) follow-up samples, four (4) must have no detectable generic *E. coli* and the one (1) remaining sample must have levels no greater than (≤) 10 MPN / 100 mL. 3) If test results meet the acceptance criterion for generic *E. coli*, the water system can be used as a Type A system. Testing Failure: When one sample has more than (>) 10 MPN / 100 mL or more than one sample have detectable generic *E. coli*, the agricultural water system is disqualified for Type A usage. Perform a root cause analysis to identify and correct the failure (see Appendix A for mitigation measures). In the interim, the water can be used as a Type B agricultural water system.
Test Method: Any FDA-allowed method[22]	
Records: Each water sample and analysis shall record the water source, date, time, and location of the sample, the method of analysis, and, if quantitative, the detection limit. All test results and remedial actions shall be documented and available for verification from the producer/shipper who is the responsible party for a period of two years.	
C3. Routine Verification of Microbial Water Quality	
Target Organisms: Generic *E. coli*	
Sampling Procedure Three (3)-100 mL sample aseptically collected at the end of the delivery system (e.g., the last sprinkler head). **Sampling Frequency** Sample and test each distinct irrigation system for generic *E. coli* at least once during the season. **Acceptance Criteria** Non-detectable generic *E. coli* in 100 mL water samples and ≤ 10 MPN as the single sample maximum for one (1) in three (3) samples **Note**: For the purposes of water testing, MPN and CFU are considered equivalent.	To verify irrigation water continues to meet the acceptance criteria throughout the season, design your sampling plan so each distinct irrigation system that is in use is sampled and tested at least once during the season. If two (2) or more of the samples have detectable levels of generic *E. coli* or the level in at least one sample is greater than (>) 10 MPN, prior to the next irrigation event perform a **Level 1 Assessment** as outlined in Table 2F.
Test Method: Any FDA-allowed method[22]	
Records: Each water sample and analysis shall record the water source, date, time, and location of the sample, the method of analysis, and, if quantitative, the detection limit. All test results and remedial actions shall be documented and available for verification from the producer/shipper who is the responsible party for a period of two years.	

FIGURE 3A. IRRIGATION WATER FROM TYPE A AGRICULTURAL WATER SYSTEMS SOURCED FROM PRIVATE WELLS OR REGULATED TERTIARY TREATED RECYCLED WATER SUPPLIES – SEE TABLE 2C

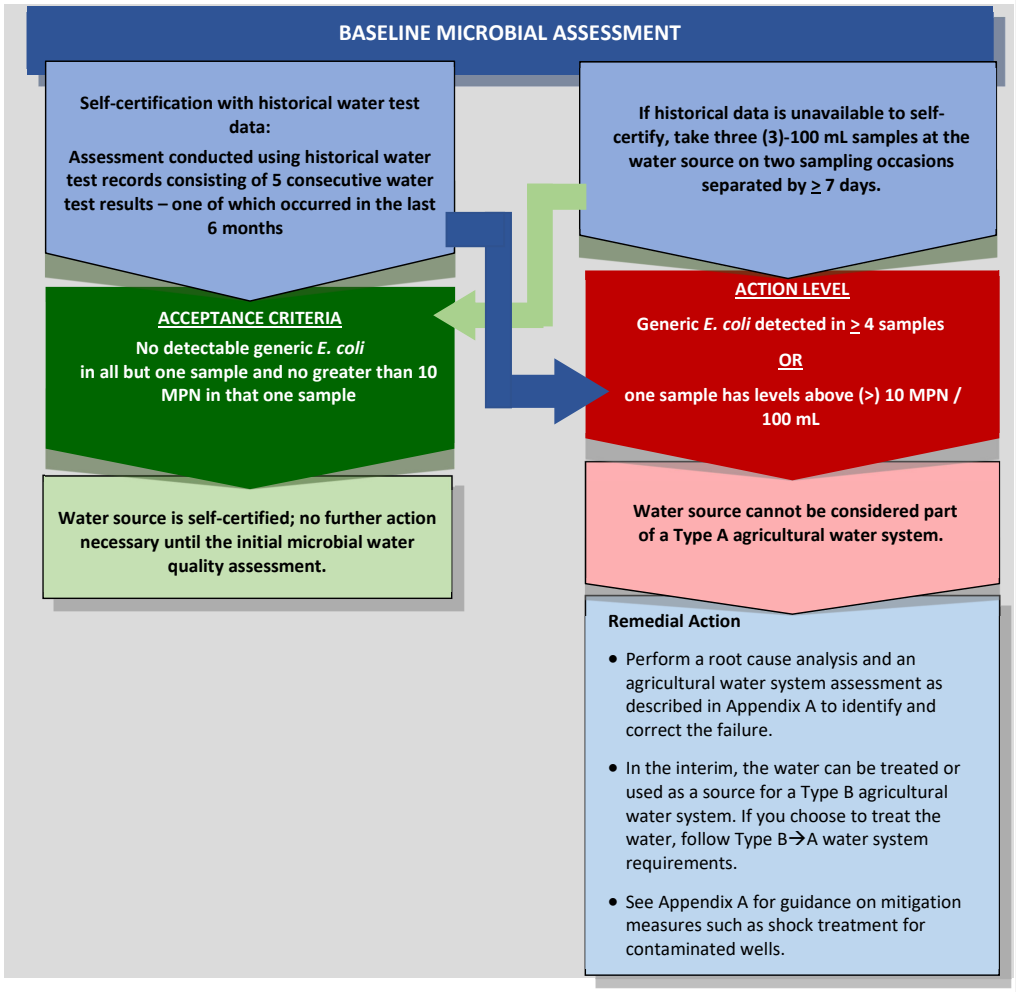


FIGURE 3B. IRRIGATION WATER FROM TYPE A AGRICULTURAL WATER SYSTEMS SOURCED FROM PRIVATE WELLS OR REGULATED TERTIARY TREATED RECYCLED WATER SUPPLIES - SEE TABLE 2C

690 **FIGURE 3C. IRRIGATION WATER FROM TYPE A AGRICULTURAL WATER SYSTEMS SOURCED FROM PRIVATE WELLS OR**
691 **REGULATED TERTIARY TREATED RECYCLED WATER SUPPLIES - SEE TABLE 2C**

ROUTINE MONITORING of MICROBIAL WATER QUALITY

- For Type A agricultural water from regulated recycle water / private well sources for overhead applications when used **within (≤) 21 days** of the scheduled harvest date. When using Type A agricultural water from these sources for overhead applications **up to (>) 21 days** of the scheduled harvest date follow water metrics in Table 2E/Figure 5 for Type B agricultural water systems.
- Collect three (3) samples at the end of the delivery system (e.g., last sprinkler head); test each distinct irrigation system in use at least once during the season.
- Test for generic *E. coli* using a FDA-allowed method.
- Assess microbial quality using the three (3) collected samples.

ACCEPTANCE CRITERIA

No detectable generic *E. coli* in at least 2 of 3 samples
AND
≤10 MPN in one remaining sample

No further action necessary. Water may be used in leafy green operations as outlined in Table 2C.

ACTION LEVEL

Generic *E. coli* detected in ≥ 2 samples
OR
One sample has levels above (>) 10 MPN / 100 mL

CONDUCT A LEVEL 1 ASSESSMENT:

1) If generic *E. coli* levels in your water exceed the acceptance criteria, prior to the next irrigation event conduct an agricultural water system assessment as described in Appendix A.
2) Retest the water for generic *E. coli* during the next irrigation event in five (5) - 100 mL samples. Water can be pulled from the end of any system nodes/branches in the irrigation system of concern. If these water samples also fail to meet the acceptance criteria, discontinue use of this water for overhead applications while continuing to evaluate your water system to identify and correct any failures and continuing to test as described in this step until the water is back in compliance (see Appendix A for guidance on troubleshooting irrigation system failures).
3) If this water (the water from the initial sampling to the last of the follow-up sampling) has been applied to leafy greens, either consider the crop unsuitable for the fresh market or test the crop from all affected lots (i.e., lots that have been irrigated with this water within the <21 days-to-scheduled-harvest window) for STEC (including *E. coli* O157:H7) and *Salmonella.* Product needs to be tested prior to harvesting and after your last irrigation event. Sample crop per the protocol described in Appendix C. If any individual sample tests positive for any of these human pathogens, the crop within that lot shall NOT be harvested for the fresh market and human consumption.

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693 **TABLE 2D. IRRIGATION WATER FROM TREATED TYPE B→A AGRICULTURAL WATER SYSTEMS – SEE FIGURE 4**

Metric	Rationale /Remedial Actions
Example of treated water from a Type B→A ag water system: Water may arrive at the production area in an irrigation district canal or lateral from which it is pumped and treated before being used in overhead sprinkler irrigation.	When water from a Type B agricultural irrigation water system is used in an overhead application within (≤) 21 days to the scheduled harvest date, it must be treated to move it from a Type B agricultural water system to a Type A system (B→A) by a scientifically valid antimicrobial water treatment - i.e., contain an approved antimicrobial water treatment at sufficient concentration to prevent potential contamination risk during overhead applications. Overhead application(s) of nutrients and/or crop protection chemicals (i.e. fertigation, chemigation) is allowable within the 21 days-to-scheduled harvest window. (See Table D3 below) Microbial and/or physical/chemical testing of the source and system must be performed, as appropriate to the specific operation, to demonstrate that performance criteria have been met before use within (≤) 21 days to the scheduled harvest date and continues to be met throughout its use. Water in open delivery systems (e.g., reservoirs and ponds) may be used in overhead applications within 21 days to the scheduled harvest if it is treated at the same time it is applied to crops.
D1. Routine Verification of Microbial Water Quality	
Target Organisms: • Total coliforms (TC) • Generic *E. coli*	
Routine Verification Sampling Procedure: Aseptically collect at least three (3)-100 mL samples during one irrigation event with at least one sample at the end of the delivery system (e.g., last sprinkler head). **Routine Verification Sampling Frequency:** Sampling is conducted monthly. If the irrigation treatment system is being used within the 21-days-to-harvest-window, sample each distinct irrigation treatment system on at least two occasions separated by at least three (3) days. **Routine Verification Acceptance Criteria:** Generic *E. coli*: No detection in two (2) of the last three (3) water samples with a	Routine water sampling is performed to verify irrigation water continues to meet the microbial quality acceptance criteria throughout the season. Routine verification of treated irrigation water systems is focused on the function of the system. Sampling needs to occur at a frequency that allows operators to verify they have control of their treatment system. An essential component of this verification process is building a dataset so microbial quality can be analyzed to best inform you how to effectively run your water treatment system. Sample and test the system for total coliform and generic *E. coli* in three (3)-100 mL samples. To maintain its Type A status, water samples must have: ▪ no detectable generic *E. coli* in at least two (2) of the three (3) samples with a maximum level no greater than (≤) 10 MPN in the remaining sample, and ▪ data monitoring for total coliform at a level no greater than (≤) 99 MPN in 100 mL *, and

maximum level of (<u><</u>) 10 MPN allowed in one (1) sample (consecutive values) **Routine Verification Data Monitoring Criteria:** <u>Total coliform</u>: A maximum level of <u><</u> 99 MPN in 100 mL in all water samples or an adequate log reduction based on the untreated water's baseline total coliform levels* **Note**: For the purposes of water testing, MPN and CFU are considered equivalent.	* As an alternative to the threshold approach for total coliform (<u><</u> 99 MPN / 100 mL), operators can verify their irrigation treatment system by conducting paired pre- and post-treatment microbial testing of water distribution system (see Appendix A for additional guidance on conducting a log reduction assessment). If two (2) or more of the three samples do not meet the acceptance criteria for generic *E. coli* level and at least one sample is greater than (>) 10 MPN, prior to the next irrigation event perform a **Level 1 Assessment** as outlined in Table 2F.
Test Method: Any FDA-allowed method[2][~~3~~]	
Records: Each water sample and analysis shall record the water source, date, time, and location of the sample, the method of analysis, and, if quantitative, the detection limit. All test results and remedial actions shall be documented and available for verification from the producer/shipper who is the responsible party for a period of two years.	
D2. Routine Water Treatment Monitoring	
Antimicrobial water treatments - USEPA-approved for use in agricultural water. **Target Variable:** Antimicrobial irrigation water treatment or manufacturer's operational specifications (e.g., per manufacturer's recommendations, chemical concentration, etc.).	
Testing Procedure: • Chemical reaction-based colorimetric test, or • Ion-specific probe, or • Other as recommended by antimicrobial water treatment supplier or manufacturer's specifications. **Testing Frequency:** Monitoring must be conducted whenever the irrigation treatment system is in use. Continuous monitoring with periodic verification by titration **OR** routine monitoring if the system can be shown to have a low degree of variation.	Monitor the efficacy of the water treatment method per the manufacturer's label or operational instructions. To demonstrate the irrigation system is performing as intended <u>during each water treatment irrigation event</u>, document: • Flow rates • Treatment-related parameters such as residual antimicrobial levels, pH, dose settings, UVT etc. If water quality falls outside the acceptable monitoring parameters, conduct a microbial testing per D1**.** Routine Verification of Microbial Water Quality.
Test Method: Per label instructions	
Records: During every irrigation event, treatment-related parameter values such as residual antimicrobial levels, pH, dose settings, UVT, etc. must be documented to demonstrate the system is working as intended. Each water sample and analysis shall record the	

water source, date, time, and location of the sample, the method of analysis, and, if quantitative, the detection limit. All test results and remedial actions shall be documented and available for verification from the producer/shipper who is the responsible party for a period of two years.

D3. When Adding Crop Nutrients and/or Crop Protection Materials within 21 Days To Scheduled Harvest

Target Organism: Generic *E. coli*

Sampling procedure: Collect one sample pre- treatment from the source.

Sampling Frequency: Sampling is conducted during the irrigation event when crop nutrition/protection chemicals are being applied.

Crop Nutrition and Crop Protection is necessary within the 21 days-to-scheduled-harvest (DTSH) window. These chemicals may be incompatible with water treatment chemicals and therefore may require non-treated water for their application. The timing of applications should be carefully considered using historical data and risk assessments. When making decisions consider chemical compatibility, label restrictions, manufacturers recommendations, chemical concentration, timing of irrigation to harvest, etc.

The use of crop nutrition and crop protection materials may be necessary within 21 days to scheduled harvest. This allowance only applies to overhead application (i.e. chemigation, fertigation) of crop nutrition and crop protection compounds when they are incompatible with water treatment.

If necessary, water treatment will not be required within 21 days of scheduled harvest, ONLY during the time when crop nutrition/protection materials are being applied via overhead irrigation. Food safety risks should be evaluated and mitigations implemented as necessary. There are two options available for use when utilizing this section.

Option 1:

A window for application of crop nutrition and crop protection materials is allowed at the beginning of the irrigation event when followed by antimicrobial water treatment. Impacted crops will need to be pre-harvest tested for pathogens. (See Table 2F). (Test the crop from all affected lots (i.e. lots that have been irrigated with this water within the 21 days to scheduled harvest window) for STEC (including E. coli 0157:H7) and Salmonella. Product needs to be tested prior to harvesting and after the last irrigation event.

Option 2:

A window for application of crop nutrition and crop protection materials is allowed at the beginning of the irrigation event when followed by antimicrobial water treatment. Collect 1-100ml water sample as close to the point of use but prior to injection of chemicals. Sample must be taken at the time of use and test for generic E. coli. Once test results are obtained, utilize the following table to determine course of action.

Test results must be obtained prior to harvest or pre-harvest testing is required.

Table X. Microbial Water Quality Acceptance Criteria:

Days to scheduled harvest	Pre-treatment water test result (Generic E. Coli MPN/100 mL)	Action
0-14	0-10	No action required
	>10	Pre-Harvest Product Sampling required (Reference Appendix C)
15-21	0-10	No action required
	11-235	Die-off must be met (Reference Appendix A)
	>235	Pre-Harvest Product Sampling required (Reference Appendix C)
>21	Follow metrics for Type B water	

FIGURE 4. IRRIGATION WATER FROM TYPE B→A (TREATED) AGRICULTURAL WATER SYSTEMS - SEE TABLE 2D

ROUTINE VERIFICATION of MICROBIAL WATER QUALITY

- Collect three (3) – 100 mL samples, with at least one from the end of the distribution irrigation system (e.g., last sprinkler head)
- Sample monthly (or at the next irrigation event if greater than monthly) during use and test for generic *E. coli* and total coliform using a FDA-allowed method.
- If the irrigation system is being used within the 21-days-to-harvest-window, sample each distinct irrigation system on two occasions separated by at least three (3) days.

ACCEPTANCE CRITERIA

No detectable generic *E. coli* in at least 2 of 3 samples
AND
≤ 10 MPN in one sample

DATA MONITORING CRITERIA

≤ 99 MPN in 100 mL
OR
an adequate log reduction based on the untreated water's baseline total coliform levels

No further action necessary. Water may be used in leafy green operations as outlined in Table 1.

ACTION LEVEL

Generic *E. coli* detected in ≥ 2 samples
OR
level above (>) 10 MPN / 100 mL in a single sample

CONDUCT A LEVEL 1 ASSESSMENT:

When using Type B→A agricultural water for overhead applications **within (≤) 21 days** of the scheduled harvest date:

1) If generic *E. coli* levels in your water exceed the acceptance criteria, prior to the next irrigation event conduct an agricultural water treatment system assessment as described in Appendix A to determine why the treatment was not effective.
2) Retest the water for generic *E. coli* during the next irrigation event in five (5) - 100 mL samples. Water can be pulled from any point in the distribution systems in the irrigation treatment system of concern with at least one coming from the last sprinkler head. If these water samples also fail to meet the acceptance criteria, discontinue use of this water for overhead applications while continuing to evaluate your water system to identify and correct any failures and continuing to test as described in this step until the water is back in compliance (see Appendix A for guidance on troubleshooting irrigation system failures).
3) If this water (the water from the initial sampling applied to the crop within 21 days to harvest to the first and last of the follow-up sampling) has been applied to leafy greens, either consider the crop unsuitable for the fresh market or test the crop from all affected lots (i.e., lots that have been irrigated with this water within the <21 days-to-scheduled-harvest window) for STEC (including *E. coli* O157:H7) and *Salmonella.* Product needs to be tested prior to harvesting and after your last irrigation event. Sample crop per the protocol described in Appendix C. If any individual sample tests positive for any of these human pathogens, the crop within that lot shall NOT be harvested for the fresh market and human consumption.

TABLE 2E. IRRIGATION WATER FROM TYPE B AGRICULTURAL WATER SYSTEMS INTENDED FOR OVERHEAD IRRIGATION PRIOR TO 21 DAYS – SEE FIGURE 5

Metric	Rationale /Remedial Actions
Example of water from a Type B agricultural water system - water may arrive at the field in an irrigation district canal from which it is then used to overhead irrigate crop prior to 21 days to the scheduled harvest date.	Water from Type B agricultural water systems is untreated and exposed to the environment (e.g., open sources and/or delivery systems) so that its quality may be inadequate for overhead irrigation within (≤) 21 days to the scheduled harvest date. Water from these systems is restricted to use in overhead irrigation when applied prior to (>) 21 days to the scheduled harvest date. Also, water from Type A agricultural water systems can be sampled and tested under Type B agricultural water system requirements when it is used for overhead irrigation prior to 21 days before the scheduled harvest date.
E1. Routine Verification of Microbial Water Quality	
Target Organisms: Generic *E. coli*	
Routine Verification 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. preseason irrigation water may be tested and utilized. **Routine Verification 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 hours apart and at least monthly (or at the next irrigation event if greater than monthly) during use from points within the water distribution system. **Routine Verification Acceptance Criteria:** **< 126 MPN / 100 mL** (geometric mean) and ≤ **235 MPN/100mL** for any single sample.	When using water from Type B agricultural water distribution systems for overhead applications **prior to (>) 21 days** of the scheduled harvest date, samples for microbial testing shall be taken as close as practicable to the point-of-use (i.e., to be determined by the sampler, to ensure the integrity of the sample, using sampling methods as prescribed in Table 2D) so as to test both the water source and the water distribution system. In a closed water distribution system (meaning no connection to the outside) water samples may be collected from any point within the system but are still preferred at the point-of-use. No less than one (1) sample per month (or at the next irrigation event) per water distribution system is required under these metrics. If there are multiple potential point-of-use sampling points in a water distribution system, then samples shall be taken from different point-of-use locations each subsequent sampling event (randomize or rotate sample locations). Water for pre-harvest, direct edible portion contact prior to (>) 21 days before scheduled harvest shall meet or exceed antimicrobial standards for recreational water, based on a rolling geometric mean of the five (5) most recent samples. However, a rolling geometric mean of five samples is not necessarily required prior to irrigation or harvest. If less than five (5) samples are collected prior to irrigation, the acceptance criteria depend on the number of samples taken. For example: ▪ If only one (1) sample has been taken, it must be below (<) 126 MPN /100 mL. ▪ Once two (2) 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 five (5)-sample rolling geometric mean.

Note: For the purposes of water testing, MPN and CFU are considered equivalent.	The *rolling* geometric mean calculation starts after five (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 water distribution system. Ideally, pre-harvest water used prior to 21 days before harvest for overhead applications 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 an agricultural water system assessment of water source and water distribution system to determine if a contamination source is evident and can be eliminated. Eliminate identified contamination source(s). • For wells, perform an agricultural water system assessment and/or treat as described in Appendix A. • Or begin water treatment Retest the water after conducting the agricultural water system assessment and/or taking remedial actions to determine if it meets the outlined microbial acceptance criteria for this use. Retest the water daily, take three samples, no less than 18 hours apart at the point closest to use. This sample should represent the conditions of the original water system, if feasible this test should be at the original sampling point. A more aggressive sampling program (i.e., sampling once per week instead of once per month) or water treatment 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.
Test Method: Any FDA-allowed method[22]	
Records: Each water sample and analysis shall record the water source, date, time, and location of the sample, the method of analysis, and, if quantitative, the detection limit. All test results and remedial actions shall be documented and available for verification from the producer/shipper who is the responsible party for a period of two years.	

FIGURE 5. IRRIGATION WATER FROM TYPE B AGRICULTURAL WATER SYSTEMS INTENDED FOR OVERHEAD IRRIGATION – SEE TABLE 2E

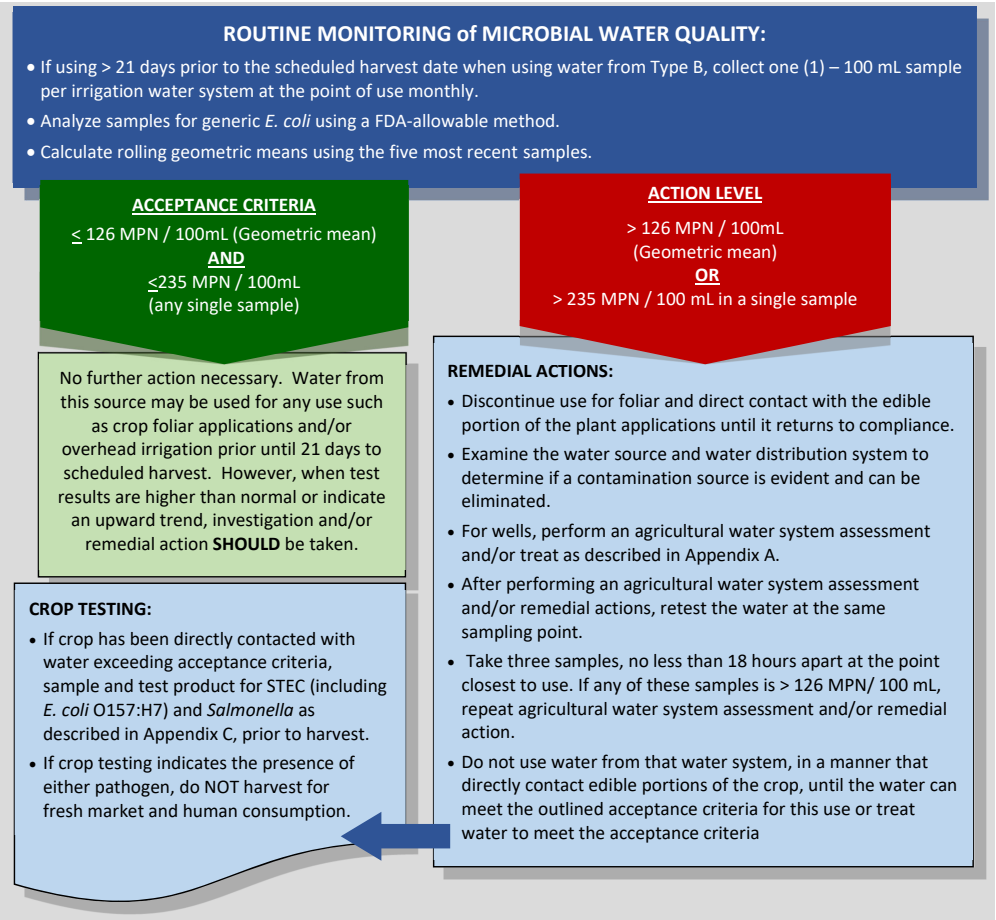

TABLE 2F. REMEDIAL ACTIONS FOR TYPE A AND B→A AGRICULTURAL WATER SYSTEMS – SEE FIGURE 4

Level 1 Assessment

Target Organisms: Generic *E. coli*

Remedial Actions Sampling Procedure:

Aseptically collect five (5)-100 mL sample from any point in the delivery system with a minimum of one from the last sprinkler head, i.e., at the last point of contact with the crop - last sprinkler head.

Remedial Actions Sampling Frequency:

Sample water during the next consecutive irrigation event after a sample fails the acceptance criteria.

Remedial Actions Acceptance Criteria:

80% non-detectable generic *E. coli* in 100 mL and ≤ 10 MPN as the single sample maximum for one (1) sample

When using agricultural water systems for overhead applications **up to (>) 21 days** of the scheduled harvest date:

Follow water metrics in Table 2D for Type B agricultural water systems.

When using water from Type A and/or B→A agricultural water systems for overhead applications **within (≤) 21 days** of the scheduled harvest date:

Generic E. coli

1) If generic *E. coli* levels in your water exceed the acceptance criterion, prior to the next irrigation event conduct an agricultural water system assessment as described in Appendix A. During the next irrigation event, collect five (5)-100 mL samples from the irrigation system and test for generic *E. coli*. Water can be pulled from any point in the delivery systems in the irrigation treatment system of concern with at least one coming from the last sprinkler head. If these water samples also fail to meet the acceptance criteria, discontinue use of this water for overhead applications while continuing to evaluate your irrigation treatment system to identify and correct any failures and continuing to test as described in this step until the water is back in compliance (see Appendix A for guidance on troubleshooting irrigation treatment system failures).

- If this water (the water from the initial sampling to the last round of sampling) has been applied to leafy greens, test the crop from all affected lots (i.e., lots that have been irrigated with this water within the <21 days-to-scheduled-harvest window) for STEC (including *E. coli* O157:H7) and *Salmonella.* Product needs to be tested prior to harvesting and after your last irrigation event. The crop within that lot shall NOT be harvested for the fresh market if either pathogen is present. Sample crop per the protocol described in Appendix C. If any individual sample tests positive for any of these human pathogens, the crop within that lot shall NOT be harvested for human consumption.

Test Method: Any FDA-allowed method[2]

Records: Each water sample and analysis shall record the water source, date, time, and location of the sample, the method of analysis, and, if quantitative, the detection limit. All test results and remedial actions shall be documented and available for verification from the producer/shipper who is the responsible party for a period of two years.

TABLE 2G. HARVEST DIRECT PRODUCT CONTACT, HARVEST FOOD-CONTACT SURFACES AND HAND WASH WATER (*ON-FARM PRACTICES ONLY*) - SEE FIGURE 6

Metric	Rationale /Remedial Actions
Water Type **Municipal, Well (Type A) and Reverse Osmosis** **Microbial Testing** **Target Organism:** Generic *E. coli*. **Sampling Procedure:** Prior to use, a 100 mL sample collected aseptically at the water source. **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 hours and at least monthly during use. **Municipal & Well Exemption:** If generic *E. coli* are below detection limits for five consecutive samples, the requirements for 60 days and monthly sampling are waived, and the sampling frequency may be decreased to no less than once every 180 days. This exemption is void if there is a significant water source or distribution system change. Reverse Osmosis Systems: No less than one sample per month per system is required. **Test Method:** Any FDA allowed method [2] ~~2~~ **Acceptance Criteria:** Negative or below DL for all samples	Water used during harvest operations that directly contacts edible portions of harvested crop, used on food-contact surfaces such as equipment or utensils, or water used for hand washing, shall be sourced from municipal, well (Type A) or reverse osmosis water sources. Testing must be conducted to demonstrate that this water meets the Maximum Contaminant Level Goal for generic *E. coli* as specified by U.S. EPA or contain an approved disinfection method at sufficient concentration or of sufficient wavelength 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. **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 multi-pass water has no detectable *E. coli* (e.g. minimally 1 ppm for chlorine). **Remedial Actions**: Develop an SOP that determines what corrective actions will be required when harvest water does not meet acceptance criteria. If any single sample exceeds the acceptance criteria, then DO NOT USE THE WATER until remedial actions have been completed and generic *E. coli* or disinfectant levels are within acceptance criteria: • Conduct an agricultural water system assessment 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 an agricultural water system assessment and/or treat as described in Appendix A. • Retest the water at the same sampling point after conducting the agricultural water assessment for water
Physical/Chemical Testing **Target Variable:** Water disinfectant (e.g., chlorine or other disinfectant compound, UV transmittance). **Multi Pass Water Acceptance Criteria:** Chlorine	

≥ 1 ppm free chlorine after application and pH 5.5 – 7.5Other approved treatments per product EPA label for human pathogen reduction in water. **Testing Procedure:** • Chemical reaction-based colorimetric test (i.e. test strips), or • Ion-specific probe, or UV transmittance • Other as recommended by disinfectant supplier. **Testing Frequency:** • Prior to first use on day of harvest. • During harvest, samples shall be taken at routine intervals (i.e. hourly, breaks, lunch, etc.) as determine by historical data showing typical degree of variation.	used for harvest and/or taking remedial actions to determine if it meets the outlined microbial acceptance criteria for this use. For example, if the water intended for use on food-contact surfaces has detectable *E. coli*, DO NOT USE THE WATER. Examine the distribution line and source inlet as described in Appendix A and retest from the same point of use. If physical/chemical testing criteria are not being met for single or multi-pass water, take remedial actions per SOP, retest the water to determine if it meets the outlined acceptance criteria. After corrective actions have been implemented and verified the water may be used for harvest operations and hand wash water.
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 6. HARVEST– DIRECT PRODUCT CONTACT AND HARVEST FOOD-CONTACT SURFACES AND HAND WASH WATER (*ON-FARM PRACTICES ONLY*) – SEE TABLE 2G

Water Type: Municipal, Wells (Type A), and Reverse Osmosis):

Water that directly contacts edible portions of harvested crop 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 hours apart and a least monthly during use.

- Sample sources using sampling methods as prescribed in Table 2G.
- Analyze samples for generic *E. coli* using any FDA allowed method.

ACCEPTANCE CRITERIA
Negative or below DL /100 mL generic *E. coli*
OR
MULTI PASS WATER ACCEPTANCE CRITERIA
Chlorine
≥1 ppm free chlorine (pH 5.5 - 7.5)
OR
Sufficient Disinfectant; Physical Treatment- sufficient wavelength to prevent cross-contamination

Other approved treatments per product EPA label for human pathogen reduction in water.

No further action necessary.
Water from this source may be used for any purpose.

ACTION LEVEL
Positive generic *E. coli*
OR
If the disinfectant or wavelength is not sufficient to prevent cross-contamination

REMEDIAL ACTIONS:

- DO NOT USE THE WATER.
- Follow your SOP for corrective action to meet acceptance criterial.
- For wells, perform an agricultural water system assessment and/or treat as described in Appendix A.
- After agricultural water system assessment on water used for harvest and/or remedial actions have been taken, retest the water at the same sampling point.
- After corrective actions have been implemented and verified the water may be used for harvest operations

7. ISSUE: SOIL AMENDMENTS AND CROP INPUTS

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 are 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 an initial rapid die-off from high pathogen populations, but a characteristic and prolonged low-level survival. Survival is typically less than 8 weeks following incorporation, but pathogens have still been detected at over 12 weeks (Jiang et al. 2002; Islam et al. 2004). Under some test conditions and using highly sensitive detection techniques, pathogen populations have been recovered demonstrating persistence beyond this period. 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).

Crop inputs are applied for pest and disease control, greening, and to provide organic and inorganic nutrients to the plant during the growth cycle. One type of crop input is known as Biological Products. Biological Products are used to manage plant diseases; enhance nutrient uptake and improve crop growth; manage insects and related pests; and manage weeds. For the purposes of this document, soil amendment and crop inputs will be categorized as follows:

7A – Biological of animal origin

7B – Biological of non-animal origin (fungal/bacterial extracts, green/plant waste, plant extracts, vegetative material, algae, yeast extract, pre/post-consumer waste not containing products of animal origin, etc.)

7C – Processed products

7D – Synthetic and inorganic

7E – Mixed components (blending categories 7a, 7b, 7c, and 7d)

THE BEST PRACTICES FOR SOIL AMENDMENTS ARE:

- DO NOT USE raw manure or soil amendments containing untreated animal by-products, un-composted / incompletely composted animal manure and/or green waste, or non-thermally treated animal manure to lettuce and leafy green production areas.
- Do not use biosolids as a soil amendment for production of lettuce or leafy greens or as an ingredient for soil amendments and crop inputs used for lettuce and leafy greens production.
- The use of soil amendments, made from mortality composting processes, shall follow all local, state, and federal regulations.

- When creating compost and/or soil amendments, use feedstocks and ingredients that will minimize the amount of biological, physical, and chemical food safety hazards that will be introduced to the process. Do not use materials that are not verified to be safe for food production (i.e., green waste from processing facilities).
- Post-consumer waste materials shall be used according to all local, state, and federal regulations.
- Implement an SOP regarding storage and application controls that establishes management controls that significantly reduce the likelihood that soil amendments being used may contain human pathogens. The SOP must address:
    - Supplier Approval
    - Source and Quality of the amendment
    - Delivery and transport
    - Surplus/unconsumed inventory
    - Length of Storage and storage location prior to crop application
    - Timing of application in the crop cycle and processes used for application.
    - Weather events (wind, rain and water runoff)
    - Potential for animal intrusion while on farm
    - Visitor and employee movements
    - Vehicle traffic
- If on-farm soil amendments may have become contaminated, the product must be segregated and prevented from being used until it is determined to be safe for food production. If a product can be re-conditioned there must be verification that it is free of pathogens such as a COA.
- Verify that the time and temperature during the composting process, controls, or eliminates the potential for human pathogens. Consider the moisture content of the finished product.
- Maximize the time interval between soil amendment application and time to harvest. When applying materials that may contact the edible portion of the crop consider the type of product being grown, the stage of the product growth, and the application process.
- Implement practices that control, reduce or eliminate likely contamination of lettuce/leafy green fields in close proximity to on-farm stacking of manure. Consider potential wind dispersed and aerosolized sources of contamination.
- Use soil amendment application techniques that control, reduce or eliminate likely contamination of surface agricultural water and/or edible portion of covered produce being grown in adjacent fields.
- Do not stockpile compost and/or other soil amendments near open system irrigation sources, including on-farm sources and those that serve multiple users, unless best management practices have been employed to prevent cross-contamination of common water sources (e.g. run-off protection such as berms, covering compost
- When compost is stockpiled and/or adjacent to covered produce/lettuce and leafy greens production areas perform a risk assessment based on the type and stage of crop per the adjacent land section.
- For on-farm soil amendment handling, preparation, distribution, applications use effective means of equipment sanitation or use dedicated on-farm equipment before subsequent use that effectively reduce the potential for cross-contamination. Efforts should be made to assure proper flow of equipment to

maintain segregation of raw and finished product. Soil amendment suppliers and on-farm composting operations shall have written sampling procedures.

- Soil amendment suppliers shall have Standard Operating Procedures to prevent cross-contamination of in-process and finished soil amendments with raw materials. Producers shall annually obtain proof that these SOP's exist. SOPs should consider the following:
  - Equipment
  - Runoff
  - Wind
  - Instructions for handling, conveyance and storage
  - In-process or finished soil amendments that have become contaminated.
- Temperature monitoring and turning records for compost applied to lettuce and leafy greens crops shall be maintained for at least two years. Producers purchasing compost shall annually obtain proof from their supplier that this documentation exists. When insulation materials are used during aerated static pile compost production, the insulation materials must be used in a way to minimize cross contamination. All air equipment should be maintained to minimize recontamination of the compost.
- Perform microbiological testing of composted soil amendments prior to application (Table 3).
- Any soil amendment that does not contain animal manure or other animal by-products must have a document (e.g., COAs, ingredient list, statement of identity, letter of guaranty, etc.) from the producer or seller confirming that the soil amendment is manure / animal by-product-free.
  - 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, products of animal origin, or other non-synthetic products (of animal or non-animal origin) have not been added.
  - The document confirming the soil amendment is manure-/animal by-product-free must be available for verification before harvest begins.
  - Assure product is handled properly from production to delivery.
- Documentation of all ingredients, processes and test results by lot and/or Certificates of Analysis is required to be available for inspection for of at least two years. If there is a significant process or ingredient change the results must be updated.

THE BEST PRACTICES FOR CROP INPUTS ARE:

- Do not use crop inputs that contain raw manure or other untreated animal products or by-products for lettuce or leafy green produce.
- When creating crop inputs, use ingredients that will minimize the amount of biological, physical, and chemical food safety hazards that will be introduced to the process.
- Post-consumer waste materials shall be used according to all local, state, and federal regulations.
- Do not apply untreated agricultural or compost teas containing added nutrients (e.g., carbohydrates, molasses, yeast extract, algal powder, etc.) intended to increase microbial biomass directly to lettuce/leafy greens.

- All crop inputs, in their final composition/end product, that will have contact with the edible portion of the crop need to have proof that they are free of pathogens of concern.
- Crop inputs that are biologically active must have assurances that they are pathogen free. A COA shall be available showing the input is free of pathogens of concern.
- The use of crop inputs, made from mortality composting processes, shall follow all local, state and federal regulations.
- Water used to make agricultural teas must minimally meet water quality requirements for harvest water use in Table 2G. Liquid crop inputs such as agricultural or compost teas may be used in water distribution systems provided all other requirements herein are met.
- Implement an SOP regarding storage and application controls that establishes management controls that significantly reduce the likelihood that crop inputs being used may contain human pathogens. The SOP must address:
    - Supplier Approval
    - Source and Quality of the amendment
    - Delivery and transport
    - Surplus/unconsumed inventory
    - Length of Storage and storage location prior to crop application
    - Timing of application in the crop cycle and processes used for application.
    - Weather events (wind, rain and water runoff)
    - Potential for animal intrusion while on farm
    - Visitor and employee movements
    - Vehicle traffic
- For on-farm crop input handling, preparation, distribution, applications use effective means of equipment sanitation or use dedicated on-farm equipment before subsequent use that effectively reduce the potential for cross-contamination. Efforts should be made to assure proper flow of equipment to maintain segregation of raw and finished product. All sanitation events must be documented.
- Verify that the time and temperature process used during crop input manufacture reduces, controls, or eliminates the potential for human pathogens being carried in the non-synthetic crop input materials.
- Maximize the time interval between the crop input applications and time to harvest. When applying materials that may contact the edible portion of the crop consider the type of product being grown, the stage of the product growth, and the application process.
- 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 inputs (see Table 0 for additional metrics).
- Use crop input application techniques that control, reduce or eliminate the likely contamination of surface water and/or edible crops being grown in adjacent fields.
- When mixing multiple partial lots of materials, ensure there is lot integrity.
- Do not mix and use materials that are not verified to be safe for food production or do not have a labeled use. (i.e., the production process has verified pathogen reduction, pathogens are tested, heavy metal analysis, etc.

- Retain all documentation for inspection for a period of at least two years.
- See Table 3 and Decision Trees (Figures) for numerical criteria and guidance for soil amendments and crop inputs used in lettuce and leafy greens production fields. **[Decision Trees for the Soil Amendments and Crop Inputs be added prior to the 2021/2022 season]**

TABLE 3. SOIL AMENDMENTS AND CROP INPUTS

Amendment	Metric/Rationale
Raw manure, untreated animal products/by-products, or not fully composted green waste, biosolids, and/or animal manure-containing soil amendments and crop inputs	**DO NOT USE OR APPLY** soil amendments, or crop inputs that contain un-composted, incompletely composted or non- treated animal manure and/or animal product/by-products, or *biosolids to fields which will be used for lettuce and leafy greens production or to lettuce and leafy greens crops. If these materials have been applied to a field, wait one year prior to planting and producing lettuce and leafy greens. Applications include, but are not limited to, the intentional use of an untreated soil amendment or crop input, the use of animals for field management of weeds and crop residue, the unintentional application due to drift from an adjacent area. **If applied to the crop the crop cannot be harvested for the fresh market.** *For Class A Biosolids use the one calendar year guidance. For Class B Biosolids the field cannot be replanted for a minimum of 38 months from discontinued use of Class B Biosolids. Soil testing must also be conducted demonstrating the soil meets the standard for compost.
Time interval and mitigations before planting can commence following the application of unallowed materials.	• Minimum (1) one calendar year after application of the product. Please note that certain environmental conditions particularly heavy rains, long periods (or unusual amounts) of rain or moisture, and increased humidity can cause pathogens of concern to persist for longer periods of time or to re-grow after being shown to be nondetectable. Also, the type, and amount of the soil amendment and crop input can also impact the persistence of pathogens which may change the minimum time required before replanting. When deemed acceptable, and guided through a proper risk assessment, appropriate soil testing can be used to shorten this period to no less than **270 days** prior to planting. • Suitable representative samples shall be collected for the entire area suspected to have been exposed to the applied products. This testing must be performed in a manner that accurately represents the production field. • Results must indicate that soil levels of microorganisms meet the recommended standards for processed compost. o 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.

Amendment	Metric/Rationale
	○ Appropriate mitigation and mitigation strategies are included in the text portion of the document.
7A - Composted Soil Amendments and Crop Inputs (containing animal manure or animal products) *Composted soil amendments should not be applied after emergence of plants.	**Please see Decision Tree for Use of Composted Soil Amendments and Crop Inputs of Animal Origin.** **Composting Process Validation:** <u>Enclosed or within-vessel composting</u>: Active compost must maintain a minimum of 131°F for 3 days or longer <u>Windrow composting:</u> Active compost must maintain aerobic conditions for a minimum of 131°F for 15 days or longer, with a minimum of five turnings during this period followed by adequate curing. <u>Aerated static pile composting:</u> Active compost must be covered with insulating materials per federal, state, and local regulation and maintain a minimum of 131°F for 3 days or longer with proper management to ensure elevated temperatures throughout all materials followed by adequate curing. **Target Organisms:** • Fecal coliforms • *Salmonella* spp. • *STEC* **Acceptance Criteria:** • Fecal coliforms: < 1,000 MPN / gram of total solids (dry weight basis) • *Salmonella* spp.: Negative or < DL (< 1 MPN / 30 grams) • *STEC*: Negative or < DL (< per methodology used) **Recommended Test Methods:** • Fecal coliforms: U.S. EPA Method 1680; multiple tube MPN • *Salmonella* spp.: U.S. EPA Method 1682 • *STEC*: Any laboratory validated method for compost sampling. • Other U.S. EPA, FDA, AOAC, TMECC or validated/accredited methods may be used as appropriate. **Sampling Plan:** • A composite sample shall be representative, random and obtained as described in the California state regulations. Alternative sampling plans should minimally meet the CA state regulations for location, depth, number of samples taken and shall be detailed in a Company SOP. • Sample may be taken by a trained representative. **Testing Frequency:** • Each lot before application to production fields. A sampling lot is defined as a unit of production equal to or less than 5,000 cubic yards. • A unit of production is meant to be physically unique. Some characteristics could include the same ingredients, same time of production, same production

Amendment	Metric/Rationale
	conditions, same equipment, etc. i.e. for each production lot, take one sample per each 5,000 cu yards. • Reconditioned/re-processed product suspected of being contaminated. • Bulk finished product, not enclosed or packaged, must be re-tested at minimum annually if it is stored for greater than one calendar year and none of the product has been distributed. If some part has been distributed the remaining product should be reconditioned minimally annually and re-tested. **Application Interval:** • Must be applied > 45 days before harvest. *Note: See best practices regarding what to consider when applying materials that may contact the edible portion of the crop.* **Documentation:** • All products must have documentation that demonstrates they are free of pathogens of concern. • All test results, Certificates of Analysis, and documentation shall be current, reviewed before use, and available for verification from the producer (the responsible party) for a period of two years. Policies, procedures, letters of guarantee, and similar types of documents, must be updated annually. • 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 are based on allowable levels from California state regulations for compost (CCR Title 14 - Chapter 3.1 - Article 7), with the addition of testing for *STEC* (including *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. • All products must be used in accordance with all local, state, and federal regulations.

Amendment	Metric/Rationale
7B[1] - Composted NOT Containing products of animal origin (green/plant waste, vegetative material, pre/post-consumer waste not containing products of animal origin, etc.)	**Please see Decision Tree for Use of Biological Soil Amendments and Crop Inputs of Non-Animal Origin.** **Composting Process Validation:** <u>Enclosed or within-vessel composting</u>: Active compost must maintain a minimum of 131°F for 3 days or longer. <u>Windrow composting:</u> Active compost must maintain aerobic conditions for a minimum of 131°F for 15 days or longer, with a minimum of five turnings during this period followed by adequate curing. <u>Aerated static pile composting:</u> Active compost must be covered with insulating materials and per federal, state, and local regulation maintain a minimum of 131°F for 3 days or longer followed by adequate curing. **Target Organism:** • Fecal coliforms • *Salmonella* spp. • *STEC* **Acceptance Criteria:** • Fecal coliforms: < 1000 MPN / gram of total solids (dry weight basis) • *Salmonella:* Negative or <DL (<1/30 grams) • *STEC:* Negative of <DL (< per methodology used) **Recommended Test Methods:** • Fecal coliforms: U.S. EPA Method 1680; multiple tube MPN • *Salmonella* spp.: U.S. EPA Method 1682 • *STEC* Any laboratory validated method for compost sampling. • Other *U.S. EPA, FDA, AOAC, TMECC* or validated/ accredited methods may be used as appropriate. **Sampling Plan:** • A composite sample shall be representative, random and obtained as described in the California state regulations. Alternative sampling plans should minimally meet the CA state regulations for location, depth, number of samples taken and shall be detailed in a Company SOP. • Sample may be taken by a trained representative. **Testing Frequency:** • Each lot before application to production fields. A sampling lot is defined as a unit of production equal to or less than 5,000 cubic yards. • A unit of production is meant to be physically unique. Some characteristics could include the same ingredients, same time of production, same production

Amendment	Metric/Rationale
	conditions, same equipment, etc. i.e. for each production lot, take one sample per each 5,000 cu yards. • Reconditioned/re-processed product suspected of being contaminated. • Bulk finished product, not enclosed or packaged, must be re-tested at minimum annually if it is stored for greater than one calendar year and none of the product has been distributed. **Application Interval:** • Must be applied > 45 days before harvest. *Note: See best practices regarding what to consider when applying materials that may contact the edible portion of the crop.* **Documentation:** • All products must have documentation that demonstrates they are free of pathogens of concern. • Any biological soil amendment or crop input that DOES NOT contain products of animal origin must have documentation that shows the material is free of products of animal origin. • All test results, Certificates of Analysis, and documentation shall be current, reviewed before use, and available for verification from the producer (the responsible party) for a period of two years. Policies, procedures, letters of guarantee, and similar types of documents, must be updated annually. • Records of process control monitoring for on-farm produced soil amendments must be reviewed, dated, and signed, within a week after the records completed, by a supervisor or responsible party. **Rationale:** • The microbial metrics and validated processes are based on allowable levels from California state regulations for compost (CCR Title 14 - Chapter 3.1 - Article 7), with the addition of testing for STEC (including *E. coli* O157:H7) as the 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. • All products must be used in accordance with all local, state, and federal regulations.

Amendment	Metric/Rationale
7B[2] - Non-Composted, Solid and Liquid, Soil Amendments and Crop Inputs Not Containing products of Animal origin (fungal/bacterial extracts, green/plant waste, plant extracts, vegetative material, algae, yeast extract, pre/post-consumer waste not containing products of animal origin, etc.) *These products have not gone through a validated treatment process to reduce microorganisms of concern.	**Products** Products included in this section could include: Biofertilizers, biologicals, biorationals, bio-stimulants, biopesticides, agricultural and compost teas not of animal origin, and other products not derived from ingredients of animal origin. Biopesticides that have gone through regulatory review are exempt from the testing requirements listed in this section. Ex. EPA registered products **Target Organisms:** • Fecal coliforms: • *Salmonella* spp. • *STEC* • *Listeria monocytogenes* **Acceptance Criteria:** • Fecal coliforms: < 1000 / gram of total solids (dry weight basis) • *Salmonella* spp.: Negative or < DL (< 1 MPN / 30 grams) • *STEC*: Negative or < DL (< per methodology used) • *Listeria monocytogenes: Negative* **Recommended Test Methods:** • Other U.S. EPA, FDA, AOAC, TMECC or validated/accredited methods may be used as appropriate. **Sampling Plan:** • A composite sample shall be representative, random and obtained as described in the California state regulations. Alternative sampling plans should minimally meet the CA state regulations for location, depth, number of samples taken and shall be detailed in a Company SOP. • Sample may be taken by a trained sampler and/or verified automated process. **Testing Frequency:** • Each lot before application to production fields. • Lot means a specific quantity of a finished product or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture. • Reconditioned/re-processed product suspected of being contaminated. **Application Interval** • If a COA is available demonstrating that the input meets the microbial acceptance criteria outlined above, then no time interval is needed between application and harvest. *Note: See best practices regarding what to consider when applying materials that may contact the edible portion of the crop.* **Documentation:**

Commented [KVH5]: Add language to clarify Biopesticides testing requirements are not required here. TSC voted on 7.11.23

Amendment	Metric/Rationale
	• All products must have documentation that demonstrates they are free of pathogens of concern. • All test results, Certificates of Analysis, and documentation shall be current, reviewed before use, and available for verification from the grower (the responsible party) for a period of two years. Policies, procedures, letters of guarantee, and similar types of documents, must be updated annually. • Records of process control monitoring for on-farm produced soil amendments must be reviewed, dated, and signed, within a week after the records completed, by a supervisor or responsible party. • Lot information shall be described on the COA or lot information must accompany the COA if the information cannot be described on the COA. Lot information is required to be able to conduct traceability for the material applied to the growing location and to link the product to a test result. Information that could be used to confirm the lot description could be lot identification # associated with a treatment step, shift, time parameters, sanitation breaks, volume, weight, size but other parameters could also be used based on a specific production process. • Any biological soil amendment or crop input that DOES NOT contain products of animal origin must have documentation that shows the material is free of products of animal origin. **Rationale:** • Verification and COA testing should have statistically relevant sample units to provide high probability of detection. For solids a minimum of n=60 samples. For Liquids sample size needs to be per production process lot sizes. • All products must be used in accordance with all local, state, and federal regulations.
7C - Biological soil amendments and/or crop inputs that have gone through a validated treatment process (not including composting) (Chicken pellets, blood meal, bone meal, feather meal, soybean meal, kelp meal, alfalfa meal, cotton seed meal, mustard meal, rice bran, treated fish	**Please see: 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 the process is capable of reducing pathogens of human health significance to acceptable levels. **Target Organism:** • Fecal coliforms • *Salmonella* spp. • STEC • *Listeria monocytogenes* **Acceptance Criteria:** • Fecal coliforms Negative or <DL per gram • *Salmonella:* Negative or <DL (<1/30 grams) • STEC Negative or <DL (< per methodology used) • *Listeria monocytogenes:* Not detected or < DL (<1 CFU/5 grams)

Amendment	Metric/Rationale
emulsion, treated agricultural teas, etc.	**Recommended Test Methods:** • Fecal coliforms: U.S. EPA Method 1680; multiple tube MPN • *Salmonella* spp.: U.S. EPA Method 1682 • *STEC* and *Listeria monocytogenes*: Any laboratory validated method for testing soil amendments. • U.S. EPA, FDA, AOAC or other validated / accredited methods may be used as appropriate. **Sampling Plan:** • A sample shall be representative and random. • Sample may be taken by a trained sampler and/or verified automated process. • For solids a minimum of n=60 samples or equivalent based on the manufacturer's production process. For Liquids sample size needs to be per production process lot sizes. **Testing Frequency:** • Each lot before application to production fields. • Lot means a specific quantity of a finished product or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture. • Reconditioned/re-processed product suspected of being contaminated. **Application Interval** • If the heat treatment process used to inactivate human pathogens of significant public health meets the microbial acceptance criteria outlined above, 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 is not validated but will likely significantly reduce microbial populations of human pathogens and product COAs meet microbial acceptance criteria outlined above, then a 45-day interval between application and harvest is required. *Note: See best practices regarding what to consider when applying materials that may contact the edible portion of the crop.* **Documentation:** • All test results, Certificates of Analysis, and documentation shall be current, reviewed before use, and available for verification from the grower (the responsible party) for a period of two years. Policies, procedures, letters of guarantee, and similar types of documents, must be updated annually. • Records of process control monitoring for on-farm produced soil amendments must be reviewed, dated, and signed, within a week after the records are completed, by a supervisor or responsible party.

Amendment	Metric/Rationale
	• Lot information shall be described on the COA or lot information must accompany the COA if the information cannot be described on the COA. Lot information is required to be able to conduct traceability for the material applied to the growing location and to link the product to a test result. Information that could be used to confirm the lot description could be lot identification # associated with a treatment step, shift, time parameters, sanitation breaks, volume, weight, size but other parameters could also be used based on a specific production process. • All products must be used in accordance with all local, state, and federal regulations. **Rationale:** 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.
7D – Synthetic and/or inorganic Soil Amendments or Crop inputs	• Any soil amendment or crop input that is synthetic or inorganic must have documentation that it is free of non-synthetic products and not containing ingredients of animal origin or manure. • All products shall be produced, transported, stored, and applied to prevent contamination of lettuce and leafy greens crops and production areas. • All products must be used in accordance with all local, state, and federal regulations. • The documentation must be available for verification before use. • 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. *Note: See best practices regarding what to consider when applying materials that may contact the edible potion of the crop.*
7E - Combined Components	• Any soil amendment or crop input that is combined must follow the criteria for the highest risk ingredient. (See 7A, 7B, 7C, and 7D above) • The documentation must be available for verification before use. • Any test results and/or documentation shall be available for verification from the grower who is the responsible party for a period of two years. ***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 that are mixed with soil amendments not containing animal manure would require a process certification for the heat-treated (or*

Amendment	Metric/Rationale
	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).

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878 **FIGURE 7A. DECISION TREE FOR COMPOSTED BIOLOGICAL SOIL AMENDMENTS AND CROP INPUTS**

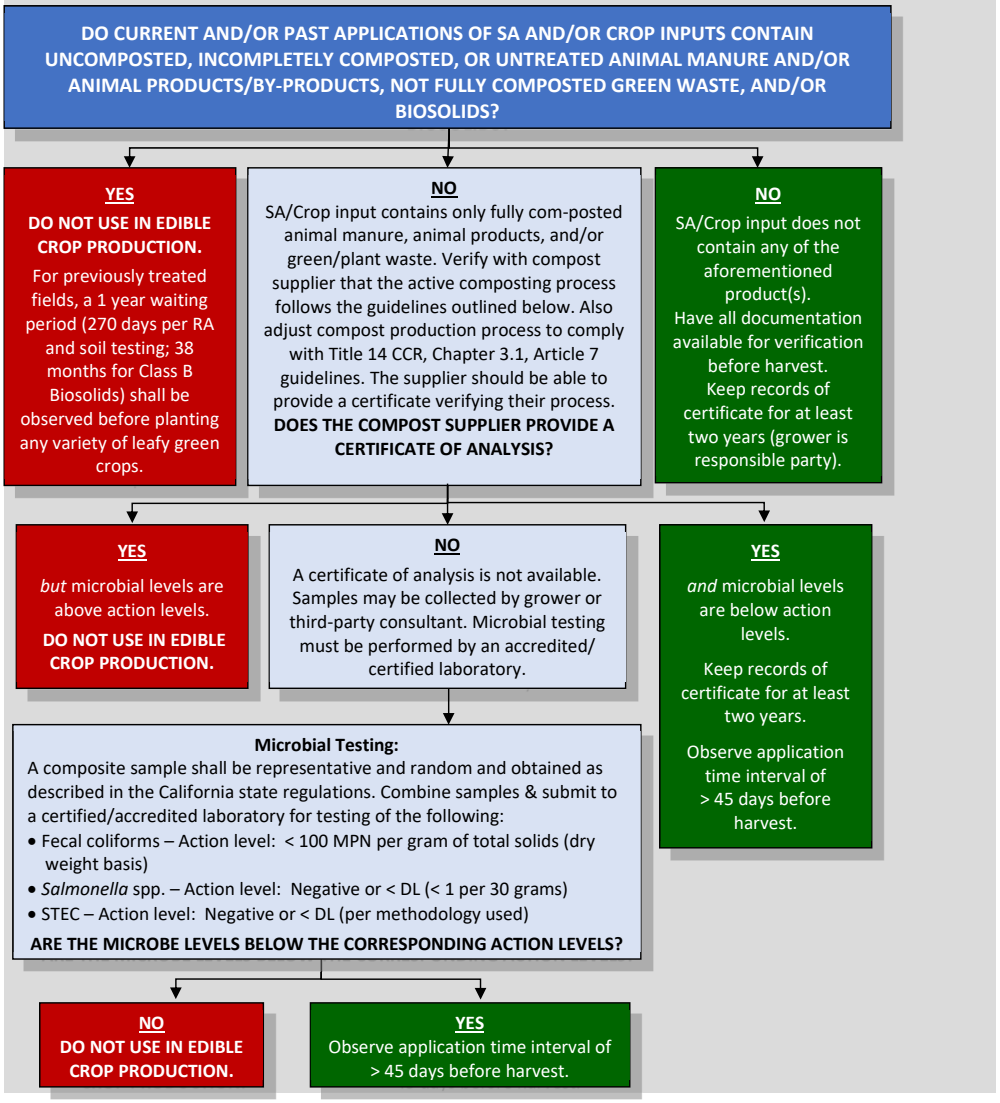

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FIGURE 7B. DECISION TREE FOR NON-COMPOSTED SOLID AND LIQUID SOIL AMENDMENTS AND CROP INPUTS NOT CONTAINING PRODUCTS OF ANIMAL ORIGIN

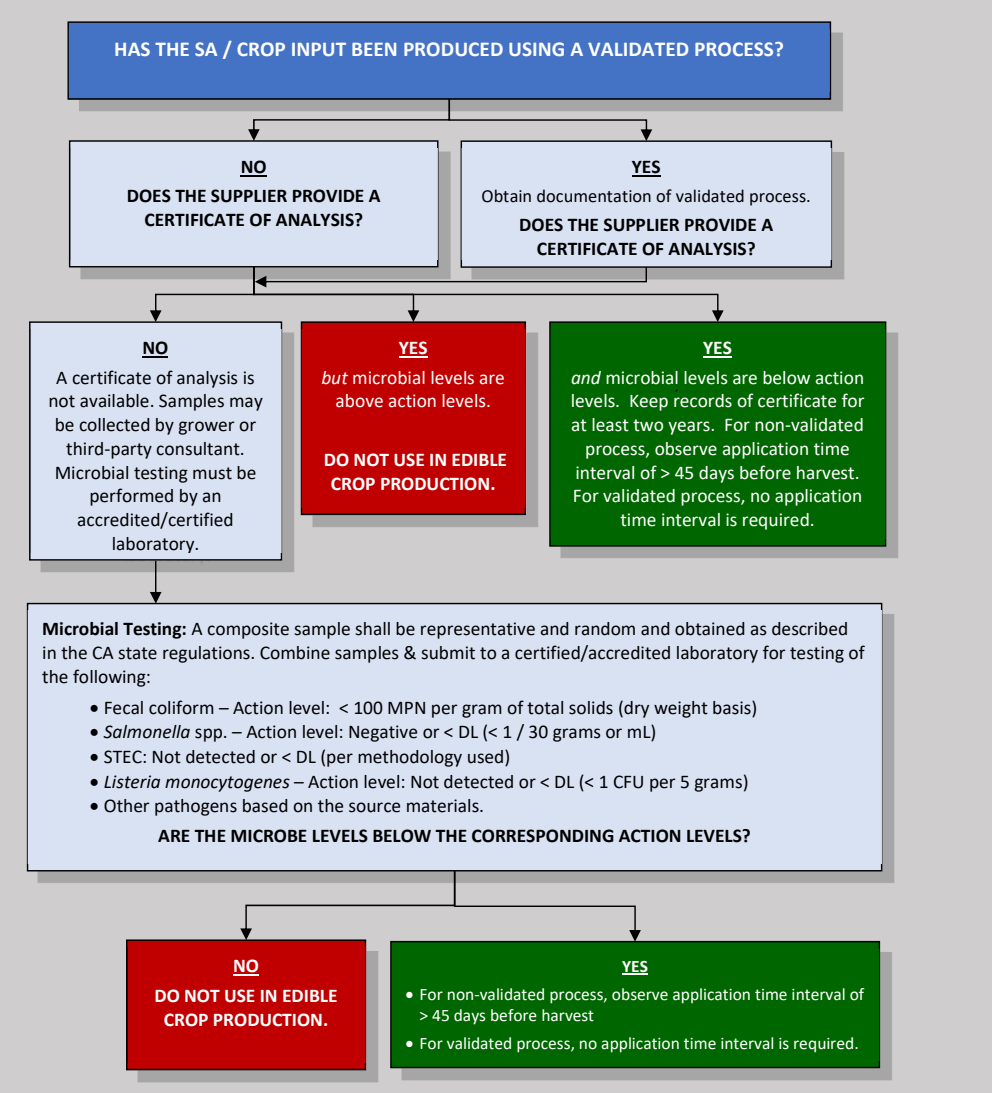
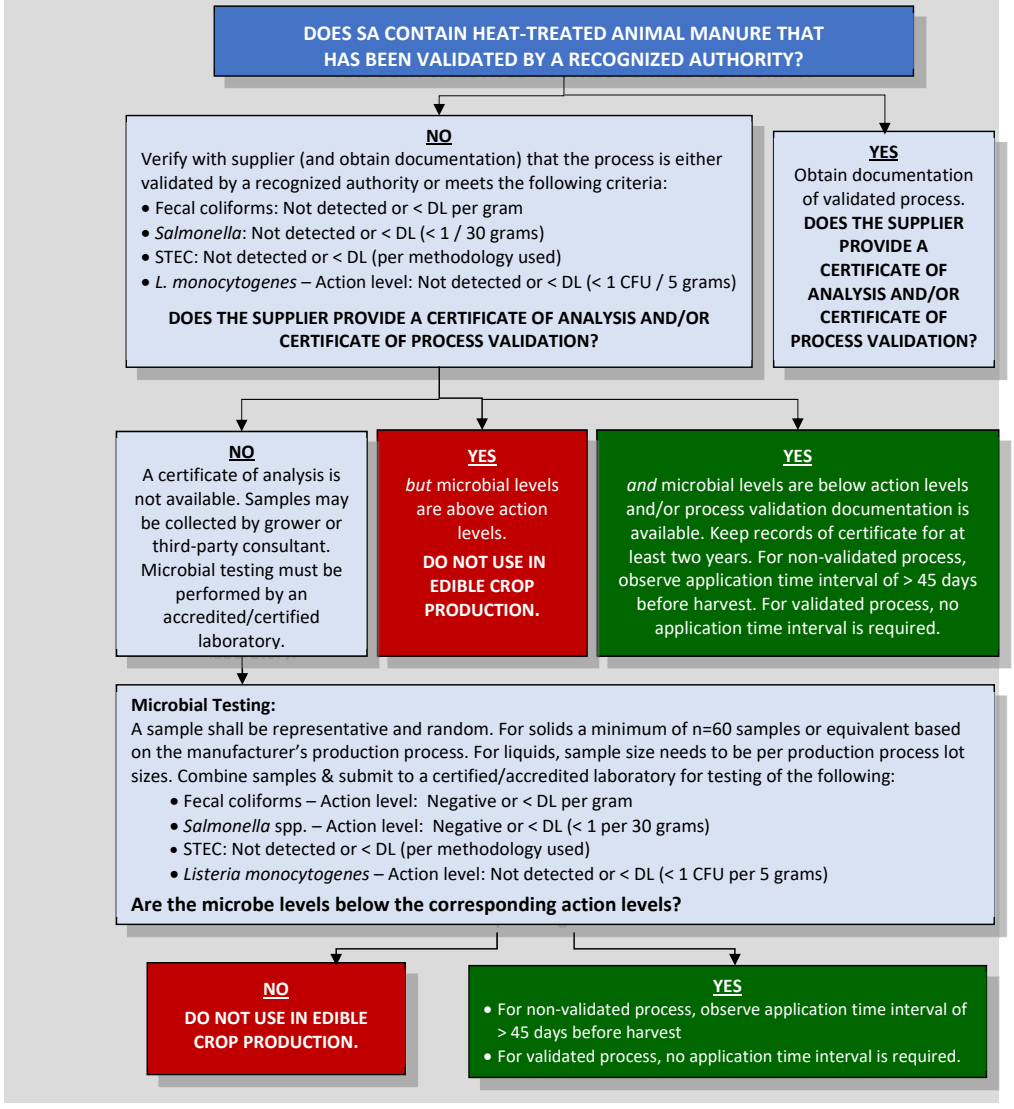


FIGURE 7C. DECISION TREE FOR BIOLOGICAL SOIL AMENDMENTS AND CROP INPUTS THAT HAVE GONE THROUGH A VALIDATED TREATMENT PROCESS



8. ISSUE : HARVEST EQUIPMENT, TOOLS, CONTAINERS, PACKAGING MATERIALS, AND BUILDINGS (FIELD SANITATION)

This section addresses harvest and harvest aid equipment, tools, 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, topped and/or tailed, or other field-based lettuce and leafy greens operations that use various harvest equipment and aids.

THE BEST PRACTICES ARE:

- Design harvest equipment and tools to facilitate cleaning. Harvest equipment must be constructed and maintained to ensure effective cleaning of the equipment over its lifespan. The equipment should be designed as to prevent bacterial ingress, survival, growth, and reproduction on both food-contact and non-food-contact surfaces.
- Protect lettuce/leafy greens, food-contact surfaces, production areas, and agricultural water sources and distribution systems from contamination.
- Equipment cleaning and sanitizing operations should take place away from product and other equipment to reduce the potential for cross-contamination
- Clean and sanitize food-contact surfaces on harvest equipment at the end of each daily harvest or when moving between commodities and fields and when excessive soil has built up.
- 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.
- Harvester sanitation personnel must utilize PPE equipment such as gloves, aprons, boots, face shields, respirators (if required) in such a way as to prevent cross-contamination of harvest equipment, tools, etc.
- Harvest sanitation crew must store all cleaning and sanitation chemicals in a secure location.
- All water utilized in cleaning and sanitizing of equipment must meet harvest water acceptance criteria. (See Table 2G)
- Documentation (logs or records) must be maintained for each harvest equipment cleaning and sanitation event (e.g. containers, tools, etc.).
- Records must be reviewed, dated, and signed by a supervisor or responsible party within a reasonable time after the records are made. FDA guidance suggests review within a week, but time can be lessened or increased on occasion. The company's documentation control SOPs shall designate the maximum number of days that will be necessary for the review, dating and signing of records.
- 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.
- Prepare an SOP for harvest equipment and tools that addresses the following:
  - Clean and sanitize equipment when moving between commodities and fields
  - Prior to beginning harvest, conduct a daily inspection that addresses cleaning and sanitation or noticeable change in conditions since prior sanitation. If necessary, rinse and sanitize food-contact surfaces on harvest equipment (i.e., accumulation of dirt, debris, dust, droppings, etc.).
  - Proper cleaning, sanitation and storage of hand-harvest equipment (knives, scythes, etc.).

- Prior to harvest crews exiting for breaks, harvest tools should be placed in a receptacle.
  - Water used should be safe and of adequate sanitary quality for its intended use.
    - Consider methods that aid in sanitation verification (i.e., ATP, rapid detection of residuals, microbial swabs, etc.).
    - Maintenance, cleaning, and sanitation schedules for equipment used in hydration must be maintained.
    - Management procedures for when equipment is not in use (i.e., end of season). To include a policy for removal of equipment from the work area (i.e., containers scabbards, sheathes or other harvest equipment).
- Prepare an SOP for sanitary operation of equipment which addresses the following:
  - Spills and leaks
  - Inoperative water sprays
  - Exclusion of foreign objects (including glass, plastic, metal and other debris)
  - Establish and implement procedures for the storage and control of water tanks and equipment used for hydration when not in use
  - Maintain logs documenting cleaning and sanitation
  - Retention of these records for at least two years
- If re-circulated rinse or antioxidant solutions are used on the cut surface, ensure that water used meets requirements in Table 2G. Take all practicable precautions to prevent rinses and solutions 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.
- Develop and implement Sanitation Standard Operating Procedures (SSOPs) to address frequency of cleaning and sanitizing of non-food-contact surfaces and food-contact surfaces to reduce and control the potential for microbial cross-contamination
  - Develop and implement a sanitation schedule for machine harvest operations (e.g., transportation tarps, conveyor belts, etc.).
  - Develop and implement appropriate cleaning, sanitizing, storage, and handling procedures of all equipment and food-contact surfaces
  - If equipment, tools, and 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.
- Food packing materials, containers, and packaging must be of adequate food safety design and quality for their intended use, which includes:
  - Cleanable and/or designed for single use to prevent the possible growth or transfer of pathogens.
  - Store packing containers and packaging materials off the floor, ground or soil and protected to the degree possible to prevent contamination.

- If containers or packaging materials are re-used, ensure that food-contact surfaces are clean or lined with a new liner.
- Consider obtaining a letter of guarantee for reusable containers if not cleaned in-house.

- Prepare an SOP for handling and storage of harvest containers and packaging materials that addresses the following:
  - Daily inspection
  - Proper cleaning and sanitation – routine cleaning and for changes in conditions of materials (i.e. weather events, pest activity, etc.)
  - Overnight storage
  - Contact with the ground or soil
  - Container assembly (RPC, fiber bin, plastic bin, etc.)
  - Damaged containers
  - Use of containers only as intended
- 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 tools and storage of harvest containers and food-packaging materials if applicable.
  - Reduce the potential for contamination of food-contact surfaces by effective building design including the separations of operations in which contamination is likely to occur. Considerations for 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.

9. Issue: Harvest - Direct Contact with Soil and Contaminants during Harvest (Field Sanitation)

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

The Best Practices Are:

- Allow adequate distance for the turning and manipulation of harvest equipment to prevent cross-contamination from areas or adjacent and nearby land that may pose a risk.
- Cut surfaces are vulnerable to microbial contamination. Prepare an SOP that addresses the following:
  - Prohibit ground or soil contact to avoid cross-contamination and minimizes the potential introduction of contamination during and after harvest operations (mechanical, hand, etc.).

- Ensure employees have been trained on the importance of minimizing the potential of cut product to contact the ground or soil.
- Evaluate the field for conditions that are likely to increase the risk of ground, soil, or post-harvest plant debris contact with harvest containers or cut product, and employ measures to minimize the potential introduction of human pathogens through ground or soil contact of cut product surface after harvest (e.g. frequency of knife sanitation, no placement of cut surfaces of harvested product on the ground or soil, container sanitation, single-use container lining, etc.).
- Discard and do not pack any lettuce/leafy greens dropped on the ground or soil during harvest.
- Packaging material should not have direct contact with the ground or soil. Physical barriers (i.e. liners, covers, existing plant material or other clean barriers) should be used to separate from ground or soil.
- Establish and implement a 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.

10. 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 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 practices program (i.e., an SOP) for verifying employee compliance with company food safety policies. 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, recordkeeping, and proper labeling of chemicals.
- Follow and be trained in proper 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.
    - Use of antiseptic/sanitizer or wipes, as a substitute for soap and water, is not permitted.
    - 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.
    - Prohibit use of personal gloves and taking gloves home.

- Avoiding contact with any animals.
- Confinement smoking, eating, and drinking of beverages other than water to designated areas.
- Prohibitions on spitting, urinating, or defecating in the field.
- Advise visitors 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 program for leafy green products that are intended for further processing. The program must address the following:
  - Head coverings and hair restraints.
  - Aprons, gloves, protective sleeves, other specialized PPE if used in handling or harvesting of lettuce and leafy greens and the maintenance, cleaning, sanitizing and/or replacement if no longer intact or unable to maintain in a sanitary condition
  - Physical hazard prevention associated with employee clothing and jewelry (rhinestones, sequins, 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 an employee/worker health practices program (i.e., an SOP) addressing the following issues:
  - Workers with diarrheal disease or symptoms of other infectious disease are prohibited from being in the field and handling fresh produce and food-contact surfaces.
  - Additional training and education on infectious illnesses that can be asymptomatic (e.g., cyclosporiasis, hepatitis, salmonellosis, norovirus).
  - Workers with open cuts or lesions are prohibited from handling fresh produce and food-contact surfaces without specific measures to prevent cross-contamination.
  - Instruct personnel to notify their supervisors if they may have a health condition that may result in contamination of covered produce or food contact surfaces. Companies shall develop and communicate return to work policies for returning employees to food contact positions after an illness or injury.
  - A policy describing procedures for handling/disposition of produce or food-contact surfaces that have come into contact with blood or other body fluids.

11. ISSUE: FIELD AND HARVEST - TRANSFER OF HUMAN PATHOGENS AND SANITARY FACILITY PRACTICES (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 associated with personal hygiene and toilet use. Cleaning and maintenance activities involving field sanitary units (toilets) must be conducted in such a way as to protect lettuce and leafy greens, food contact surfaces, production areas, and agricultural water sources and distribution systems from contamination.

THE BEST PRACTICES ARE:

- Establish and implement preventive measures to minimize the potential for contamination of lettuce and leafy greens associated with the use, cleaning, maintenance, and storage of sanitary facilities.
- A field sanitary facility program (i.e., an SOP) shall be implemented, and it should address the following issues:
  - Establish portable toilet cleaning procedures to prevent any potential risk of contamination (i.e. gray water, black water, overspray/drift or runoff) of growing fields and ranch roads.
  - Prohibit dumping gray water (collected hand wash water) within the production locations of the ranch.
  - The number, condition, frequency, type, and location of cleaning (i.e., field permanent vs. harvest placement)
  - Federal, state or local regulation
  - The accessibility of the units to the work area
  - Facility maintenance
  - Facility supplies (i.e., hand soap, water, hand sanitizer or antiseptic wipes, single-use paper towels, toilet paper, etc.)
  - Facility signage
  - Facility cleaning and servicing
  - A response plan for leaks or spills.
- During production, harvest, packing, and holding activities, hand-washing facilities with running water that meets the standards outlined in Table 2G for hand wash 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 sanitary 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 employee/visitor 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.
- Whenever appropriate, segregate and properly label, (i.e., color code, tool description) cleaning and sanitizing equipment and tools to prevent misuse or cross-contamination (i.e., tools used for bathroom cleaning).
- If applicable, ensure that workers are trained regarding portable unit cleaning procedures.
- If applicable, cleaning tools used for sanitary units shall only be used for sanitary unit cleaning and shall be stored in a manner to prevent contamination when not in use
- Establish and implement equipment and supply storage and control procedures when not in use. Indicate storage of harvest sanitary units when not in use and cleaning procedures prior to placing back into service before transporting to harvest or field location.
- Maintain documentation of maintenance and sanitation schedules and any remedial practices for a period of two years. Servicing records (either contracted or in-house) should be available for review to verify this is occurring according to SOP.

12. ISSUE: ON-FARM EQUIPMENT FACILITATED CROSS-CONTAMINATION (FIELD SANITATION)

When farm equipment has had direct contact with raw untreated manure, untreated compost, waters of unknown quality, animals, uncovered produce as defined in the PSR, excessive soil (See Issue 14), or other potential human pathogen reservoirs it may be a source of cross-contamination. If farm equipment comes into contact with a potential source of contamination, steps need to be set in place to address cleaning and sanitation to prevent 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:

- Allow adequate distance for the turning and manipulation of farm equipment to prevent cross-contamination from areas or adjacent and nearby land that may pose a risk.
- 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 and tools used in high-risk operations or potentially exposed to high levels of contamination.
- If equipment was previously used in a high-risk operation, use effective means of cleaning and sanitation before subsequent equipment use in lettuce/leafy greens production.
- Develop an SOP that requires the re-cleaning and sanitation of any equipment that becomes contaminated with potential pathogens.
- 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.
- When harvest equipment is not used, implement control and storage procedures that ensure recleaning of equipment before its next use.
- Maintain appropriate records related to equipment cleaning and possible cross-contamination issues for a period of two years.

13. 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 5.

THE BEST PRACTICES FOR PRODUCT THAT HAS COME INTO CONTACT WITH FLOOD WATER ARE:

- See Table 5 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 5. 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 ft. distance is the turn around 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).

14. 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 and harvest activities. It is important to tailor practices and procedures to prevent cross-contamination and promote food safety for the unique environments in which each crop may be produced.

The Best Practices Are:

- 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.
- Do not allow runoff from adjacent properties to come into contact with produce.
- Take care to reduce the potential for windborne soil, including soil from roads adjacent to fields, or other media that may be a source of contamination to come into direct contact with the edible portions of the lettuce and leafy greens.
- Establish an SOP for production locations that have an environmental source of pathogens (i.e. CAFO, AFO, dairy, hobby farm, manure storage or compost facility) and the potential for contamination during weather conditions and events.
- Consider harvest practices such as removing soiled leaves, not harvesting soiled heads, etc., when excessive soil or mud builds up on lettuce/leafy greens.
- When soil has accumulated on plants, remove soil at harvest or during further processing.

15. 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 0 provides a list of these uses and recommended buffer distances.

THE BEST PRACTICES ARE:

- See Tables 6 and 0 and Decision Tree (Figure 9) for numerical criteria and guidance applicable to animal encroachment and adjacent and nearby land uses. The Technical Basis Document (Appendix B) describes the process used to develop these metrics.
- During the Environmental Assessments discussed in Section 5, the location of any adjacent and nearby land uses that are likely to present a food safety risk should be documented and a detailed risk assessment of adjacent and nearby land shall be performed to determine the risk level as well as to evaluate potential strategies to control or reduce the introduction of human pathogens.
- In addition, as specified in Table 0, any deviations from the recommended buffer distances due to mitigation factors or increased risk should be documented in a detailed risk assessment of adjacent and nearby land.
- Evaluate and monitor animal activity in lettuce/leafy greens fields and production environments and in adjacent and nearby land. Conduct and document periodic monitoring and pre-season, pre-harvest, and harvest assessments. If animals present a probable risk (medium/high hazard), make 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 or 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 0 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 6 and 0.
- DO NOT harvest areas of fields where unusually heavy activity by animals has occurred (see Figure 9 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 an accident, 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 Arizona Department of Environmental Quality, Arizona Game & Fish Department, USDA APHIS Wildlife Services-Arizona Division, U.S. Fish and Wildlife Services) to confirm the details of these requirements. In addition, producers may wish to consult with local USDA Natural Resources Conservation Service (NRCS) staff to evaluate, develop, and document strategies to manage or reduce the food safety risks associated with wildlife, livestock, domestic animals on adjacent and nearby land uses and to minimize the potential introduction of human pathogens for each production block.

FIGURE 9. PRE-HARVEST AND HARVEST ASSESSMENT – ANIMAL HAZARD/FECAL MATTER DECISION TREE

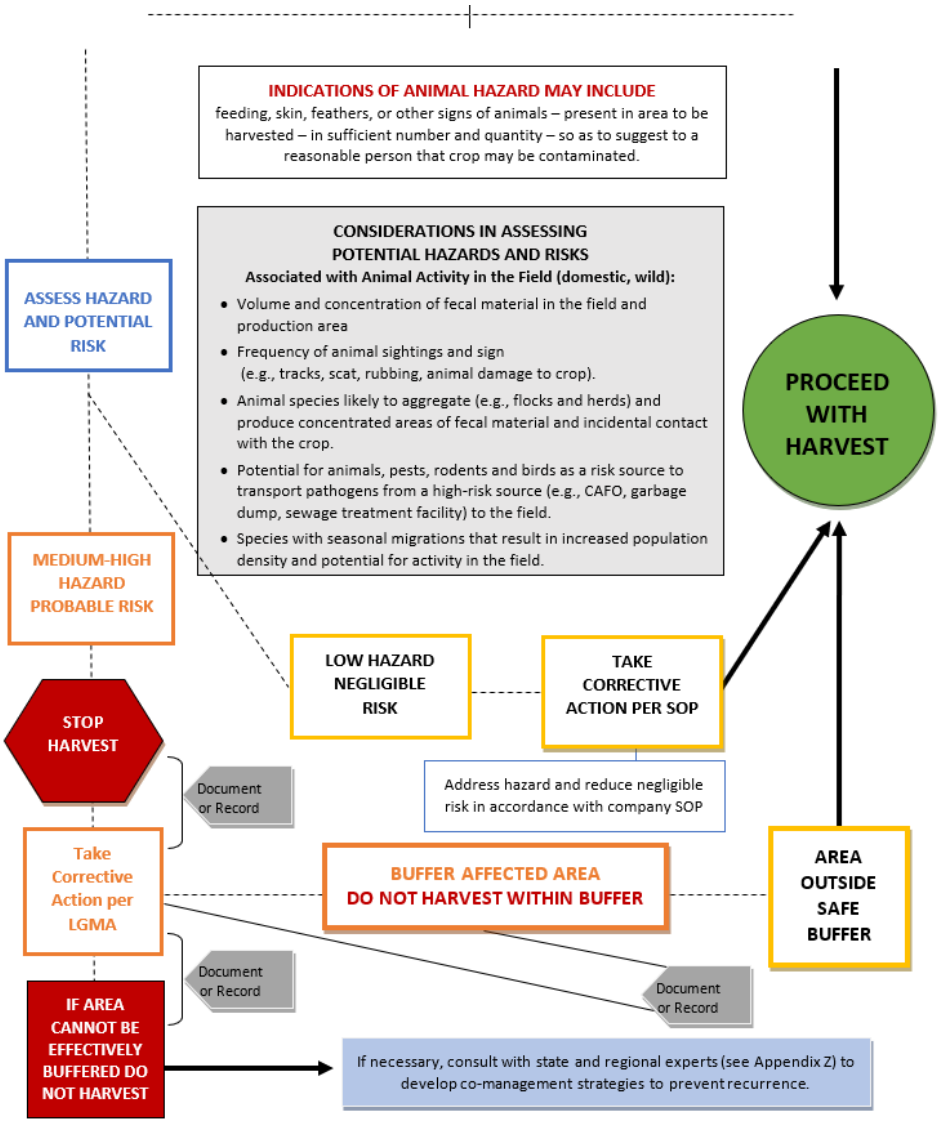


TABLE 6. ANIMAL HAZARD IN FIELD (WILD OR DOMESTIC)

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 small 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 regulate wildlife deterrence measures, including hazing, harassment, lethal and non-lethal removal, etc. • Food safety assessments and corrective actions shall be documented and available for verification for a period of two years.
Allowable Harvest Distance from Evidence of Intrusion		
Please see Figure 9. 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		

Issue	Metric	Remedial Actions
		• 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. <u>Intrusion</u> • 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 to high hazard (probable risk) intrusion should include a three-foot buffer radius around a do not-harvest area where the impacted crop has been isolated. <u>Daily Harvest Assessment ONLY</u> 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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16. 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

17. DETAILED BACKGROUND GUIDANCE INFORMATION

REFERENCE DOCUMENTS

1. FDA Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (www.foodsafety.gov/~dms/prodguid.html)
2. National GAPs Program Cornell University: Food Safety Begins on the Farm: A Grower Self-Assessment of Food Safety Risks
3. FDA Food Safety Modernization Act (FSMA) rule on *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*
4. FDA Food Safety Modernization Act (FSMA) rule on Sanitary Transportation of Human and Animal Food

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