Commodity Specific Food Safety Guidelines
for the Production, Harvest, Post-Harvest,
and Processing Unit Operations of

Fresh Culinary Herbs

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Version 1

DISCLAIMER

These guidelines are intended only to convey the best practices associated with the industry as research and practice advance; however, guidelines may change. For this reason, it is recommended that readers periodically evaluate the applicability of any recommendations in light of particular situations and changing standards. The authors, 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 these documents do not certify compliance with these guidelines and do not endorse companies or products based upon their use of these guidelines.

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The diversity of methods in the production of fresh culinary herbs makes a single, universally applicable approach to food safety planning complicated. For the purposes of this document, the term, fresh culinary herbs includes all varieties of basil, chervil, chives, cilantro, culantro, dill, lemon verbena, marjoram, mint, oregano, parsley, rosemary, sage, savory, sorrel, tarragon, and thyme. It is important that each firm that grows and handles fresh culinary herbs assess its operations and implement methods to meet their individual needs. What is most important is that basic food safety program components are implemented by producers to ensure fresh culinary herb product safety for consumers. Whatever the preferred production method for a single producer, fresh culinary herb producers and handlers agree that the following basic principles should serve as the foundation for all food safety programs within their segment of the industry:

- Fresh culinary herbs have occasionally been associated with human pathogens and illness; therefore, in addressing the potential sources of contamination, fresh culinary herb food safety programs should pay special attention to planting and growing conditions, agricultural practices at all phases of production, and harvest and post-harvest fresh culinary herb handling.
- Fresh culinary herb producers and handlers recognize that once fresh culinary herbs are contaminated, completely removing or killing pathogens is unlikely; therefore, prevention of microbial contamination at all steps from production to distribution is strongly favored over treatments to eliminate contamination after it has occurred.
- Fresh culinary herb producers and handlers support implementation and documentation of food safety programs that utilize risk assessment techniques in order to identify all plausible risks, prioritize operation-specific risks, and use a preventive approach to ensure the safety of fresh culinary herbs.
- Fresh culinary herb producers and handlers also support and encourage routine and regularly scheduled food safety awareness training for all persons who handle fresh culinary herbs during production, harvesting and processing operations.

In the sections that follow, the Best Practices were developed to address each identified potential food safety issue. However, it is the responsibility of individuals and companies involved in the field-to-fork fresh culinary herb supply chain to determine what actions are appropriate in their individual operations. The potential food safety issues identified in each unit operation section are focused only on fresh culinary herbs and may or may not apply to other specialty crops. Particular best practices that address any identified issue are not the only means by which the issue may be addressed. Individuals and companies are encouraged to use this document to evaluate, develop, and enhance their own food safety programs.

The document contains a list of reference documents that offer detailed and important background information regarding how to develop food safety programs. Each company's comprehensive food safety program and its various components (e.g. employee training, standard operating procedures) should be developed based upon an analysis of the potential hazards in that specific company's operations. As presented, this guidance document is not sufficient to serve as an action plan for any specific operation, but should be viewed as a starting point. This guidance document is intended to supplement, not replace, already established food safety program components such as Good Agricultural Practices (GAPs), current Good Manufacturing Practices (cGMPs), and Hazard Analysis Critical Control Point (HACCP) and/or Hazard Analysis and Risk-Based Preventive Control Point (HARPC) guidelines for the fresh fruit and vegetable industry.

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AFOs: Animal feeding operations
AOAC: Association of Official Analytical Chemists
ATP: Adenosine tri-phosphate
BAM: Bacteriological analytical manual
CAFOs: Concentrated animal feeding operations
CCPs: Critical control points
CDC: Centers for Disease Control and Prevention
CDFA: California Department of Food and Agriculture
CDHS: California Department of Health Services
CFR: Code of Federal Regulations
CFU: Colony forming units
cGMP: Current good manufacturing practices
COA: Certificate of analysis
DL: Detection limit
FAO: Food and Agriculture Organization
FDA: Food and Drug Administration
FFDCA: Federal Food, Drug, and Cosmetic Act
GAPs: Good agricultural practices
GLPs: Good laboratory practices
HACCP: Hazard analysis critical control point
MSDS: Material safety data sheets
MPN: Most probable number
NGO: Nongovernmental organization
NRCS: Natural resources conservation service
ORP: Oxidation reduction potential
OSHA: Occupational Safety and Health Administration
PCR: Polymerase chain reaction
PPM: Parts per million
RAC: Raw agricultural commodity
RFR: Reportable Food Registry
RPCs: Returnable plastic containers
RTE: Ready-to-eat
SAs: Soil amendments
SOPs: Standard operating procedures
SSOPs: Sanitation standard operating procedures
USDA: United States Department of Agriculture
US EPA: United States Environmental Protection Agency
UV: Ultraviolet

Glossary

Terms defined in this glossary represent the use of the term in the context of this particular document. These definitions may not represent the term as it may be used in a different context.

active compost	Compost feedstock that is unstable and in the process of being rapidly decomposed and 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.[7]
aerosolized	The dispersion or discharge of a liquid substance that generates a suspension of fine particles in air or other gas.
agricultural material	Material of plant or animal origin resulting from the production and processing of farm, ranch, agricultural, horticultural, aquacultural, silvicultural, floricultural, vermicultural, or viticultural products, including manures, orchard and vineyard prunings, and crop residues.[7]
animal by-product	Most parts of an animal that do not include muscle meat including organ meat, nervous tissue, cartilage, bone, blood and excrement.
adenosine tri-phosphate (ATP)	A high energy phosphate molecule required to provide energy for cellular function.
ATP test methods	Exploits knowledge of the concentration of ATP as related to viable biomass or metabolic activity; provides an estimate of cleanliness.
biosolids	Solid, semisolid, or liquid residues generated during primary, secondary, or advanced treatment of domestic sanitary sewage through one or more controlled processes.
clean	When food or food-contact surfaces are washed and rinsed and are visually free of dust, dirt, food residues, and other debris. [1]
colony forming units (CFU)	Viable microorganisms (bacteria, yeasts, and mold) capable of growth under the prescribed conditions (medium, atmosphere, time and temperature) develop into visible colonies (colony forming units) on agar which are counted.
coliforms	Gram-negative, non-spore forming, rod-shaped bacteria that ferment lactose to acid and 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.

1 FDA. 1998. Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064574.htm#i

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. The number and types of animals covered by this definition can be found in the Federal Register's definition of medium and large CAFOs (CFR Title 40, Part 122.23).[2]
control	Means to manage the condition of an operation in order to be consistent with established criteria, and to follow correct procedures. [1]
control measure	Means any action or activity that can be used to prevent, reduce, or eliminate a microbiological hazard. [1]
critical control point	A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.[3]
cross-contamination	The transfer of microorganisms, such as bacteria and viruses, from a contaminated surface or media to a previously uncontaminated surface or media.
culinary	Of or relating to the kitchen or cookery.
current Good Manufacturing Practices (cGMPs)	Regulations that are found in 21 CFR 110 (Current Good Manufacturing Practices in Manufacturing, Processing, Packing, or Holding Human Food).
E. coli	*Escherichia coli* are common bacteria that live in the lower intestines of animals (including humans). Though generally not harmful, the presence of generic *E. coli* is frequently used as an indicator of fecal contamination.
environmental assessment	An evaluation of the growing environment taking into consideration factors including topography, hydrology, geographical features, climatic conditions, land history, near-by land use, agricultural water, and domestic animal and wildlife presence to evaluate any safety risks that may affect the potential for leafy greens to be contaminated. Environmental assessments may be conducted prior to planting, during production, and immediately prior to each harvest. [4]

2 E-CFR. 2010. Title 40: Protection of Environment. Part 122—EPA Administered Permit Programs: The National Pollutant Discharge Elimination System: Subpart B—Permit Application and Special NPDES Program Requirements http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&rgn=div8&view=text&node=40:21.0.1.1.12.2.6.3&idno=40

3 FDA. 1997. Hazard Analysis and Critical Control Point Principles and Application Guidelines http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/HACCPPrinciplesApplicationGuidelines/default.htm#defs

4 FDA. 2009. Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens; Draft Guidance. http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm174200.htm#def

facilities	Buildings and other physical structures used for or in connection with the harvesting, washing, sorting, storage, packaging, labeling, holding, or transport of fresh produce. [4]
fecal coliforms	Coliform bacteria that grow at elevated temperatures. Useful to monitor effectiveness of composting processes. Also called "thermotolerant coliforms."
field container	Containers used in the field to transport fresh culinary herbs to the packinghouse or processing facility.
finished product container	Containers used to hold fresh culinary herbs that are ready for shipping. Typically waxed fiberboard cartons, wax-less fiberboard cartons, or plastic returnable produce containers (RPCs).
flooding	The flowing or overflowing of a field with water outside a grower's control.
food contact surface	Those surfaces that contact human food and those surfaces from which drainage onto the food or onto surface that contact the food ordinarily occurs during the normal course of operations; includes utensils and equipment surfaces.[5]
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 professional	Person entrusted with management level responsibility for conducting food safety assessments before food reaches consumers; requires training or experience sufficient to establish a solid understanding of the principles of food safety as applied to agricultural production.
fresh culinary herbs	The green leaves or needles of perennial, biennials, or annual plants that are typically used as part of a leafy green salad mix or in relatively small amounts in cooking to add flavor or garnish to food. Includes all varieties of basil, chervil, chives, cilantro, dill, lemon verbena, marjoram, mint, oregano, parsley, rosemary, sage, savory, sorrel, tarragon, and thyme.

5 CFR. 2009. Code of Federal Regulations, Title 21 Part 110.3 Definitions http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=110

fresh-cut produce	Fresh fruits and vegetables for human consumption that have been minimally processed and altered in form by peeling, slicing, chopping, shredding, coring, or trimming, with or without washing, prior to being packaged for use by the consumer or a retail establishment; does not require additional preparation, processing, or cooking before consumption, with the possible exception of washing or the addition of salad dressing, seasoning or other accompaniments.[6]
GAPs guide	Guidelines set forth in the "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," which was issued by FDA in 1998.
geometric mean	Mathematical def.: the *n*-th root of the product of n numbers, or the *n*-th root of $(X_1)(X_2)...(X_n)$, where X_1, X_2, etc. represent the individual data points, and *n* is the total number of data points used in the calculation. Practical def.: the average of the logarithmic values of a data set, converted back to a base 10 number.
green waste	Any plant material that is separated at the point of generation, contains no greater than 1.0 percent of physical contaminants by weight, and meets the requirements of section 17868.5. Green material includes, but is not limited to, yard trimmings, 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.[7]
hazard	A biological, chemical or physical agent that is reasonably likely to cause human illness or injury in the absence of control. [1]
HACCP plan	A written document that delineates the formal procedures for following the Hazard Analysis and Critical Control Point principles developed by The National Advisory Committee on Microbiological Criteria for Foods.[8]
handler	An individual or entity that receives, acquires, cleans, sells, consigns, or imports fresh culinary herbs in their natural form including both raw agricultural commodities and processed products.

6 FDA. 2008. Guide to Minimize Microbial Hazards in Fresh-cut Fruits and Vegetables.

7 CCR Title 14, Chapter 3.1, Article 1, Section 17852

8 http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/HACCPPrinciplesApplicationGuidelines/default.htm

human pathogen	Microorganisms (yeast, mold, bacteria parasite, protozoa or virus) capable of causing illness or disease to people. This is different from plant pathogens which may cause disease to plants.[1]
indicator microorganisms	A fundamental monitoring tool used to measure both changes in environmental (water) quality or conditions and the potential presence of hard-to-detect target pathogenic organisms. An indicator organism provides evidence of the presence or absence of a pathogenic organism surviving under similar physical, chemical, and nutrient conditions.[9]
market withdrawal	Removal or correction of a distributed product which involves a known or suspected adulteration prior to shipment that would not be subject to legal action by the FDA or which involves no violation.[10]
metrics	Established measurable best practices and guidelines for a variety of process areas judged to be potential contributors to the risk of microbial contamination.
microorganism	Yeasts, molds, bacteria, parasites, protozoa and viruses some of which are capable of causing illness or disease in people.
most probable number (MPN)	Estimated values that are statistical in nature used for enumeration of microbes in a sample when present in small numbers.
nonsynthetic crop treatments	Any crop input that contains animal manure, an animal product, and / or an animal by-product that is reasonably likely to contain human pathogens.
oxidation reduction potential (ORP)	An intrinsic property that indicates the tendency of a chemical species to acquire elections and so be reduced; the more positive the ORP, the greater the species' affinity for electrons.
packaging material	Any item that is used in holding and transporting finished fresh culinary herbs during storage and shipment.
packinghouse	A facility where raw agricultural commodities are washed, trimmed or sorted and packed in commercial containers, e.g., cartons or totes.
parts per million (ppm)	A measure of concentration in solution; in particle of a given substance for 1,000,000 particles.[11]

9 EPA. National Beach Guidance and Required Performance Criteria – Appendix 1C1: Indicator Organisms http://water.epa.gov/grants_funding/beachgrants/app1c.cfm

10 http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/Recalls/default.htm

11 Centers for Disease Control and Prevention. (http://www.cdc.gov/oralHealth/infectioncontrol/glossary.htm)

pathogen	A microorganism (yeast, mold, bacteria parasite, protozoa or virus) capable of causing illness or disease.
pest	Any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.
pooled water	An accumulation of standing water; not free-flowing.
post-harvest container	Containers that are used to transport fresh culinary herbs within the packinghouse / processing facility.
potable water	Water that meets the standards for drinking purposes of the state or local authority having jurisdiction or water that meets the quality standards prescribed by the U.S. Environmental Protection Agency's National Interim Primary Drinking Water Regulations, published in 40 CFR Part 141.[12]
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.
processing facility	A facility with a controlled temperature environment that operates under cGMPs and it is used in the processing, packaging, labeling, and holding of fresh culinary herbs.
raw agricultural commodity (RAC)	Any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.[13]
ready-to-eat (RTE)	Food that is in a form that is edible without additional preparation to achieve food safety, as specified under the Food Code; includes raw fruits and vegetables that are thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption.[14]
ready-to-use (RTU)	Describes fresh culinary herbs that have been minimally processed – cleaned, trimmed, and possibly cut before being packaged, and require further washing and preparation prior to consumption.
recirculated water	A closed water system, where water is used more than one time before it is discharged into a wastewater system.

12 OSHA. 1987. Field Sanitation –1928.110. http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10959

13 FDA. 2010. Federal Food, Drug and Cosmetic Act. Sec. 201, Chapter II – Definitions (http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterIandIIShortTitleandDefinitions/ucm086297.htm)

14 FDA. 2009. Food Code: U.S. Public Health Service.

Registered Food Facility	Facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States under FFDCA section 415(a); exempt industries include farms, retail food establishments, restaurants, nonprofit food establishments, fishing vessels, and facilities regulated exclusively by the USDA.
Reportable Food Registry	An electronic portal for Registered Food Facilities to report when there is reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals; a requirement for Registered Food Facilities.
riparian areas	Lands that occur along watercourses and water bodies such as flood plains and stream banks that are distinctly different from surrounding lands because of unique soil and vegetation characteristics strongly influenced by the presence of water.[15]
risk	A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard or hazards in food.
risk mitigation	Actions to reduce the severity / impact of a risk.
***Salmonella* spp.**	A rod-shaped, non-spore-forming, Gram-negative bacterium that is a member of the family Enterobacteriaceae (as is *E. coli* and coliforms) and causes illness (salmonellosis) in humans. Environmental sources include water, soil, insects, manufacturing surfaces, animal feces, eggs and raw meats, poultry or seafood.[9]
sanitary facility	Toilet facilities and hand-washing stations.
sanitary survey	An inspection of the entire water system, including water source, facilities, and equipment, for the purpose of identifying conditions that may result in microbial contamination. [4]
sanitation standard operating procedures (SSOPs)	A set of written instructions that addresses sanitation conditions and practices before, during, and after processing including but not limited to water quality, food contact surfaces, cross-contamination, pest control, employee hygiene and health, maintenance of hand-washing and toilet facilities, etc.
sanitize	A process that is effective in destroying or substantially reducing the numbers of microorganisms of public health concern, as well as other undesirable microorganisms. [1]

15 USDA. Natural Resources Conservation Service. (http://www.nrcs.usda.gov/technical/rca/ib11text.html)

sanitization (food contact surfaces)	The application of cumulative heat or chemicals on cleaned food contact surfaces that, when evaluated for efficacy, is sufficient to yield a reduction of 5 logs, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance.[16]
soil amendment	Elements added to the soil, such as compost, peat moss, or fertilizer, to improve its capacity to support plant life.
standard operating procedures (SOPs)	A set of written instructions detailing all steps and activities required to perform a given task or in reaction to a given event; the purpose of which is promote quality by minimizing variation and facilitating consistency.
surface water	Water at or above the land surface.[17]
touch point	Any occasion when the food is handled by a worker or contacts an equipment surface.
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, scientific study that considers and determines limits for all process variables that may impact the process' objectives.
water distribution system	All pipes, pumps, valves, storage tanks, reservoirs, meters, fittings, and other components used to carry water from its primary source to other areas of the property, building, etc.
wetlands	Those areas that are inundated or saturated by surface or ground water at a frequency and duration sufficient to support, and that under normal circumstances do support, a prevalence of vegetation typically adapted for life in a saturated soil conditions; generally includes swamps, marshes, bogs, and similar areas.[18]
wildlands	Forests, native grasslands, shrubs, wetlands, and transitional lands (mostly clear-cuts); excludes orchards, arable lands (e.g. row crops) and pasture.[19]

16 FDA. 2009. Food Code. U.S. Department of Health and Human Services. Public Health Service,

17 United States Department of the Interior – Bureau of Reclamation. Glossary and Acronyms: Pursuant to the Biological Assessment. http://www.usbr.gov/lc/region/g2000/assess/glossary.htm

18 US Army Corps of Engineers http://www.wetlands.com/coe/87manp2a.htm

19 USDA. Forestry Service. (http://tinyurl.com/3lptv6b)

In 1998, the U.S. Food and Drug Administration (FDA) issued the document entitled, "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." The practices outlined in this document are collectively known as Good Agricultural Practices (GAPs) and current Good Manufacturing Practices (cGMPs). GAPs provide 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. On the other hand, cGMPs describe the methods, equipment, facilities, and controls for producing processed food.

More specifically, GAP guidance documents inform fruit and vegetable growers and handlers primarily about the potential microbiological hazards associated with various aspects of the production pipeline including: land history, adjacent land use, water quality, worker hygiene, equipment sanitation, and product transportation. Physical and chemical hazards are also addressed in relation to agricultural chemical handling and storage, and the presence of physical objects such as glass or other debris contaminating fresh produce in the field. For the most part, the produce industry has proactively adopted GAPs as part of normal production operations. Indeed, the majority of fruit and vegetable producers undergo either internal and/or external third-party audits on a seasonal basis to monitor and verify adherence to GAPs. These audit results are often shared with customers as verification of the producer's commitment to food safety and GAPs.

Conversely, cGMPs help to ensure that food for human consumption is safe and has been prepared, packed, and held under sanitary conditions. Parts 100-169 of Title 21 of the Code of Federal Regulations (21 CFR 100-169) prescribe the condition under which food should be processed, packed, handled, held, labeled, etc. cGMPs are regulations as set forth in 21 CFR 110. cGMPs are enforceable by law and serve as one basis for FDA inspections. In addition to the cGMPs, FDA published a "Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables" ("Fresh-cut Guide") in 2008.1 FDA developed this guidance to complement the cGMPs and recommend more specific food safety practices relevant to processors of fresh produce.

Commercial fresh produce processors are one of the most regulated segments of the produce farm-to-table continuum. Preeminent among these regulations is the U.S. Federal Food, Drug, and Cosmetic Act (FFDCA) which outlines legal standards of performance to assure that foods are safe to eat as well as produced and held under sanitary conditions. Management plans or programs should be in place to verify with documentation that a food processing facility is in compliance with all applicable federal, state, and local statutes.

Regulatory Background

While the produce industry has an admirable record of providing the general public with safe, nutritious fruits and vegetables, a few highly visible food safety failures have increasingly focused the attention of consumers, consumer advocacy groups, public health organizations, government agencies and buyers on produce food safety. To address the concern, the U.S. Food and Drug Administration (FDA) promulgated a produce safety action plan in 2004 that specifically requested produce industry leadership to develop the next generation of food safety guidance for fruit and vegetable production. Since then, several commodity-specific food safety guidelines have been developed to both address potential issues and to reduce the likelihood of future foodborne illness outbreak occurrences. For example, after the 2006 E. coli outbreak in spinach, the leafy green industry developed commodity-specific food safety guidelines in 2007, as did the tomato industry in 2008, and the green onion industry in 2010. The FDA responded by developing the Fresh-cut Guide in 2008 and drafting food safety guidelines for leafy greens, tomatoes, and melons in the summer of 2009 (FDA, 2009a; FDA, 2009b; FDA, 2009c).

In 2009 the U.S. House of Representatives introduced a food safety bill (H.R. 2749) that included the regulation of vegetable production and harvesting. This bill passed in July 2009 and the Senate version known as the FDA Food Safety Modernization Act, S. 510 (FSMA) passed in December 2010 and was signed into law on January 4, 2011. The FSMA states, "not later than 1 year after the date of enactment of the FDA Food Safety Modernization Act, the Secretary, should publish a notice of proposed

1 FDA. 2008. Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables. http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064458.htm#ch8

rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death."

At this time it is unknown if specific commodities will be targeted or if key practices will be addressed; however, cilantro specifically was singled out by the FDA following detection of *Salmonella* on cilantro samples. In March 2011, the FDA issued a letter to firms that grow, harvest, sort, pack, or ship fresh cilantro encouraging these firms "to access hazards unique to production of cilantro and to develop commodity-specific preventive control strategies that would identify potential hazards that may be specific to fresh cilantro." In light of these developments pertaining to fresh produce in general and to cilantro specifically, the fresh culinary herb industry has decided that proactive development of fresh culinary herb-specific food safety guidelines is important and that moving forward ahead of an FDA mandate will help increase the safety and security of the U.S. fresh culinary herb supply chain.

In addition to food safety efforts for fresh culinary herbs in the U.S., the Mexican government, in conjunction with its fresh produce industry, has developed food safety standards, and in 2009 the Canadian Horticultural Council (CHC) and its fresh produce industry members in collaboration with the Canadian government developed GAPs for fresh leafy vegetables including fresh culinary herbs. The CHC-managed program, called CanadaGAP is verified by third-party certification and audit companies that are approved and subject to oversight by CHC. This document is designed to complement the Mexican and Canadian governments' food safety efforts while making necessary adaptations to meet U.S. requirements.

Purpose

The purpose of this document is to provide fresh culinary herb growers, packers, and shippers with effective guidelines to reduce the potential of microbial contamination as well as potential for contamination related to mishandling of chemicals and the presence of foreign objects in the production and handling environments. The issues identified are based on the core elements of GAPs and cGMPs. The specific practices contained herein are intended for fresh culinary herbs only. If these specific practices are effectively implemented this would constitute the Best Practices for a comprehensive food safety program for the production, harvest, packing and processing of fresh culinary herbs. When growing any type of produce, growers should comply with the FDA's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" and requirements established in the upcoming Produce Safety Rule.[2]

Human pathogens that are associated with produce and cause infection and illness can be present in large numbers in the feces of humans and animals. Therefore, food safety programs for the production and handling of fresh culinary herbs should pay special attention to controlling, reducing, and eliminating potential fecal contamination through water, soil, people, and animals (both domestic and wild).

In addition to this document, several supplemental documents have been prepared to explain the rationale for the guidelines and assist the grower with activities in the field. These documents include a technical basis document that describes in detail and with appropriate citations the bases for the best practices included in this document, a sanitary survey document that describes the processes for assessing the integrity and remediation of water systems, crop and soil testing plan protocol examples, an example of an environmental risk assessment SOP, a list of resource agency contacts, and a document describing standards for composting. All of these items can be found as appendices to this document.

Scope

This document is designed to offer food safety guidance for growers and handlers of fresh culinary herbs during production, harvesting, packing, and shipping operations (see Figure 1). It includes four sections: 1) Elements of a Food Safety Programs Relevant to All Unit Operations, 2) Production and Harvest Unit Operations, 3) Post-Harvest Unit Operations, and 4) Processing Unit Operations.

This document pertains only to fresh culinary herbs and does not include fresh culinary herbs that are

2 FDA. 1998. Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables. http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/UCM064574

typically used in medicinal products. Fresh culinary herbs include all varieties of basil, chervil, chives, cilantro, dill, lemon verbena, marjoram, mint, oregano, parsley, rosemary, sage, savory, sorrel, tarragon, and thyme. This document offers food safety guidance that is applicable for fresh culinary herbs grown outdoors in field environments and in controlled environments such as greenhouse production using both conventional and organic growing methods. Producers that follow organic standards are responsible for satisfying the food safety best practices in this document in accordance with their organic certification standards.

Fresh culinary herbs are both mechanically and manually harvested, and can be packed in the field, in a packinghouse or in a processing plant. Due to harvesting by hand, quality sorting, and the practice of bunching and packing these commodities, there are numerous "touch points" early in the supply chain. Each of these "touch points" represents a potential opportunity for contamination. Fresh culinary herbs are primarily sold as a raw and processed product. In a processing environment, fresh culinary herbs are cleaned, trimmed, sometimes cut, and packed in some form of plastic, protective packaging. Therefore, fresh culinary herbs offer several unique opportunities to employ food safety risk management practices to enhance their safety.

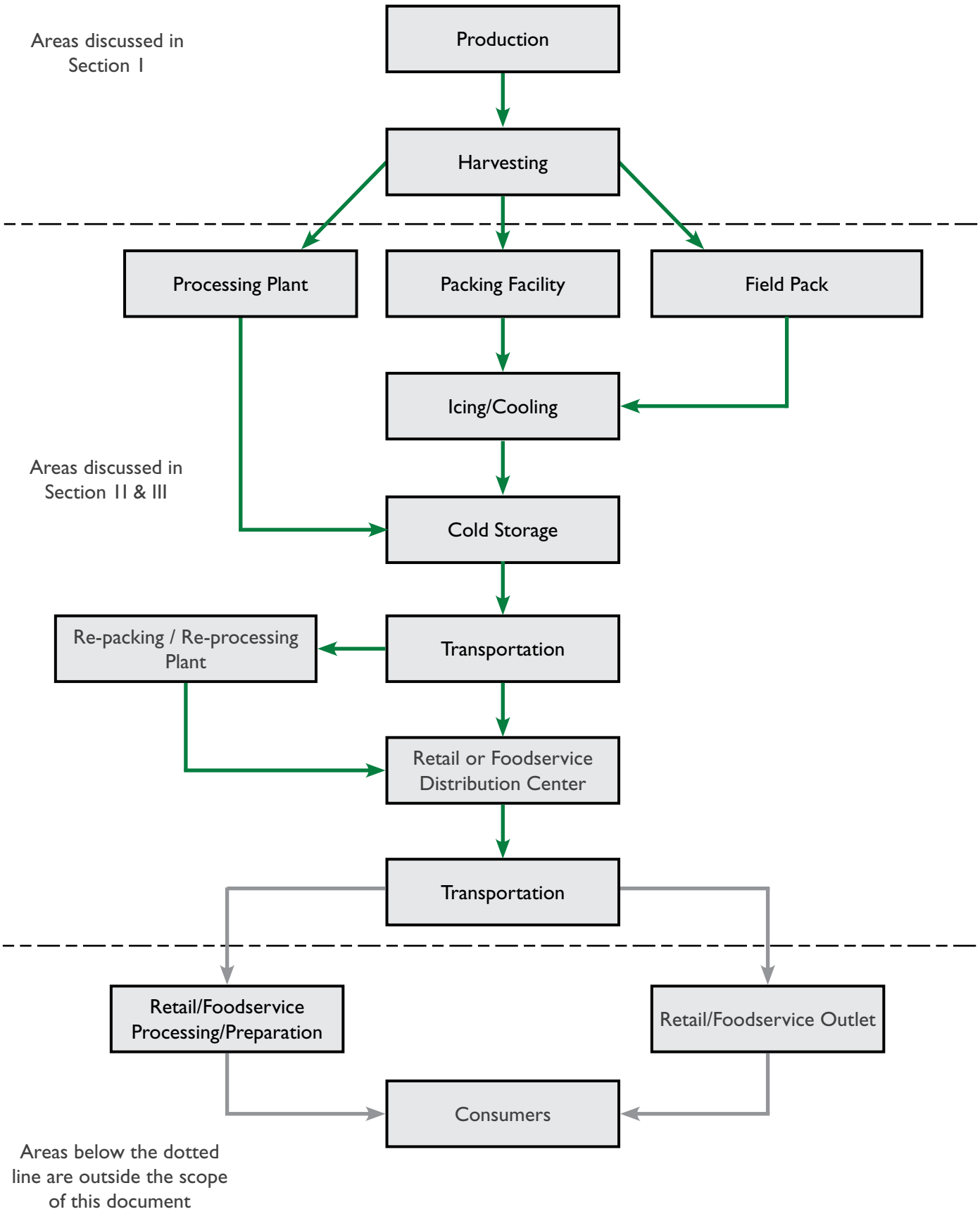
Safe production, packing, processing, distribution, and handling of fresh culinary herbs depend upon a myriad of factors and the diligent efforts and food safety commitment of many parties throughout the distribution chain. No single resource document can anticipate every food safety issue or provide answers to all food safety questions. These guidelines primarily focus on minimizing microbial food safety hazards by providing options to prevent, reduce, control, or eliminate microbial contamination of fresh culinary herbs in the field-to-fork supply chain. Guidelines for potential chemical and physical hazards are limited to mishandling and inappropriate storage of agricultural chemicals and the presence of trash and debris in close proximity to production and handling areas.

It is suggested that all companies involved in the fresh culinary herbs' farm-to-table supply chain consider the best practices contained within these guidelines to ensure the safe production and handling of fresh culinary herb products. Every effort to provide food safety education to supply chain partners should be made as well. 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 fresh culinary herbs to the market place.

Due to close association between production areas and environmentally sensitive areas in many locations, consultation with appropriate land and natural resource management agencies, many of whom are identified in Appendix Z, is encouraged when any mitigation strategies that may impact these areas are employed. Growers should implement strategies that not only protect the safety of their fresh culinary herb crops, but also support co-management. All parties involved with implementing the practices outlined in this document should be aware that these guidelines are not, in any way, meant to encourage growers to violate environmental regulations or be in conflict with or discourage co-management practices and principles.

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

Figure 1. General Supply Chain Flow for Fresh Culinary Herbs



SECTION I:

Elements of Food Safety Programs Relevant to All Unit Operations

SECTION I

In addition to the area-specific best practices discussed in later sections, there are best practices that are part of an effective food safety program for all companies in the fresh culinary herb production-to-processing supply chain.

1.0 Issue: **General Items**

In addition to the area-specific best practices discussed in later sections, there are best practices that are part of an effective food safety program for all companies in the fresh culinary herb production-to-processing supply chain. These best practices are outlined below.

1.1 The Best Practices Are:

- Every company should have a written policy signed by senior management that outlines the company's commitment to food safety, how it is implemented and how it is communicated to employees.
- A written comprehensive Fresh Culinary Herbs Food Safety Plan based on an individual operation's risk analysis which specifically addresses the Best Practices of this document should be prepared. This plan should identify all locations of operation covered by the plan and should address potential physical, chemical, and microbiological hazards and hazard control procedures, including monitoring, verification and recordkeeping for the following areas: water, soil amendments (SAs), environmental factors, worker practices (NOTE – this includes employee monitoring), equipment, and field sanitation. The Best Practices in this document are based on current science-based knowledge and some practices may change as new and additional information becomes available.
- Every company should have a policy that establishes corrective actions when food safety policies are not in compliance.
- Every company should develop and implement a visitors policy that addresses issues related to food safety and security.
- Every company should have a documented self-audit procedure. Self-audits should be conducted at least annually by assigned personnel who are knowledgeable of the Food Safety Plan and a written record of required corrective actions should be documented.
- Companies should review their Fresh Culinary Herbs Food Safety Plan at least annually and make revisions as appropriate to their particular situation based on their operation-specific risk assessments, updated or new guidance, regulations, and / or changes to their operations (e.g., new field location, new equipment, new product formulations or new season).
- Handlers should have up-to-date lists of growers and buyers with contact and location information on file. Growers should have an up-to-date buyers list with contact and location information on file.
- Anyone that manufactures, processes, packs, or holds fresh culinary herbs for consumption in the U.S. is required to report when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health

consequences or death to humans or animals. This reporting is conducted through the FDA's Reportable Food Registry (RFR).[1] Firms that only grow fresh produce are exempt from reporting.

- Handlers must 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), imports, and registration.[2]
- Limit access to production areas, packinghouse, and processing facility.
- Each grower and handler should designate an individual responsible for their operation's food safety program with an alternative individual assigned in the event that the primary designated individual is unavailable. These individuals should have training in food safety principles, procedures and practices sufficient to their responsibilities. Twenty-four hour contact information should be available for these individuals in case of food safety emergencies.

Documentation List:

- ☐ A written, signed Food Safety Policy
- ☐ A written comprehensive Food Safety Plan
- ☐ Contact information for food safety personnel

2.0 Issue: **Documentation and Recordkeeping**

As a general practice, it is important that companies producing and handling fresh culinary herbs maintain, and have readily available, documentation and records related to operational information about their product and practices, as well as tracing information about the product. It also is important to note that subject to certain exceptions, existing FDA regulations at 21 CFR part 1, subpart J, "Establishment, Maintenance, and Availability of Records," already establish certain recordkeeping requirements on persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the U.S.

In addition, processing facilities are subject to record keeping practices

...it is important that companies producing and handling fresh culinary herbs maintain, and have readily available, documentation and records related to operational information about their product and practices, as well as tracing information about the product.

1 FDA Reportable Food Registry registration: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/OnlineRegistration/default.htm

2 FDA. 2009. Establishment and Maintenance of Records—FDA Actions of the Bioterrorism Act of 2002. http://www.fda.gov/Food/FoodDefense/Bioterrorism/Recordkeeping/default.htm
FDA. 2010. Food Facility Registration—FDA Actions on Bioterrorism Act of 2002 Legislation. http://www.fda.gov/Food/FoodDefense/Bioterrorism/FoodFacilityRegistration/default.htm
FDA. 2010. Prior Notice of Imported Food Shipments—FDA Actions on Bioterrorism Act of 2002 Legislation. http://www.fda.gov/Food/FoodDefense/Bioterrorism/PriorNotice/default.htm

as specified under the Bioterrorism Act of 2002. The records that must be kept are specified in the regulations and are needed to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging. These records must include information that identifies the food product. The regulation requires, among other things, that records maintained by nontransporters include an "adequate description" of the food, including brand name and specific variety. The best practices below complement, but do not supersede, existing recordkeeping requirements in existing FDA regulations.

Effective product tracing systems can serve as an important element of a comprehensive food safety program intended to prevent microbial contamination.

2.1 Operational Records

Operational records about products and practices can be helpful to firms. First, such records help ensure consistency of production, packing, and processing operations and end-product quality and safety. They are more reliable than human memory and serve as a useful tool to identify areas where inconsistencies occur in operations and corrective actions or employee training may be needed. Furthermore, maintaining adequate documentation and records could assist in identifying or ruling out potential contributing factors of contamination if product implicated in an outbreak is traced to a particular farm or facility.

2.1.1 The Best Practices Are:

- Develop and maintain written SOPs and SSOPs for areas such as handling and storage practices, facility and vehicle cleaning and sanitation, pest control, employee training programs, etc.
- Maintain records for significant activities performed, such as monitoring of water sources and use; water quality testing; treatment of water; cleaning and sanitation of equipment, containers and vehicles; employee training; and corrective actions taken.
- Record information such as the date and time, name of person(s) who completed the record, and the activity being monitored in the documentation.

2.2 Product Traceability

Product traceability refers to the ability to follow the movement of a food through specified stage(s) of production, packing, processing, and distribution. Tracing information about fresh culinary herbs facilitates tracking the physical movement of fresh culinary herb products from their original source through intermediate sources to their final recipient and tracking product from the final recipient back to the source. Effective product tracing systems can serve as an important element of a comprehensive food safety program intended to prevent microbial contamination.

2.2.1 The Best Practices Are:

- Utilizing information outlined in the FDA's "Fresh-cut Guide" and "Guide to Traceback of Fresh Fruits and Vegetables" to develop a product tracing system applicable to the fresh culinary herb supply chain.
- Provisions of the 2002 Bioterrorism Act require that shippers have the ability to identify the immediate previous source of the product, immediate subsequent recipient of the product and the transporters. Commingling of product may occur at the packinghouse facility and operators should have product tracing systems in place to be in compliance with the Act.
- Develop and maintain standardized, clear records that can be used to enhance the ability to follow the movement of your fresh culinary herb products. Examples of such records include labels with product identifying information, invoices, inventory records, bills-of-lading, and shipping / receiving records. Records should comply with Bioterrorism Act provisions; this may include packaging material records.
- Perform a trace back and trace forward exercise at least annually by facility. This exercise should achieve accurate traceability as based on effectiveness checks established by the company. FDA has various requirements for the effectiveness of recall efforts based on the recall class, potential risk to public health, and other factors.
- Establish a documented program with written procedures to facilitate stock recovery, market withdrawal, and recalls that includes:
  - A designated team with team members' 24-hour, seven-days-a-week contact information.
  - An incident management plan.
  - A mock exercise performed annually by facility which follows the company's written program.
  - A trace back and trace forward exercise performed at least annually for each facility.
  - 24-hour contact list of customer point persons to be called if product requires recall
  - Contact list of key regulatory officials (federal and state) that may need to be notified if a recall is warranted
  - Contact list of commodity organizations and trade association experts that might be called upon to provide technical help if needed.
- Make sure required documentation is provided when fresh culinary herbs are imported. FDA and USDA may have different requirements for individual importing countries; consulting with a trade specialist at these regulatory bodies is the best way to ensure that the proper documentation is provided.
- Have a labeling system in place. For the purposes of product traceability, finished product should be labeled with information that allows for effective traceability. Examples of information that may be included are:
  - Grower or Ranch ID
  - Packinghouse ID
  - Shipper ID
  - Marketer ID
  - Harvest time
  - Harvest date
  - Crew ID
  - Lot ID[3]

3 Lot coding of fresh culinary herb products may be complicated by the fact that many small blocks of land may contribute a "lot" of product packed at a packinghouse on any particular day. Also, fresh culinary herb ranches / farms may undergo multiple harvests over multiple

- Production date
- Production code
- Expiration date
- Quantities
- Transporter

- Any tags used in the packing and processing facility should be secured to finished product containers in a manner that does not create a potential for damaged packaging materials or foreign object inclusion.

Documentation List:

- ☐ Product Tracing Records
- ☐ Recall program
- ☐ Import documents

days or weeks from one contiguous plot of land. A lot should be coded in a way that allows identification of the sources.

SECTION II:

Production and Harvest Unit Operations

SECTION II

1.0 Issue: **Environmental Assessments**

This section addresses the three assessments of environmental conditions that should be completed and documented:

1. Prior to the first seasonal planting
2. Within one week prior to harvesting
3. During harvest operations

These environmental assessments are intended to identify any food safety issues related to fresh culinary herb fields and production, adjacent land uses and/ or crop damage from animals or fecal contamination that may present a risk to the production block or crop (see Table II-1A). For example, prior to planting, a grower should consider production site location and include an evaluation of the slope and the potential for runoff from nearby fields, the flood risk as well as hydrological features of nearby sites in relation to the production site. The proximity of high risk production sites, such as animal production facilities, hazardous waste sites and waste treatment facilities, should be evaluated for the potential to contaminate culinary herb production fields with microbial or other environmental hazards via, for example, run-off, fecal material, aerosols or organic waste." FDA recommends conducting environmental assessments on the topography, land history, risk of flooding, adjacent land use, and domestic animal and wildlife presence associated with the production environment, using the concepts that are outlined in the GAPs Guide (to the extent that any of these environmental factors are present).

Each grower or handler should take into account the growing environment when performing a risk assessment.

Fresh culinary herbs are grown year-round 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 fresh culinary herbs to be exposed to contaminated soil due to rain splashing. It is important to tailor practices and procedures designed to promote food safety to the unique environment in which fresh culinary herbs are produced. Each grower or handler should take into account the growing environment when performing a risk assessment.

Fresh culinary herbs 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). Uncertainties in the literature about which animals might be the most likely to contaminate fields as well as difficulty excluding some types of animals from fields (i.e., birds, reptiles) has led to the practice of not harvesting any potentially contaminated fresh culinary herbs if crop damage from animals or fecal contamination is detected. In addition, extensive development in certain farming communities has also created situations with urban encroachment and unintentional access by domestic animals, livestock, and human activity, 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 II-1B provides a list of these uses and options for buffer distances.

1.1 The Best Practices Are: Pre-planting Assessment

- Prior to the first seasonal planting perform and document an environmental risk assessment of the production field, adjacent land and surrounding area. Focus these assessments on evaluating the production area and water sources for contamination by animals, flooding, or other potential sources of contamination.
  - Assessment of Fresh Culinary Herb Fields
    - Evaluate all fresh culinary herb fields for evidence of crop damage by animals or fecal contamination in the production block. See Table II-1A and Figure 2 for numerical criteria and guidance applicable to animal encroachment.
    - When developing strategies to reduce the risk associated with animals that are endemic to a particular production area, mitigations should be designed to minimize adverse impacts to the environment.
    - Producers are advised to check for local, state, and federal laws and regulations that protect riparian areas, restrict removal of vegetation or habitat, or restrict construction of wildlife deterrent fences in riparian areas or wildlife corridors.
    - Growers are encouraged to contact the relevant agencies (e.g., the Regional Water Quality Control Board, and state and federal fish and wildlife agencies) to confirm the details of these guidelines. In addition, growers may wish to consult with their state or regional Natural Resources Conservation Service (NRCS) offices to evaluate the food safety risks associated with wildlife, livestock, domestic animals and other adjacent land uses as well as develop and document strategies to control or reduce the introduction of human pathogens through animals for each fresh culinary herb production block. Appendix Z provides contact information for resource agencies.
    - Evaluate the risk to subsequent fresh culinary herb production on production acreage that has experienced recent post-harvest grazing with or by domesticated animals.
    - The designated food safety professional or other trained personnel should evaluate the potential for microbial contamination from adjacent areas. A risk assessment must be performed to determine the risk level as well as to evaluate potential strategies to control or reduce

When developing strategies to reduce the risk associated with animals that are endemic to a particular production area, mitigations should be designed to minimize adverse impacts to the environment.

the introduction of human pathogens. Periodically monitor these factors and assess during the preseason and pre-harvest assessments (see suggestions in Table II-1A and II-1B).

- Pooled water (e.g., from rainfall, irrigation leaks) that persists for several days may present a contamination risk (i.e., underlying soil has inadequately composted soil amendments, attractant for animals) and should be part of any land use evaluation.

- Assessment of Adjacent Land Use
  - Evaluate all land and waterways adjacent to fresh culinary herb fields for possible sources of human pathogen of concern. These sources include, but are not limited to, manure storage, compost storage, Concentrated Animal Feeding Operations (CAFOs), grazing / open range areas, livestock feeding facilities, surface water, sanitary facilities, and composting operations (see Table II-1B for further detail). If any possible uses that might result in fresh culinary herb contamination are present, consult with the metrics and contact the appropriate land and/or natural resource management agency personnel identified in Appendix Z.
  - Table II-1B provides options for distances and guidance applicable to adjacent land uses that pose a risk of contamination.
  - Control risks associated with encroachment by urban development. Risks may include, but are not limited to, domestic animal-related crop damage or fecal contamination of production fields and harvest equipment and septic tank leaching.
  - Evaluate and implement practices to reduce the potential for windborne soil including soil from roads adjacent to fields, aerosols from spray application of SAs, water, or other media that may be a source of contamination to come into direct contact with fresh culinary herbs. Such practices may include (but are not limited to) berms, windbreaks, diversion ditches, and vegetated filter strips.
  - Be aware of runoff from adjacent properties and its proximity to fresh culinary herb fields, packinghouses, etc.
  - The location of any adjacent land uses that may be of potential risk should be documented. In addition, as specified in Table II-1B, any deviations from the provided buffer distances due to mitigation factors or increased risk should be documented and explained.
  - 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. Producers are responsible to 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.

- Assessment of Historical Land Use
  - To the degree practical, determine and document the historical land uses for fresh culinary herb production fields and any potential issues from these uses that might impact food safety (e.g., hazardous waste sites, heavy metal pesticides such as lead arsenate, landfills).

- Assessment of Flooding
  - Evaluate all fresh culinary herb fields for evidence of flooding. If any evidence is found, follow procedures identified in section 8.0 Flooding.

1.2 The Best Practices are: Pre-Harvest Assessment

- Within one week prior to harvesting, conduct a follow-up environmental assessment based on the pre-planting assessment. Focus this assessment on any changes that may have occurred in the field and to the surrounding areas since the pre-planting assessment.
- Establish a pre-harvest environmental assessment procedure that describes how and when the assessment is to be performed, and includes an evaluation of conditions that may potentially result in physical, chemical or microbiological contamination of fresh herbs during harvest.
- If there are conditions that potentially result in physical, chemical or microbiological contamination, document any corresponding corrective action. Table II-1A and II-1B may provide additional guidance on appropriate corrective actions.

1.3 The Best Practices are: Harvest Assessment

- During harvest operations, production fields should be assessed for:
  - Fecal material and plant damage by animals. Evidence of debris such as glass, plastic, and metal. Remove the debris or do not harvest fresh culinary herbs in close proximity to the debris if the safety of the herbs is compromised by their presence.
  - Evidence of open and / or unsecured chemicals.
  - Any other factor that might increase the risk of microbial contamination

Documentation List:

- ☐ Pre-plant environmental assessment
- ☐ Corrective actions report
- ☐ Pre-harvest environmental assessment
- ☐ Harvest environmental assessment

Table II-1A. Animal Activity in Field (Wild or Domestic):

When evidence of fecal contamination and plant damage by animals in a production block occurs.

Issue	Metric	Rationale / Corrective Actions
Evidence of Fecal Contamination and Plant Damage by Animals	**Metric** Frequency • There should be a periodic monitoring plan in place for fresh culinary herb production fields. • There should be Pre-Season, Pre-Harvest, and Harvest assessments. Variables • Observation of animals in the field • Downed fences • Animal tracks in production block • Animal feces, blood, animal carcasses or urine in production block • Crop damage (trampled, eaten plants) in production block	**Corrective Actions** • If there is evidence of crop damage from animals or fecal contamination in the production block. The block must undergo a food safety assessment by appropriately trained food safety personnel (see Glossary: food safety professional) prior to harvest, as defined in the text of this document. • In developing corrective actions, consider consulting with wildlife and / or domestic animal experts as appropriate. • If corrective 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 the herbs should be cleaned and sanitized upon exiting the field. • Formulate effective corrective actions. Prior to taking action that may affect natural resources, growers should check local, state, and federal laws and regulations that protect riparian areas, restrict removal of vegetation or habitat, or restrict construction of wildlife deterrent fences in riparian areas or wildlife corridors. • Food safety assessments and corrective actions should be documented and available for verification for a period of 2 years.
	Please see Figure 2. Decision Tree for Conducting Pre-Harvest and Harvest Assessments. **Monitoring** Conduct periodic monitoring, preseason, pre-harvest, and harvest assessments. Evaluate and document any crop damage from animals or fecal matter in fresh culinary herbs fields and production environments. **Pre-Harvest Assessment** Conduct the Pre-Harvest assessment not more than 1 week prior to harvest. If fecal contamination is discovered before harvest operations: • Do not harvest any fresh culinary herbs that have come into direct contact with fecal material. • Conduct a food safety assessment using qualified personnel. Do not harvest fresh culinary herbs found within a minimum five-foot radius buffer distance from the spot of the contamination unless corrective action can be found that adequately control the risk. The food safety professional can increase this buffer distance if deemed appropriate.	

Issue	Metric	Rationale / Corrective Actions
		• Remove fecal material from the field and dispose of properly. If evidence of crop damage from animals is found in a fresh culinary herb field, conduct a visual food safety assessment to determine whether the area can be adequately controlled, or whether a three-foot buffer radius non-harvest area should be applied. **Harvest Assessment** If evidence of fecal matter, crop damage or animals are observed in the production area during harvest operations: • Stop harvest operations. • Initiate an intensified block assessment for evidence of further contamination and take appropriate measures per the aforementioned actions. • If crop damage from animals and/or fecal contamination is discovered during production block harvest operations and equipment has been potentially contaminated by contaminated fresh culinary herbs or feces, clean and sanitize the equipment before resuming harvest operations. • Before resuming harvest operations, all employees should wash and sanitize their hands / gloves and any clothing that came in contact with feces. • If contamination is discovered in harvest containers such as bins / totes, discard and destroy the harvested fresh culinary herbs that had contact with the contaminated containers, and clean and sanitize the container before reuse.
Verification		• Archive documentation for a period of 2 years following the event. Documentation may include photographs, sketched maps, or other means of delineating affected portions of fresh culinary herb fields.
Rationale		• The basis of these metrics is qualitative assessment of the relative risk from a variety of potential contamination from animals. Animal feces and crop damage from animals are considered to be of more concern than other signs of animal activity (e.g., tracks). Because it is difficult to develop quantitative metrics for these types of risks, a food safety assessment is considered appropriate for this issue. • **Appendix B** describes in detail the process used to develop these metrics.

Table II-1B. Crop Land and Water Source Adjacent Land Use

Please keep in mind that all of the buffer distances provided in this table depend on the risk/mitigation factors listed in the column to the right – "Considerations for Risk Analysis." Evaluate risks specific to your operation and document the consideration of these risk/mitigation factors.

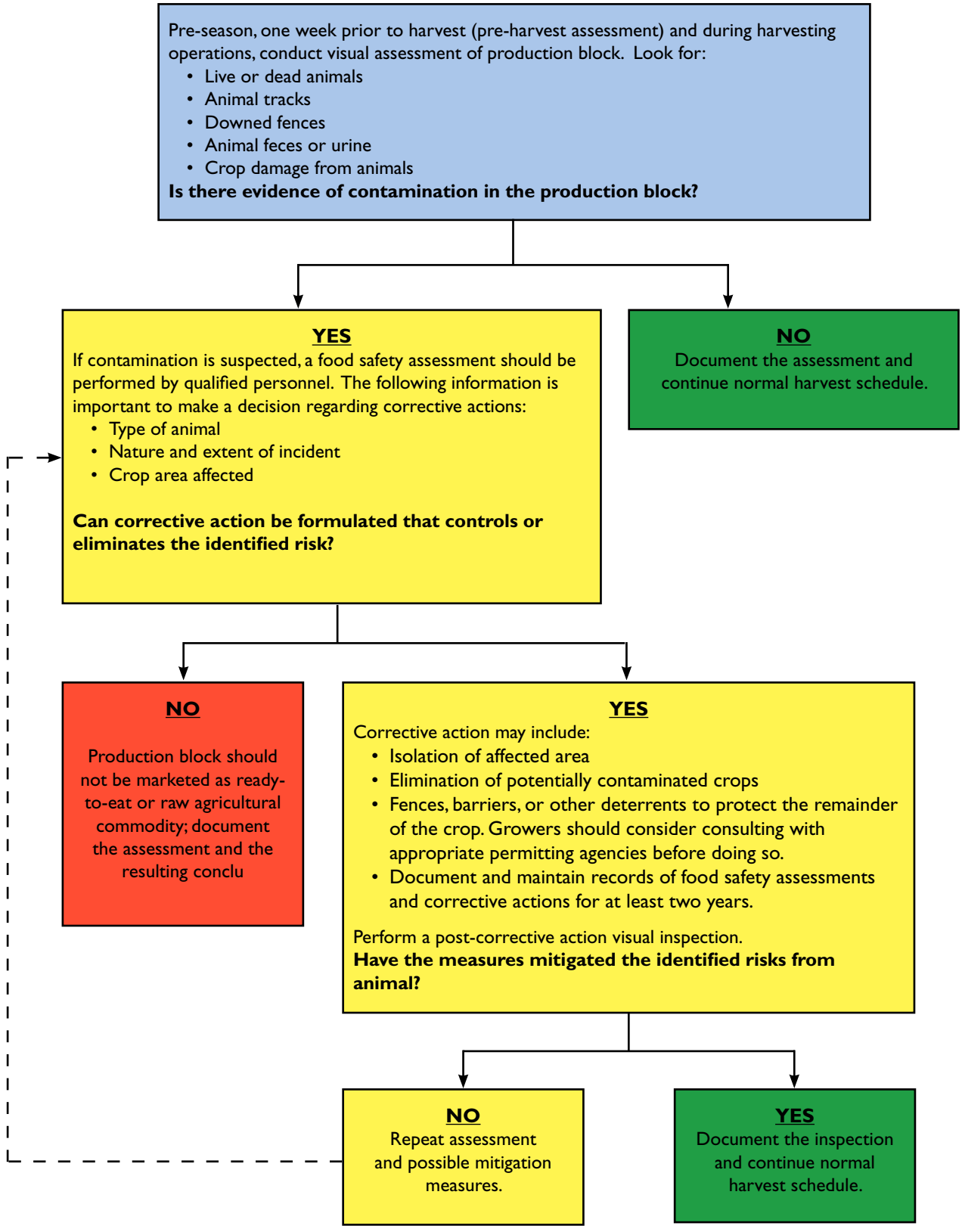
Land Use / Water Source	Metric (This distance is intended to be established by the producer and should be increased or decreased depending on the risks present and any mitigation factors employed to reduce that risk.)	Considerations for Risk Analysis*		
		Risk / Mitigation Factors	Increase Distance	Decrease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

Land Use / Water Source	Metric (This distance is intended to be established by the producer and should be increased or decreased depending on the risks present and any mitigation factors employed to reduce that risk.)	Considerations for Risk Analysis*		
		Risk / Mitigation Factors	Increase Distance	Decrease Distance
	The proximate safe distance depends on the risk / mitigation factors listed to the right. Evaluate risk and document consideration of these factors. Research is being proposed to study the appropriate distance and any adjustments in distance due to mitigating factors.	Topography: Downhill from fresh culinary herb fields		√
		Opportunity for water run off through or from non-synthetic soil amendment storage areas	√	
		Opportunity for soil leaching	√	
		Covering on pile to prevent wind dispersion		√
Grazing Lands / Domestic Animals (includes homes with hobby farms, and non- commercial livestock)	Due to the lack of science-based knowledge at this time, an interim guidance distance of 30 ft. from the edge of crop is proposed. This number is subject to change as science becomes available. The proximate safe distance depends on the risk / mitigation factors listed to the right. Evaluate risk and document consideration of these factors. Research is being proposed to study the appropriate distance and any adjustment in distance due to mitigating factors.	Fencing and other physical barriers such as berms, diversion ditches and vegetated strips can be employed to prevent intrusion of domestic animals, control runoff, etc.		√
		Topography: Uphill from fresh culinary herb fields	√	
		Topography: Downhill from fresh culinary herb fields		√
		Opportunity for water run off through or from grazing lands	√	
		Opportunity for soil leaching	√	
Homes or Other Building with a Septic Leach Field.	30 ft. from the edge of crop to the leach field.	Active leach field: < 10 yrs. old		√
		Active leach field: > 25 yrs. old	√	
		Inactive leach field		√
		Topography: Uphill from fresh culinary herb fields	√	
		Topography: Downhill from fresh culinary herb fields		√
		Physical barriers		√
Well Head Distance from Untreated Manure	200 ft. separation of untreated manure from wells.	Topography: Uphill from manure		√
		Topography: Downhill from manure	√	
		Opportunity for water runoff from or through untreated manure to well head	√	
		Opportunity for soil leaching	√	

Land Use / Water Source	Metric (This distance is intended to be established by the producer and should be increased or decreased depending on the risks present and any mitigation factors employed to reduce that risk.)	Considerations for Risk Analysis*		
		Risk / Mitigation Factors	Increase Distance	Decrease Distance
		Presence of physical barriers such as windbreaks, diversion ditches, vegetative strips		√
Surface Water Distance from Untreated Manure	At least 100 feet separation for sandy soil and 200 feet separation for loamy or clay soil (slope less than 6%; increase distance to 300 feet if slope greater than 6%).	Topography: Uphill from manure		√
		Topography: Downhill from manure	√	
		Opportunity for water runoff from or through untreated manure to surface waters.	√	
		Opportunity for soil leaching	√	
		Presence of physical barriers such as windbreaks, diversion ditches, vegetative strips		√
Rationale	• The bases for these distances above is best professional judgment of authors, contributors, and expert reviewers to prevent potential cross-contamination from adjacent land uses, taking into consideration the 200 foot distance cited in FDA (US FDA 2001) for separation of manure from wellheads and the 30 foot turn-around distance for production equipment. Because of the numerous factors that must be taken into account to determine appropriate distances, a qualitative assessment of the relative risk from various types of land use and surface waters was used to determine appropriate distances and may be different for individual operations. • **Appendix B** describes in detail the process used to develop these metrics.			

*Growers should check for local, state, and federal laws and regulations that protect riparian areas, restrict removal of vegetation or habitat, or restrict construction of wildlife deterrent fences in riparian areas or wildlife corridors.

Figure 2. Decision Tree for Conducting Pre-Harvest and Harvest Assessment of Animal Activity in Field (Wild or Domestic)



As part of a water quality management plan, analysis of microbial testing data over time provides valuable information on trends in microbial levels that may be related to environmental conditions or that may indicate the occurrence or existence of a contaminating source or event.

2.0 Issue: **Water**

Water can be a source or vehicle for microbial or chemical cross-contamination. Therefore, it is critical to conduct a thorough hazard assessment that evaluates fresh culinary herb plant architecture (e.g., tender, hollow leaves; root material), sources of water to be used, and delivery methods to determine if the quality of the water to be used for irrigation, pesticide dilution and application, or equipment sanitation on the farm is of sufficient quality for its intended use. It is important to consider the source of the water along with its intended use. For instance, a surface water source (e.g., an irrigation canal) may be a proper source of water for furrow irrigation of fresh culinary herbs but not a proper source of water for mixing pesticides that would be applied to the aerial and subsequently edible portion of the plant. With fresh culinary herbs, aerial portions of the plant are consumed, therefore, great care should be taken to ensure that these plant structures are not inadvertently contaminated by the use of water not ideally suited for the intended purpose.

The water source may also dictate different risk management measures or strategies. From a potential risk perspective, water sourced from surface water (e.g., a river or an irrigation canal) represents a very different entity than water sourced from a well. For example, for water sourced from a well, inspection of the well head and periodic microbial testing of the water would be an excellent risk management strategy. In contrast, microbial testing of canal-sourced water may not be useful or actionable as the sample is only representative for the moment of sampling (i.e., water in a canal is flowing and microbial populations fluctuate considerably over time, distance, and environments). Microbial testing of flowing water systems is primarily designed to establish baseline information on the ability of these systems to deliver water of acceptable quality. As part of a water quality management plan, analysis of microbial testing data over time provides valuable information on trends in microbial levels that may be related to environmental conditions or that may indicate the occurrence or existence of a contaminating source or event. When testing data indicates unusual microbial levels, the Sanitary Survey (Appendix A) may be used to evaluate the water system.

When water is sourced from a canal, risk management strategies should focus on keeping the laterals within the boundaries of the production area free from the accumulation of debris and other potential sources of contamination. These strategies should be in place and should include routine inspections and corrective action protocols. A management program for water quality verification should include documentation of any testing results as well as any preventive or corrective actions taken to reduce or eliminate potential contamination.

2.1 The Best Practices Are:

- A water system description should be prepared. This description can use maps, photographs, drawings, or other means to communicate the location of permanent fixtures and the flow of the water system (including any water captured for re-use). Permanent fixtures include wells, gates, reservoirs, valves, returns, and other above ground features that make up a complete irrigation system. The direction of water flow should be clearly indicated on each map. If feasible, include underground piping or conveyances. This map should be used to facilitate physical water system inspections as described in the Sanitary Survey (Appendix A) for the purpose of identifying conditions that may result in the contamination of fresh culinary herb crops.
- Establish a water quality management plan that includes preventative controls, monitoring and verification procedures, corrective actions and documentation.
- Perform a Sanitary Survey (Appendix A) prior to use of water in agricultural operations.
- Use irrigation water and water in harvest operations that meets or exceeds the acceptance criteria outlined in Table II-2.[1]
- If water quality microbial tests are at levels that exceed the acceptance criteria set forth in Table II-2, follow suggestions for corrective actions as outlined in the Table and in Figures 3A and 3B.
- Have a written procedure for water testing that includes frequency of sampling, who is taking the samples, where the samples are taken, the volume of the sample, how the sample is collected, type of test and acceptance criteria. For guidelines see Table II-2.
    - Test water as close to the point-of-use as practical, and if microbial levels are above specific action levels, take appropriate corrective actions.
    - Retain documentation of all test results and / or Certificates of Analysis available for inspection for a period of at least 2 years.

1 Water quality criteria are based on US EPA recreational and drinking water quality. These standards are being used because there are no federal agricultural water quality standards. For further information, please see Appendix B, Technical Basis for Metrics.

Table II-2. Water Use

Use	Metric	Rationale / Corrective Actions
PRE-HARVEST **Foliar Applications** (overhead sprinkler irrigation, pesticides / fungicide application, etc.)	**Target Organism:** generic *E. coli*. **Sampling Procedure:** 1 L sample collected aseptically at the point of use; e.g., one sprinkler head per water source for irrigation, water tap for pesticides. Water utilized in preseason irrigation operations may be tested and utilized. **Sampling Frequency:** One sample per water source should be collected and tested prior to use if >60 days since last test of the water source. Additional samples should be collected no less than 18 hr. apart and at least monthly during use from points within the distribution system. **Municipal & Well Exemption:** For wells and municipal water sources, if generic *E. coli* levels are below detection limits for five consecutive samples, test the water for total coliform (TC). If the TC test is zero/negative, the sampling frequency may be decreased to once every six months and the 60 and 30 day sampling are waived. This exemption is void if there is a significant source or distribution system change.	For any given water source (municipal, well, reclaimed water, reservoir or other surface water), samples for microbial testing should be taken as close to the point of use as practical (as determined by the sampler using sampling methods to ensure the integrity of the sample as prescribed in this table) where the water contacts fresh culinary herbs, so as to test both the water source and the water distribution system. In a closed water system (meaning no connection to the outside) water samples may be collected from any point within the system, but are still preferred as close to point of use as practical. There is only one sample per month per distribution system under these metrics unless a system has qualified for an exemption. If there are multiple potential point-of-use sampling points in a distribution system, then samples should be taken from different point-of-use locations each subsequent month (randomize or rotate sample locations). Water for pre-harvest, direct contact should meet or exceed microbial standards for recreational water, based on a rolling geometric mean of the five most recent samples. If the water source has not been tested in the past 60 days, the first water sample should 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 should be collected no less frequently than monthly at points of use within the distribution system. Ideally, pre-harvest water should not contain generic *E. coli*, but low levels do not necessarily indicate that the water is unsafe. Investigation and / or corrective action should be taken when test results are higher than normal or indicate an upward trend. Investigation and corrective action must be taken when acceptance criteria are exceeded. **Corrective Actions:** If the rolling geometric mean (n=5) or any one sample exceeds the acceptance criteria, then the water should not be used whereby the fresh culinary herbs are contacted by water until corrective actions have been completed and generic *E. coli* levels are within acceptance criteria: • Conduct a Sanitary Survey of water source and distribution system to determine if a contamination source is evident and can be eliminated. Eliminate identified contamination source(s). • For wells, perform a Sanitary Survey and / or treat as described in Appendix A. • Retest the water after conducting the Sanitary Survey and / or taking corrective actions to determine if it meets the outlined microbial acceptance criteria for this use. This sample should represent the conditions of the original water system. If feasible, this test should be as close as practical to the original sampling point. A more aggressive sampling program (i.e., sampling once per week instead of once per month) should be instituted if an explanation for the exceedence is not readily apparent. This type of sampling program should also be instituted if an upward trend is noted in normal sampling results.

Use	Metric	Rationale / Corrective Actions
	Test Method: FDA BAM method or any US EPA-approved or AOAC-validated method for quantitative monitoring of water for generic *E. coli.* **Acceptance Criteria:** **≤126 MPN (or CFU)*/100 mL** (rolling geometric mean n=5) and **≤235 MPN/100 mL** for any single sample. *for the purposes of water testing, MPN and CFU should be considered equivalent.	**Crop Testing**: If water testing indicates that fresh culinary herbs have been directly contacted with water exceeding acceptance criteria, fresh culinary herb plants should be sampled and tested for *E. coli* O157:H7 and *Salmonella* as well as any other microorganism deemed appropriate as described in Appendix C. If crop testing indicates the presence of pathogens, these herbs should NOT be harvested for human consumption. **Records**: Information requirements: Each water sample and analysis should record: the type of water (canal, reservoir, well) date, time, field location of the sample, and exact location in the water system and the method of analysis and detection limit. Records of the analysis of source water may be provided by municipalities, irrigation districts or other water providers. All test results and corrective actions should be documented and available for verification from the grower / handler who is the responsible party for a period of 2 years.
PREHARVEST Non-Foliar Applications Whereby Edible Portions of the Crop are **NOT** Contacted by Water (e.g., furrow or drip irrigation, dust abatement water; if water is not used in the vicinity of produce, then testing is not necessary)	**Target Organism, Sampling Procedure, Sampling Frequency Test Method and Municipal Well Exemption:** as described for foliar application. **Acceptance Criteria:** **≤126 MPN /100 mL** (rolling geometric mean n=5) and **≤576 MPN /100 mL** for any single sample.	Testing and corrective actions for pre-harvest water that does not come in direct contact with edible portions of the crop are the same as for direct contact water, but acceptance criteria are less stringent because of the reduced risk of contact of the edible portion with contamination from water. Acceptance criteria

Use	Metric	Rationale / Corrective Actions
POST-HARVEST Direct Product Contact or Food Contact Surfaces	**Microbial Testing** **Target Organism, Sampling Procedure, Test Method, and Municipal & Well Exemption:** as described for PRE-HARVEST, foliar applications. **Sampling Frequency:** One sample per water source should be collected and tested prior to use if >60 days since last test of the water source. Additional samples should be collected at intervals of no less than 18 hours and at least monthly during use. **Acceptance Criteria:** Negative or below DL for all samples (≤ 2 MPN/100 mL) [1] **Physical / Chemical Testing** **Target Variable:** Water disinfectant (e.g., chlorine or other antimicrobial chemical) **Single pass and Multi-Pass Water Acceptance Criteria*:** • US EPA-**approved treatments** per product label for human pathogen reduction in water and used in accordance with a water system-specific protocol that has been validated to show that active disinfectant is present. • **Chlorine-based disinfectants** ≥10 ppm free chlorine post-contact and pH 6.5 – 7.0 • ORP ≥ 725 mV 1 The method used to test the water should have a detection level of ≤2 MPN/100 mL. For additional discussion on this issue, see Appendix B: Technical Basis for the Guidelines	Water that directly contacts harvested fresh culinary herbs or is used on food contact surfaces, such as equipment or utensils, should meet the Maximum Contaminant Level Goal of zero or no detection for *E. coli* in drinking water as specified by US EPA or contain an approved disinfectant at sufficient concentration to prevent cross-contamination. Microbial or physical / chemical testing should be performed, as appropriate to the specific operation, to demonstrate that acceptance criteria have been met. **Single Pass and Multiple Pass Systems** Single pass use – Water should have non-detectable levels (≤ 2 MPN/100 mL) [26] of *E. coli* and sufficient disinfectant to ensure returned water has no detectable *E. coli* (minimally 10 ppm chlorine). Multi-pass use – Water should have non-detectable levels (≤ 2 MPN/100 mL) [26] of *E. coli* and sufficient disinfectant to ensure returned water has no detectable *E. coli* (minimally 10 ppm chlorine). * Single pass and recirculated water treated with chlorine-based disinfectants should be tested for free chlorine concentration (ppm) and pH OR for oxidation reduction potential (mV). The selected method should be verified periodically with the alternative process verification method AND by ensuring that established microbial acceptance criterion for generic *E. coli* in water is being met. **Corrective Actions**: If any one sample exceeds the acceptance criteria for generic *E. coli*, then the water should not be used for this purpose unless appropriate disinfectants have been added or until corrective actions have been completed and generic *E. coli* levels are within acceptance criteria: • Conduct a Sanitary Survey of the water source and distribution system to determine if a contamination source is evident and can be eliminated. Eliminate identified contamination source(s) if applicable. • For wells, perform a Sanitary Survey and / or treat as described in the Sanitary Survey (Appendix A). • Retest the water at the same sampling point after conducting the Sanitary Survey and / or taking corrective actions to determine if it meets the outlined microbial acceptance criteria for this use. For example, if a water sample for water used to clean food contact surfaces has detectable *E. coli*, STOP using that water system, examine the distribution line; source the inlet as described in the Sanitary Survey (Appendix A), and retest from the same point of use. Continue testing daily for five days at the point closest to use, and do not use the water system until it consistently delivers water that is safe, sanitary, and meets the acceptance criteria for post-harvest water outlined in this table. If any of the five samples taken during the intensive sampling period after corrective actions have been taken, have

Use	Metric	Rationale / Corrective Actions
	Testing Procedure: • Chemical reaction based colorimetric test, or • Ion specific probe, or • ORP,* or • Other as recommended by disinfectant supplier. **Testing Frequency:** Continuous monitoring (preferred) with periodic verification by titration OR routine monitoring if the system can be shown to have a low degree of variation.	detectable *E. coli*, repeat corrective actions and DO NOT use that system until the source of contamination can be corrected. **Records**: All test results and corrective actions should be documented and available for verification from the user of the water for a period of 2 years.

Figure 3A. Decision Tree for Pre-Harvest Water Use (e.g., overhead irrigation, drip irrigation, pesticide / fungicide applications)

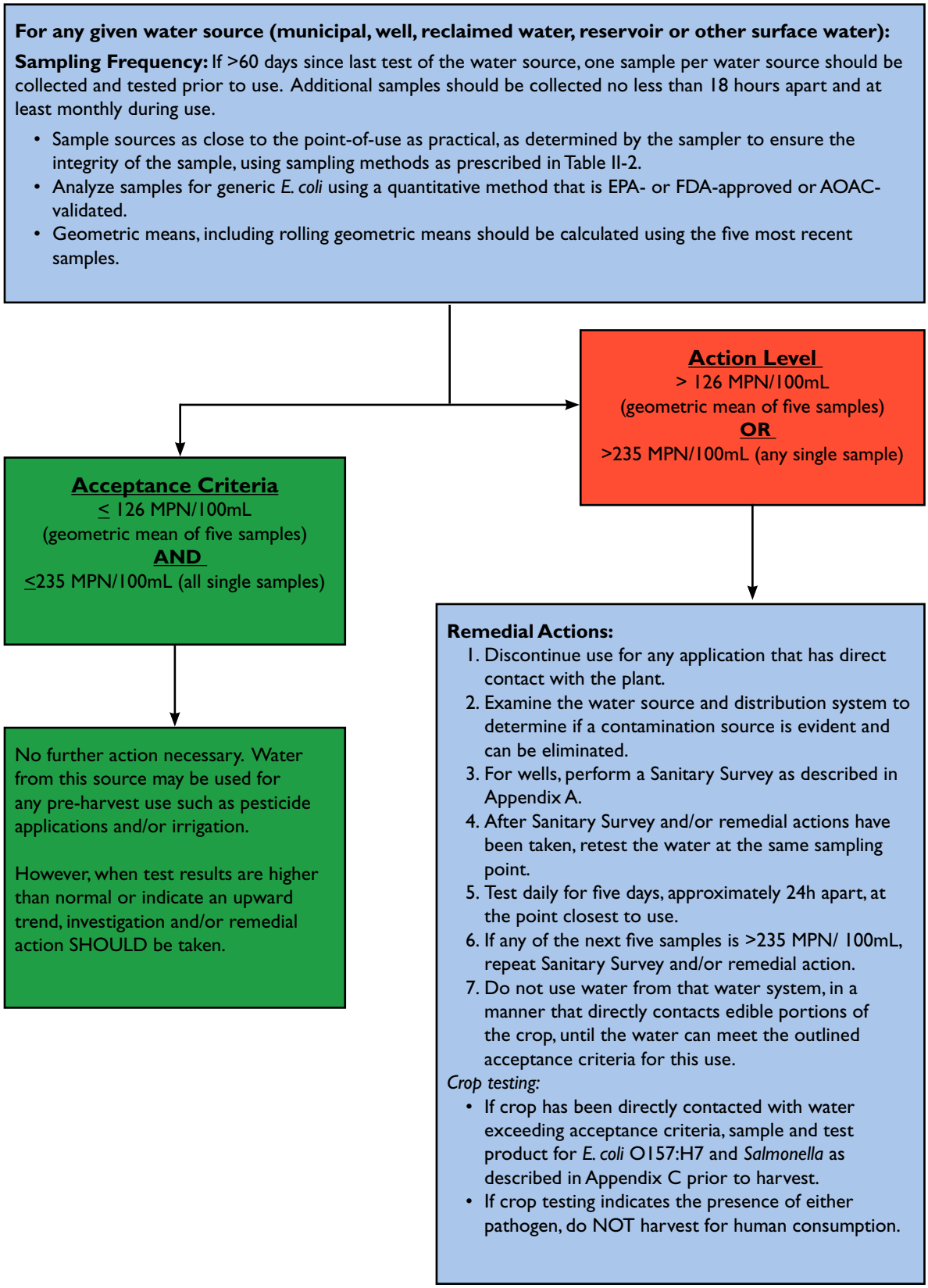


Figure 3B. Decision Tree for PRE-HARVEST WATER USE – Non-foliar applications whereby edible portions of the crop are NOT contacted by water (e.g. furrow or drip irrigation, dust abatement water)

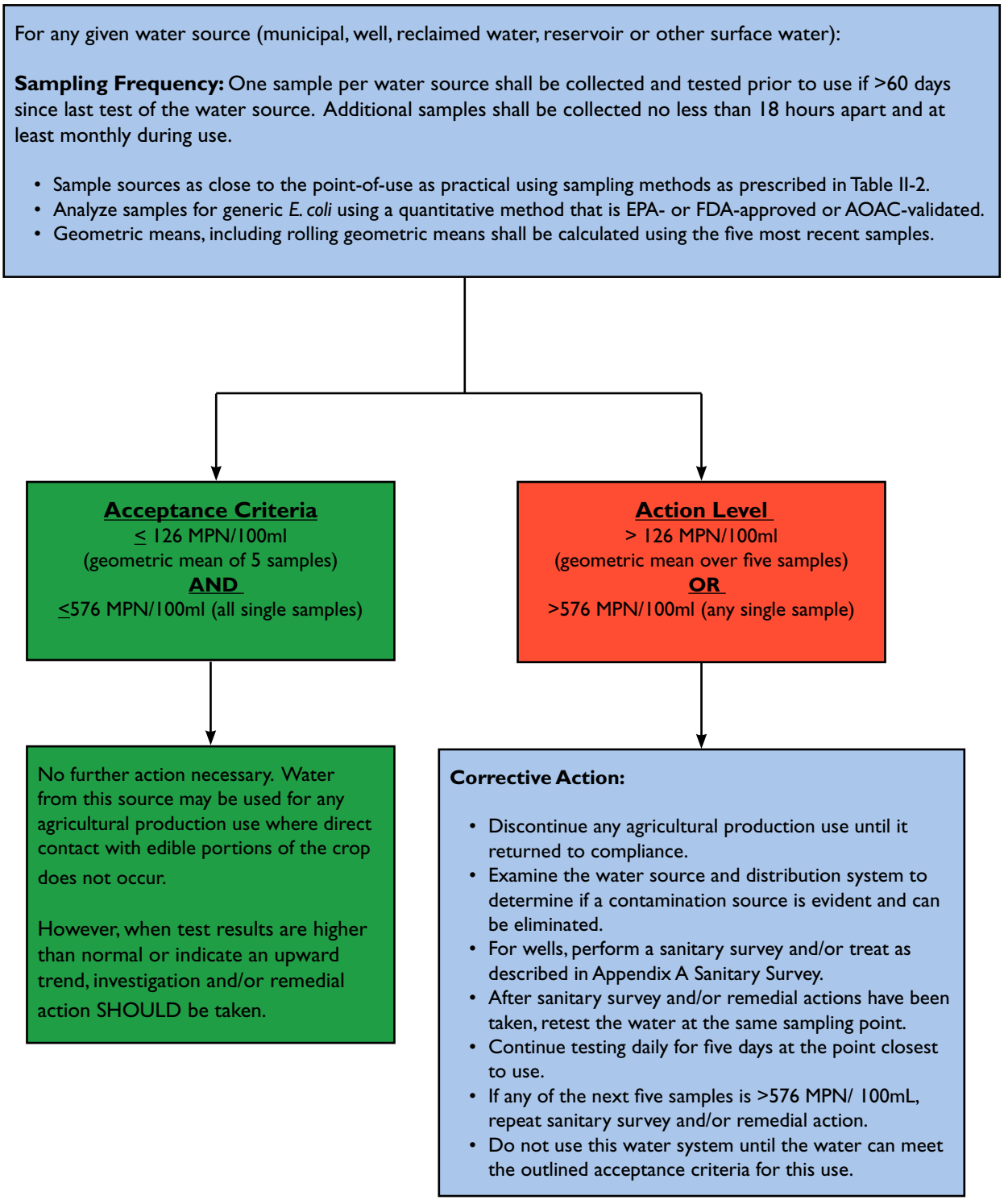
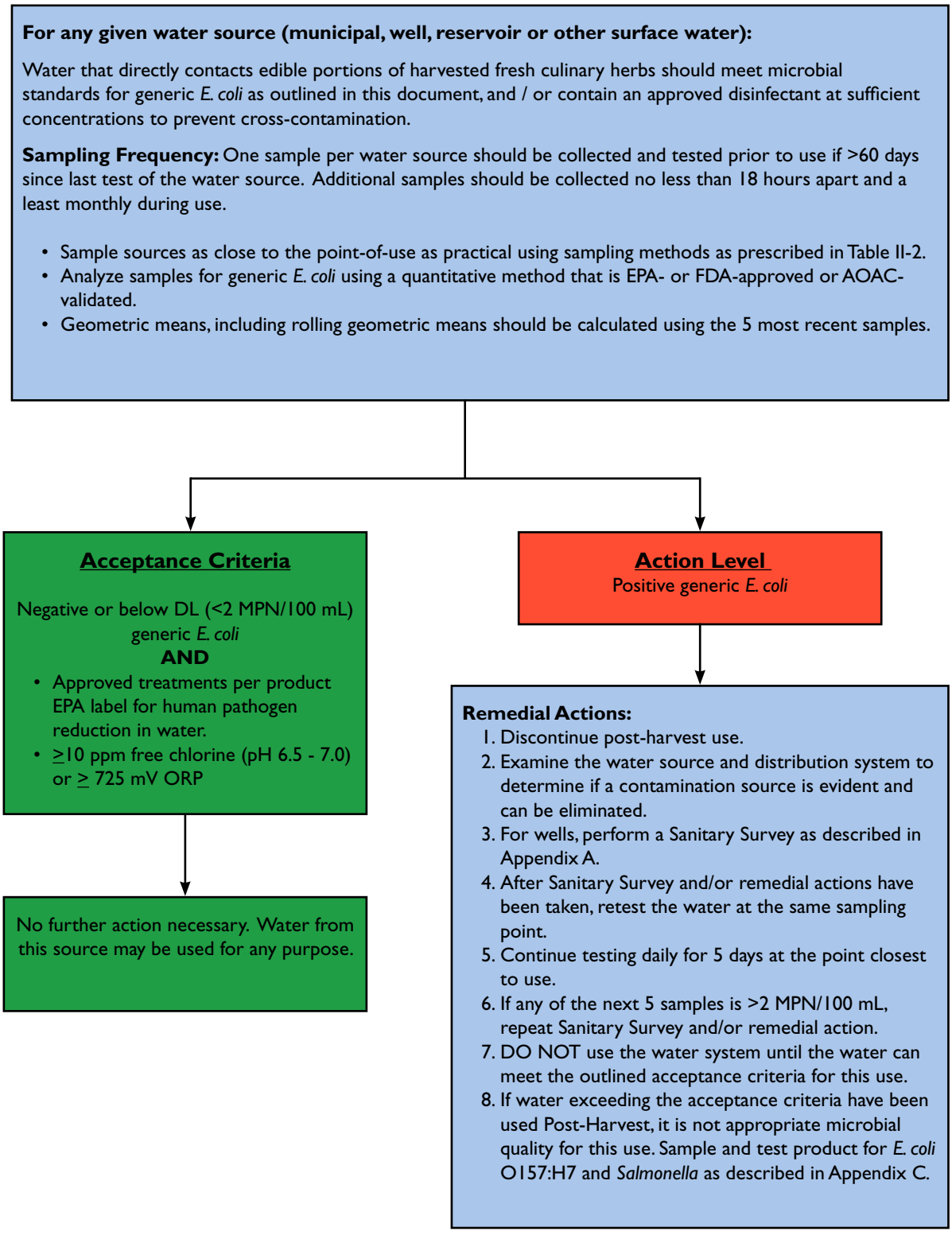


Figure 3C. Post-Harvest Water Use Direct Product Contact (e.g., re-hydration, cooling)



2.2 Other Considerations for Water

- Evaluate irrigation methods (e.g., drip irrigation, overhead sprinkler, and furrow) for their potential to introduce, support, or promote the growth of human pathogens on fresh culinary herbs. Consider such factors as the potential for depositing soil on the crop, free moisture on plant surfaces, and the presence of pooled or standing water that attracts animals.
- When water from various sources is combined, ensure all water sources meet the water quality metrics described in Table II-2.
- Storm events have considerable impact on surface waters. Bacterial loads in surface water are generally much higher than normal after a storm event, and caution should be exercised when using surface water for irrigation.
- Use procedures for storing irrigation pipes and drip tape that reduce or eliminate potential pest infestations. Develop procedures to provide for microbiologically safe use of irrigation pipes and drip tape if a pest infestation does occur.
- Reclaimed water must be subject to applicable state and federal regulations and standards. Use of this water for agricultural purposes should meet the most stringent standard as defined by state and federal regulations or Table II-2 of this document.
- If water sample results and analysis are provided by a water district or provider, they may be utilized as records of water source testing for verification and validation audits.

Documentation List:

- ☐ Water system description
- ☐ A water quality management plan including validation of water disinfection system
- ☐ SOP – Water testing
- ☐ Water test results that describes the methods used for analysis
- ☐ Water disinfectant monitoring logs

3.0 Issue: Soil Amendments

Soil amendments (SAs) are commonly (but not always) incorporated prior to planting into agricultural soils used for fresh culinary herb production to add organic and inorganic nutrients to the soil as well as to reduce soil compaction. Human pathogens may persist in animal manures for weeks or even months (Fukushima et al. 1999; Kudva et al. 1998). Proper composting of animal manures via thermal treatment will reduce the risk of potential human pathogen survival, but proper storage and handling of composted animal manures is essential in preventing recontamination. Field soil contaminated with human pathogens from inadequately composted or re-contaminated composted soil amendments may provide a means of fresh culinary herb contamination. Some studies of human pathogens conducted in cultivated field vegetable production models point towards a rapid initial die-off from high pathogen populations but often maintain a characteristic and prolonged low level pathogen survival (Hutchison et al. 2004; Ingham et al. 2004; Ingham et al. 2005; Islam et al. 2004a; Islam et al 2005; Nicholson et al. 2004). However, the persistence of many human pathogens in agricultural soils depends on many factors (e.g., soil type, crop planted, soil moisture, relative humidity, UV index, cultivation practices, stress-adaption) and the effects of these factors are under extensive investigation (Jiang et al. 2003; Islam et al. 2004a; Islam et al. 2004b; Singh et al. 2010). Human pathogens may not persist for long periods of time in high UV index and low relative humidity conditions, but may persist for longer periods of time in cool, moist climates or when SA are incorporated into the soil where UV rays do not easily penetrate and more moisture is present.

Field soil contaminated with human pathogens from inadequately composted or re-contaminated composted soil amendments may provide a means of fresh culinary herb contamination.

Fresh culinary herbs grow at varying rates so choosing an appropriate application-to-harvest interval is dependent on the variety. Similar to other fresh produce crops that grow close to the ground, the edible portions of some fresh culinary herbs are more vulnerable to contamination. Therefore, establishing application-to-harvest intervals, appropriate for specific fresh herbs as well as regional climate and field conditions, is highly recommended as an effective step towards further minimizing risk associated with soil amendments containing composted animal manure (Suslow et al. 2003).

3.1 The Best Practices Are:

- DO NOT USE raw manure, biosolids, or apply SAs that contain poulty carcasses, un-composted, incompletely composted animal manure and/or green waste, or non-thermally treated animal manure to fields which will be used for fresh culinary herb production.
- See Table II-3 and Decision Trees (Figures 4A and 4B) for numerical criteria and guidance for compost and SAs used in fresh culinary herb production fields. The Technical Basis for Metrics (Appendix B) describes in more detail the process used to develop these metrics.
- Any SA that does not contain animal manure should have a certificate (e.g., ingredient list, statement of identity, letter of guaranty) from the producer or seller demonstrating that it is manure-free. The manure-free certificate should be available for verification before application and should be saved and available for inspection for 2 years.
- Implement management plans (e.g., timing of applications, storage location, source and quality, transport) that significantly reduce the likelihood that SAs being used contain human pathogens.
    - Storage and handling practices should reduce the risk of recontamination after the composting process is complete and before it is applied to and incorporated into fields. This is especially critical for SAs that are pelletized, which provides a concentrated source of nutrients, and processed using high heat, which eliminates competing microbiological populations.
    - Verify that the time and temperature process used during the composting process reduces, controls, or eliminates the potential for human pathogens being carried in the composted materials. There are validated processes outlined in regulatory requirements that dictate critical times and temperatures for different composting methods (see Table II-3 and Appendix F for details). New research findings suggest that rapid achievement of critical temperatures is also important for pathogen die-off.
    - Do not apply composted SAs less than 45 days before

harvest. Although highly effective at reducing pathogens, composting methods and microbial testing as provided in Table II-3, do not guarantee pathogen-free SAs. Therefore, an application-to-harvest interval of greater than 45 days provides an additional hurtle for minimizing the risk of contamination. When determining appropriate application intervals, consider plant characteristics as well as climatic and field conditions (i.e., high humidity, low UV may warrant longer application-to-harvest intervals).

- Implement practices that control, reduce or eliminate likely contamination of fresh culinary herb fields in close proximity to on-farm stacking of manure or storage of other soil amendments (for suggested buffer distances see Table II-1B).
- Use SA application techniques that control, reduce, or eliminate likely contamination of surface water and / or crops being grown in adjacent fields.
- Segregate equipment used for SA handling, preparation, distribution, and application or use effective means of equipment sanitation that effectively reduces the potential for cross-contamination before subsequent use.
- Compost suppliers should have written SOPs to prevent cross-contamination of finished compost with raw materials through equipment, runoff, or wind, and growers should obtain proof that these documents exist.
- Compost operations supplying compost to fresh culinary herb crops should maintain temperature monitoring and turning records for at least 2 years, and growers should obtain proof that this documentation exists. This applies to composting operations regulated under Title 14 of California Code of Regulations (CCR) as well as operations in other states and smaller CA operations that do not fall under CCR Title 14.[2]
- Perform microbiological testing of SAs prior to application as provided in Table II-3.
- Retain documentation of all processes and test results by lot (at the supplier) and / or Certificates of Analysis available for inspection for a period of at least 2 years.

Documentation List:

- ☐ Product spec sheets
- ☐ Composted SA process verification paperwork (e.g. COA, test results)
- ☐ On-farm compost processing records
- ☐ SA application dates
- ☐ Copy of any required applicator's license
- ☐ SOP – Cleaning of SA application equipment

2 CCR. Title 14, Chapter 3.1 http://www.calrecycle.ca.gov/Laws/Regulations/title14/default.htm#Chapter3_1

Table II-3. Soil Amendments (SAs)

Amendment	Metric / Rationale
Raw manure, biosolids and/ or incompletely composted green waste, animal manure or poultry carcasses containing SAs (see composted manure process definition below)	**DO NOT USE OR APPLY** SAs that contain raw manure, biosolids, un-composted/incompletely composted green and/ or poultry carcasses, un-composted/incompletely composted or non-thermally treated (e.g., heated) animal manure to fields which will be used for fresh culinary herb production. If these materials have been applied to a field, wait one year prior to producing fresh culinary herbs,
Composted SAs (containing animal manure or animal products)	**Please see Figure 4A: Decision Tree for Use of Composted SAs.** **Composting Process Validation:** Enclosed or within-vessel composting: • Active compost shall maintain a minimum of 131°F for 3 days Windrow composting: • Active compost shall maintain aerobic conditions for a minimum of 131°F for 15 days or longer, with a minimum of five turnings during this period. Aerated static pile composting: • Active compost shall be covered with 6 to 12 inches of insulating materials and maintain a minimum of 131°F for 3 days **Target Organisms:** • Fecal coliforms • *Salmonella* spp. • *E. coli* O157:H7 **Acceptance Criteria:** • Fecal coliforms: <1000 MPN/gram • *Salmonella* spp.: Negative or < DL (<1/30 grams) • *E. coli* O157:H7: Negative or < DL (<1/30 grams) **Preferred Test Methods:** • Fecal coliforms: 9 tube MPN • *Salmonella* spp.: US EPA Method 1682 • *E. coli* O157:H7: Any laboratory validated method for compost sampling. • Other US EPA, FDA, or AOAC-accredited methods may be used as appropriate.

Amendment	Metric / Rationale
	Sampling Plan: • A composite sample shall be representative and random and obtained as described in the California state regulations (see Appendix F). • Sample may be taken by the supplier if trained by the testing laboratory. • Laboratory should be certified / accredited for microbial testing by an appropriate process authority. **Testing Frequency:** • Each lot before application to fresh culinary herb production fields. A lot is defined as a unit of production equal to or less than 5,000 cubic yards. **Application Interval:** • Should be applied >45 days before harvest. **Documentation:** • All test results and / or Certificates of Analysis should be documented and available for verification from the grower (the responsible party) for a period of 2 years. **Rationale:** • The microbial metrics and validated processes are from California state regulations for composting operations (CCR Title 14 – Chapter 3.1 – Article 7), with the addition of testing for *E. coli* O157:H7 as a microbe of particular concern. The fresh culinary herb industry also considered testing for *Listeria monocytogenes*, but did not include it as a target organism due to the current lack of validated testing methods for *L. monocytogenes* in SAs. • These guidelines provide a multiple hurdle risk reduction approach to using SA containing composted animal manure – 1) composting with an approved, validated process, 2) passing of specified microbial testing requirements, and 3) use of application-to-harvest intervals of > 45 days. The greater than 45-day application interval was deemed appropriate for SAs containing composted animal manure as an additional measure to reduce the risk associated with the acceptance criteria for fecal coliform (<1000 MPN/gram), and because composting methods and microbial testing do not guarantee pathogen-free material.

Amendment	Metric / Rationale
SAs Containing Animal Manure that has Been Physically Heat Treated or Processed by Other Equivalent Methods	• Any process applied to a soil amendment containing animal manure should be validated to assure that the process is capable of reducing pathogens of human health significance to acceptable levels. **Target Organism:** • Fecal coliforms • *Salmonella* spp. • *E. coli* O157:H7 **Acceptance Criteria:** • Fecal coliforms: < 10 MPN/gram • *Salmonella* spp.: Negative or < DL (<1/30 grams) • *E. coli* O157:H7: Negative or < DL (<1/30 grams) **Preferred Test Methods:** • Fecal coliforms: 9 tube MPN • *Salmonella* spp.: US EPA Method 1682 • *E. coli* O157:H7: Any laboratory validated method for testing SAs. • Other US EPA, FDA, or AOAC-accredited methods may be used as appropriate. **Sampling Plan:** • Extract at least 12 equal volume samples (identify12 separate locations from which to collect the sub-sample, in case of bagged product 12 individual bags). • Sample may be taken by the supplier if trained by the testing laboratory or state authority. • Laboratory should be certified / accredited by annual review of laboratory protocols based on GLPs by recognized NGO. **Testing Frequency:** • Each lot before application to fresh culinary herb fields. • In lieu of the above sampling plan, a Certificate of Process Validation issued by a recognized process authority can be substituted. This certificate will attest to the process validity as determined by either a documented (included with Certificate) inoculated pack study of the standard process or microbial inactivation calculations of organisms of significant risk (included with Certificate) as outlined in FDA CFSAN publication "Kinetics of Microbial Inactivation for Alternative Food Processing Technologies. Overarching Principles: Kinetics and Pathogens of Concern for All Technologies."[1]

1 http://www.fda.gov/Food/ScienceResearch/ResearchAreas/SafePracticesforFoodProcesses/ucm100158.htm

Amendment	Metric / Rationale
	Application Interval: • If the physical heat treatment process used to inactivate human pathogens of significant public health concern is validated and the soil amendment produced meets the microbial acceptance criteria outlined above, then no time interval is needed between application and harvest. • If the physical heat treatment process used to inactivate human pathogens of significant public health concern is not validated, but the soil amendment produced meets microbial acceptance criteria outlined above, then a >45-day interval between application and harvest is recommended. **Documentation** • Fresh culinary herb growers should keep the following documentation for a 2 year period: ○ Any SA test results and / or Certificates of Analysis should be available for verification from the grower who is the responsible party ○ A copy of the SA supplier's operation validation certificate issued by a process authority • The documentation should be available for verification before harvest begins and maintained for at least 2 years. **Rationale:** • The microbial metrics and validated processes are from California state regulations for composting operations (CCR Title 14 – Chapter 3.1 – Article 7), with the addition of testing for *E. coli* O157:H7 as a microbe of particular concern. A more stringent level of fecal coliform was also included to address the much more controlled nature of SAs produced in this manner. The above suggested application interval was deemed appropriate due to the specified multiple hurdle risk reduction approach outlined. Raw manure should be composted with an approved process and pass testing requirements before application. • FDA has established the validity of D-values and Z-values for key pathogens of concern in foods. This method of process validation is currently acceptable to U.S. regulators. Alternatively, results of an inoculated test pack utilizing the specific process is also an acceptable validation of the lethality of the process.
SAs Not Containing Animal Manure or Animal Products (e.g., synthetic fertilizer)	• Any SA that DOES NOT contain animal manure should have documentation that it is manure-free. • The documentation should be available for verification before harvest begins. • If there is documentation that the amendment does not contain manure or animal products then no additional testing is needed, and no application interval is necessary • Any test results and / or Certificate of Analysis should be available for verification from the grower who is the responsible party for a period of 2 years.

Figure 4A. Decision Tree for Composted Soil Amendments (SAs)

If raw manure has been directly applied to the field in the past, a one-year waiting period should be observed before planting any variety of fresh culinary herbs.

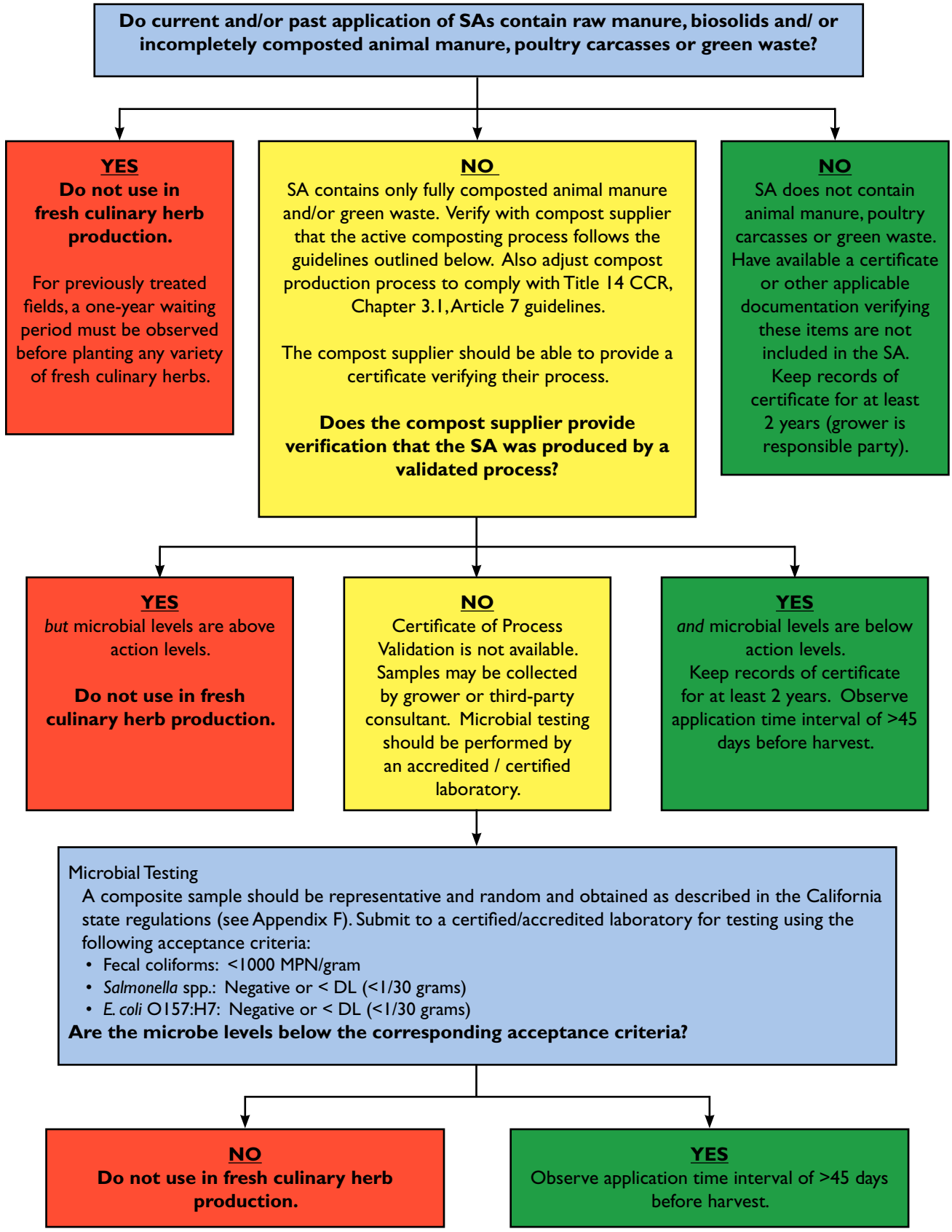
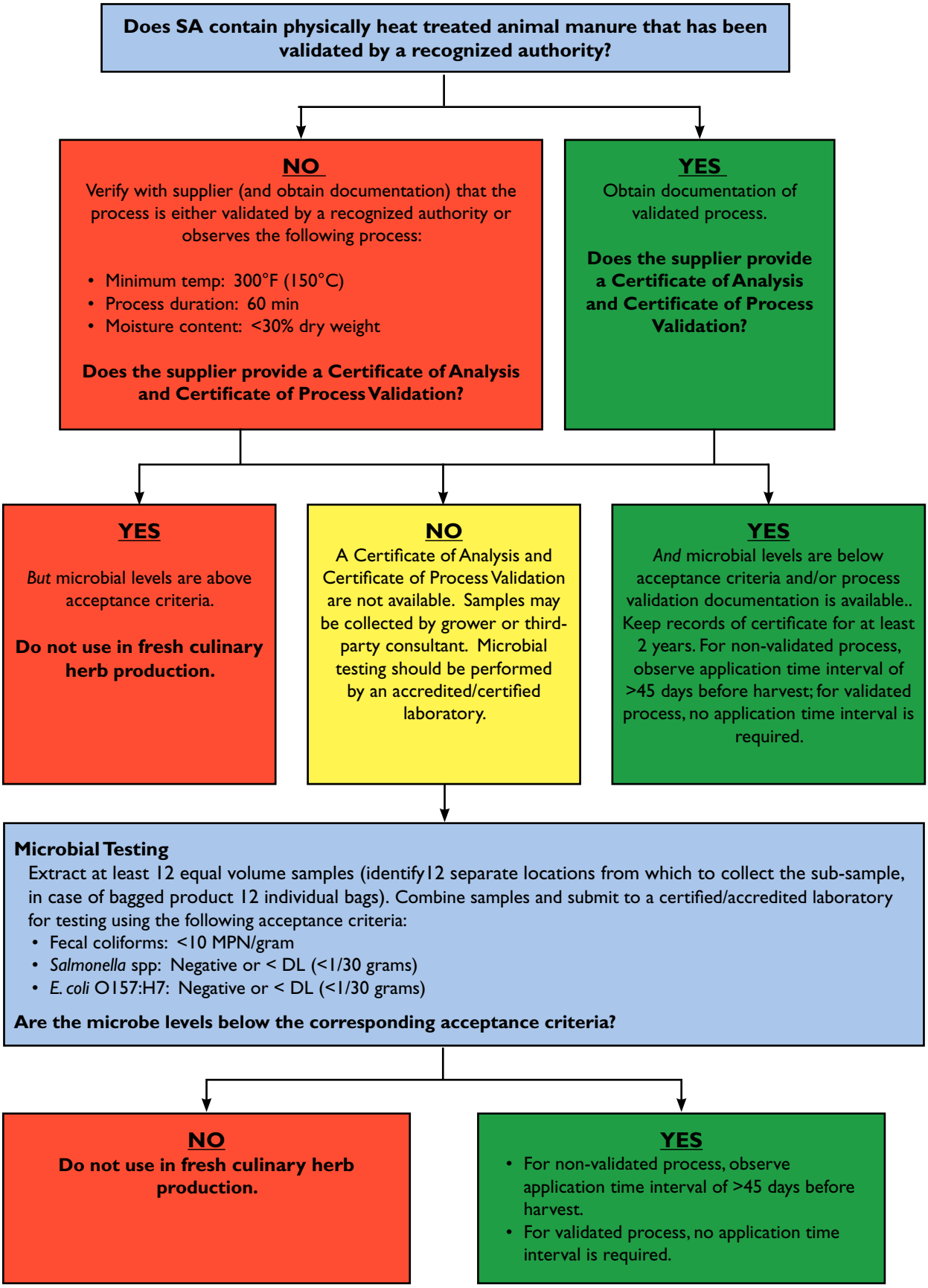


Figure 4B. Decision Tree for Physically Heat Treated Animal Manure Containing Soil Amendments (SAs)



4.0 Issue: **Nonsynthetic Crop Treatments**

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

4.1 The Best Practices Are:

- DO NOT USE crop treatments that contain raw manure for fresh culinary herb production.
- Retain documentation of all test results available for inspection for a period of at least 2 years.
- Implement management plans (e.g., timing of applications, storage location, source and quality, transport) that assure to the greatest degree practicable that the use of crop treatments does not pose a significant pathogen contamination hazard.
- Verify that the time and temperature process used to manufacture the crop treatment reduces, controls, or eliminates the potential for human pathogens being carried in the composted materials, as applicable to regulatory requirements.
- Follow the time interval between the crop treatment application and time to harvest as provided in Table II-4.
- Implement practices that control, reduce, or eliminate likely contamination of fresh culinary herb fields that may be in close proximity to on-farm storage of crop treatments (e.g., segregated storage).
- Use crop treatment application techniques that control, reduce, or eliminate the likely contamination of surface water and / or crops being grown in adjacent fields.
- Segregate equipment used for crop treatment applications or use effective means of equipment sanitation before subsequent use.
- See Table II-4 and Decision Tree (Figure 5) for numerical criteria and guidance for nonsynthetic crop treatments used in fresh culinary herb production fields.

Documentation List:

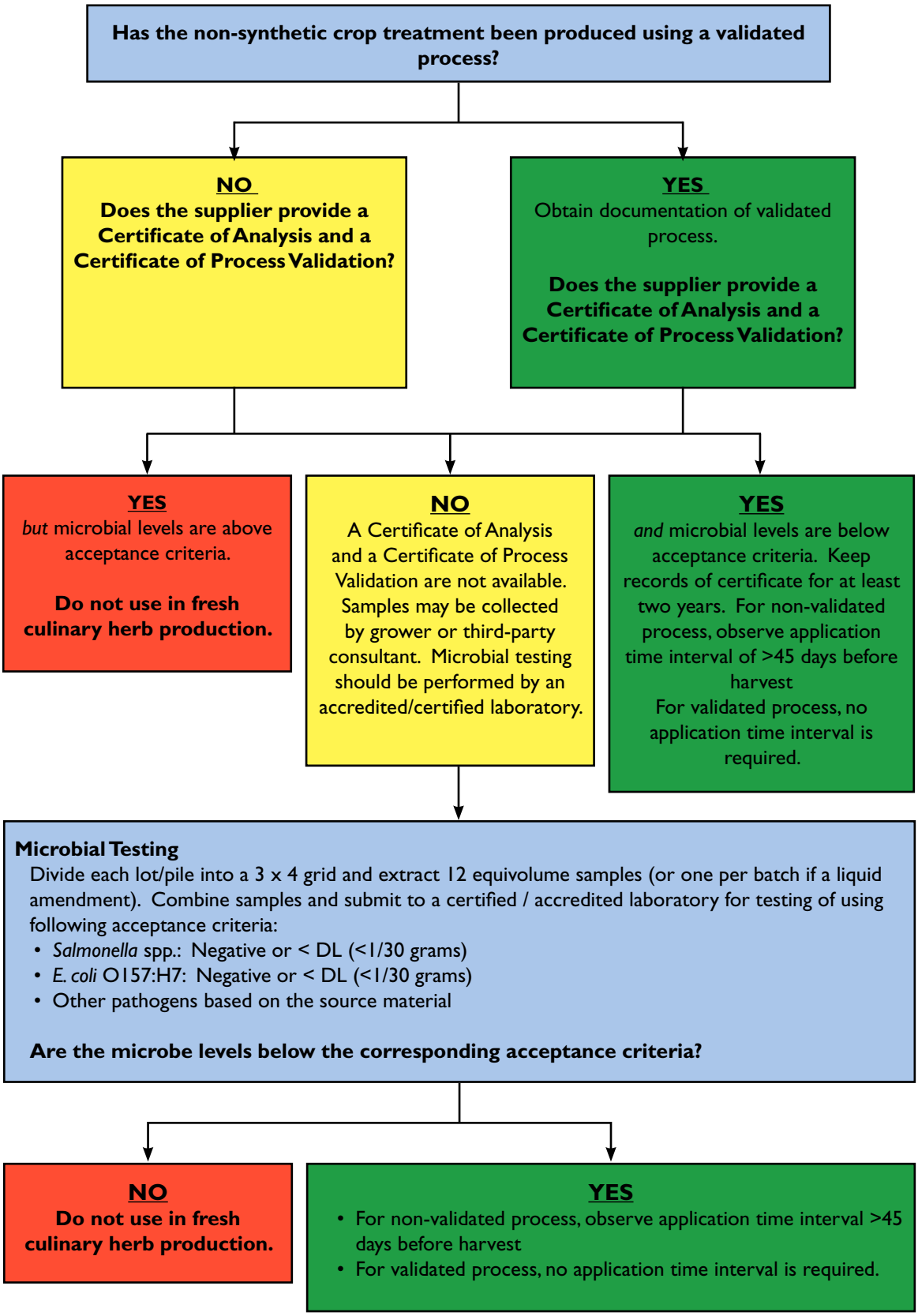
- ☐ Product spec sheets
- ☐ Composted SA process verification paperwork (e.g. COA, test results)
- ☐ On-farm processing records
- ☐ SA application dates
- ☐ Copy of any required applicator's license
- ☐ SOP – cleaning of SA application equipment

Table II-4. Nonsynthetic Crop Treatments

Treatment	Metric / Rationale
Any crop treatment that contains animal manure, an animal product, and / or an animal by-product that is reasonably likely to contain human pathogens. Examples include (but not limited to): • Compost teas • Fish emulsions • Fish meal • Blood meal • "Bio-fertilizers" commonly used for pest control, greening, disease control, fertilizing Suppliers of these products should disclose on labels, Certificates of Analysis, or other companion paperwork whether the product contains any animal manure or products.	**Nonsynthetic crop treatments that contain animal products or animal manure that have not been physically heat treated or processed by other equivalent methods should NOT be directly applied to fresh culinary herbs.** **Please see Figure 5: Decision Tree for Use of Nonsynthetic Crop Treatments.** **Process Validation** • The physical, chemical, and / or biological treatment process used to render the crop treatment safe for application to crops should be validated. **Target Organism:** • *Salmonella* spp. • *E. coli* O157:H7 • Other pathogens appropriate for the source material. **Acceptance Criteria (at point of use):** • *Salmonella* spp.: Negative or < DL (<1/30 grams) • *E. coli* O157:H7: Negative or < DL (<1/30 grams) **Preferred Test Methods:** • *Salmonella* spp.: US EPA Method 1682 • *E. coli* O157:H7: Any laboratory validated method for the non-synthetic material to be tested. • Other US EPA, FDA, or AOAC-accredited methods may be used as appropriate. **Sampling Plan:** • If solid, 12 point sampling plan composite sample, or if liquid, one sample per batch (if liquid-based, then crop treatment should meet water quality acceptance levels as described in Table II-2) • Sample may be taken by the supplier if trained by the testing laboratory. • Laboratory should be certified / accredited by annual review of laboratory protocols based on GLPs by recognized NGO. **Testing Frequency:** • Each lot before application to fresh culinary herb fields.

Treatment	Metric / Rationale
	Application Interval: • If the physical, chemical, and / or biological treatment process used to render the crop treatment safe for application to fresh culinary herbs is validated and meets that microbial acceptance criteria outlined above, no time interval is needed between application and harvest. • If the physical, chemical, and / or biological treatment process used to render the crop treatment safe for application to fresh culinary herbs is not validated yet meets the microbial acceptance criteria outlined above, observe a >45-day time interval between application and harvest. **Documentation:** • All test results and / or Certificates of Analysis should be documented and available from the grower for verification for a period of 2 years. The grower is the responsible party for maintaining the appropriate records. **Rationale:** The microbial metric for *Salmonella* spp. is from California state regulations for composting operations (CCR Title 14 – Chapter 3.1 – Article 7), with the addition of testing for *E. coli* O157:H7 as the microbe of particular concern. The above suggested application interval was deemed appropriate due to the specified multiple hurdle risk reduction approach (validated processing methods, microbial testing requirements). Any nonsynthetic crop treatment that contains animal manure should use only fully composted manure that meets the requirements outlined in Table II-3 before application to soils or directly to fresh culinary herbs. **Appendix B** describes in detail the process used to develop these metrics.

Figure 5. Decision Tree for Nonsynthetic Crop Treatments That Contain Animal Products



Note: Mixtures of SA Materials

For SAs that contain mixtures of materials, each component should meet the guidelines and regulatory requirements of its respective class of materials. The usages allowed should conform to that of the most stringent class of materials utilized in the mixture.

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

5.0 Issue: **Harvest**

This section addresses harvesting-related issues including harvest aid equipment and direct contact of harvested herbs with soil.

5.1 The Best Practices Are:

- Prior to and during harvest operations, perform an environmental assessment of the fresh culinary herb production field and surrounding area. See section 1.0 Environmental Assessments for more information.
- Prior to harvest, an individual should be designated as responsible for harvest food safety. This person should be available when fresh culinary herbs are being harvested.
- When a field is to be harvested more than once, develop practices and procedures to protect against the introduction of pathogens (for best practices see below)
- As harvest time approaches, schedule irrigation so as to avoid exposing the plants to excessive mud and soil.

5.2 Harvest Equipment

Fresh culinary herbs may be harvested by hand or machine. Hand harvest includes the use of many types of equipment including knives, containers and other tools. Harvest equipment offers an opportunity for contamination if appropriate best practices are not followed to prevent contamination from surface contact exposure. Establish appropriate equipment handling and cleaning measures that reduce and control the potential introduction of human pathogens, especially at a cut surface, during and after harvest. Due to the cut surface being more vulnerable to microbial contamination, all practical means should be taken to reduce the possibility of contamination after cutting.

Harvest equipment offers an opportunity for contamination if appropriate best practices are not followed to prevent contamination from surface contact exposure.

5.2.1 The Best Practices Are:

- Prepare an SOP for harvest equipment that addresses the following:
  - Daily inspection of all equipment used in harvesting prior to harvest activities to check for any equipment deficiencies or maintenance requirements.
    - Drip pans (to catch oil or other lubricants) should be in place and tightly secured.
    - Hydraulic hoses, hydraulic motors, and overhead hydraulic fittings should be tight and drip free with no indications of recent leakage.
    - Loose or damaged equipment parts should be removed or appropriately repaired immediately. No temporary remedies such as string, tape, wire, and / or cardboard should be used in repair of tools.

- Periodic inspections of the condition of all hand tools and replacement of damaged tools.
  - Broken, chipped, or otherwise damaged hand tools should not be returned to use until the deficiency is corrected.
  - Maintenance of cutting tools so that they are sharp and free from damage such as ragged edges.
- An accounting of all hand tools whenever employees leave the harvest line.
- Control procedures when equipment is not in use, including policy for removal of equipment from the work area or site, equipment storage, and the use of scabbards, sheathes, or other hand-held harvesting tool storage equipment.

- Prepare an SSOP for harvest equipment that addresses the following:
  - The frequency of equipment cleaning and sanitation by developing a sanitation schedule for harvest operations.
    - Harvest tools should be sanitized at the beginning and end of each day.
    - Additionally, knives or other hand tools should be sanitized when returning to work, after moving between fields, or if potential contamination occurs (i.e., the tool comes in direct contact with the soil).
  - Proper cleaning and sanitation of all harvest equipment and surfaces that come in contact with fresh culinary herbs in a manner that will not contaminate fresh culinary herbs or other equipment.
    - Cleaning of reusable containers before subsequent usage.
    - Cleaning of containers that come into direct contact with soil between uses.
    - If product hydration is performed, cleaning of containers and equipment utilized to do so.
    - A proper sanitizing solution should be readily available at the harvesting site. Receptacles with a sanitizer solution should be provided to store and sanitize all hand-held harvesting tools that are not in use. These receptacles should be constructed of stainless steel so they can be cleaned and sanitized on a regular basis.
    - Check, adjust (if necessary), and document the sanitizer concentration strength as often as necessary to assure its effectiveness. Note: an employee should be trained in the proper mixing and use of sanitizers. An MSDS for all sanitizers used should be kept on file.
  - Evaluate the use of cleaning verification methods for harvesting equipment (e.g., ATP test methods, environmental swabs, protein test strips).
  - Locate equipment cleaning and sanitizing operations away from product and other equipment to reduce the potential for cross contamination.
- Prepare an SOP for the handling and storage of product containers that addresses the following:
  - Overnight storage
  - Contact with the ground including instructions not to stack soiled bins on top of each other if the bottom of one bin has had direct contact with soil unless a protective barrier (i.e., liner, cover) is used to separate the containers.
  - If liners or other barriers are used, precautions should be taken to prevent them from becoming a source of contamination.
  - Proper container assembly (RPC, fiber bin, plastic bin, etc.)
  - Damaged containers
  - Use of containers only as intended
  - If product hydration is performed, handling of water tanks and equipment when not in use.
- All harvesting tools should be collected at the end of each day. Employees should not take these tools

home with them. An inventory control program should be implemented to enforce these practices.

- Employees should not walk, step, sit, or lie on food contact surfaces of equipment.
- If re-circulated rinse or antioxidant solutions are used on the cut surface, take all practicable precautions to prevent them from becoming a source of contamination.
- Containers should be constructed of materials other than wood that are easy to clean and sanitize.
- Knives should be constructed of stainless steel with plastic or stainless steel handles and smooth seams, welds and joints so that they can be effectively cleaned and sanitized. Wooden handles do not lend themselves to efficient sanitation and hand-held tools constructed with standard steel will not hold up to routine sanitation with most sanitizing or oxidizing agents.
- Use equipment constructed of materials that facilitate cleaning and sanitation of equipment food contact surfaces (e.g., transportation tarps, conveyor belts).
- All maintenance requiring the use of chemicals, oils, greases, and fuels should be conducted away from the field.
- Allow adequate distance for the turning and manipulation of harvest equipment to prevent cross contamination from areas where contamination has been identified. For additional information on this issue, see Section 7.0 Equipment Facilitated Cross-Contamination.

5.3 Direct or In-Direct Contact with Soil during Harvest

After harvest of fresh culinary herbs, placing or stacking fresh culinary herbs on soil before it is placed into a container may expose the product to human pathogens if the soil is contaminated. In addition, herbs may come in contact with soil if containers are stacked after they've been on the ground.

5.3.1 The Best Practices Are:

- Evaluate appropriate measures that reduce and control the potential introduction of human pathogens through soil contact at the cut surface after harvest (frequency of hand-held harvesting tool cleaning and sanitation, no placement of cut surfaces of harvested fresh culinary herbs on the soil, container cleaning and sanitation, single use container lining, etc.).
- If containers used in harvesting are placed on the ground, employ measures to avoid potential contamination of harvested herbs by contact with soil on these containers.

Documentation List:

- ☐ SOP – Harvest equipment
- ☐ SSOP – Harvest equipment
- ☐ SOP – Harvest equipment/container storage
- ☐ Harvesting tools inventory log

The importance of workers, supervisors, and senior management understanding and practicing proper hygiene cannot be overemphasized. Workers should be trained regularly, in an appropriately comprehensible language, regarding food safety and worker health and hygiene.

6.0 Issue: **Field and Harvest Personnel**

Fresh culinary herbs may undergo significant handling by harvest crews during harvest in that each plant is touched/ handled as part of the harvest process. Workers may be asymptomatic and can contaminate fresh produce, water supplies, and other workers, and transmit human pathogens if they do not understand and follow basic hygienic principles. The importance of workers, supervisors, and senior management understanding and practicing proper hygiene cannot be overemphasized. Workers should be trained regularly, in an appropriately comprehensible language, regarding food safety and worker health and hygiene. Training programs should emphasize worker roles and responsibilities in producing a safe product, sanitation principles, and sanitary practices including appropriate and effective hand washing, proper glove use (if optional or required by policy), and mandatory use of sanitary field latrines to reduce and control potential contamination.

6.1 The Best Practices Are: Training

- Mandatory food safety training for every crew member at the beginning of each harvest season regarding risk recognition and reporting requirements, proper sanitation and hygiene practices and the potential of cross-contamination of fresh culinary herbs during harvesting.
  - This training should be augmented with follow-up sessions throughout the season.
  - Document all training sessions with a general description of the subject matter, the trainer's name, the date of training, a list of all workers invited to the training and the signatures of workers attending the training indicating that they understood the information presented.
    - For chemicals used in production and harvest, workers should receive training on the use, storage, disposal of waste chemicals and empty chemical containers, cleaning of chemical application equipment, recordkeeping, and proper labeling.

6.2 The Best Practices Are: Hygiene

- Establish a written worker practices program (e.g., an SOP) that can be used to verify worker compliance with your company's food safety policy. This program should address the following operation-specific practices for field and harvest workers as well as for visitors, vendors and repair/service providers.[3]
  - Workers must wash their hands before, beginning, or returning to work, after eating, smoking, using latrines, or any other activity that may cause hands to become contaminated with pathogens.

3 Based on their operation-specific risk assessments, companies may customize these best practices to their individual operations.

- If gloves are used, a procedure for proper glove use should be established, followed, and documented. Gloves should not be powdered and should be:
  - Provided by the employer.
  - Changed as necessary during the harvest day.
  - Washed and sanitized daily, if reusable.
  - Changed after any event that may cause gloves to become contaminated.
  - Gloves should not be permitted to be worn when using the latrine, eating, or handling unsafe or non-food grade materials.
- If fresh culinary herbs are handled with bare hands, hand washing procedures must be documented.
- Workers should wear in appropriate, clean protective outer garments when beginning work each day. Heavily soiled and / or damaged protective outer garments should be replaced.
- Workers should not leave hand-held harvesting tools and protective outer garments on top of harvesting equipment or on the ground.
- Workers should not take any tools or protective outer garments inside the toilet facilities.
- The storage of personal items away from areas where they may come in contact with fresh culinary herbs or herb-contact areas. Instructions should be posted regarding this practice.
- Smoking, eating, and drinking of beverages other than water should be restricted to designated areas equipped with covered trash receptacles.
- Prohibitions on spitting, urinating, or defecating in the field.
- Children should not have access to fresh culinary herb fields as they are often asymptomatic carriers of foodborne diseases such as hepatitis A .

6.3 The Best Practices Are: Physical Hazard Prevention

An area should be designated for storage of all hand-held harvesting tools and protective outer garments, during breaks or when using toilet facilities. This area should be kept clean and should be located away from the harvest operation and the toilet facilities. Appropriate washing and / or sanitizing solutions should be available at these stations.[29]

A written physical hazard prevention program should be developed for fresh culinary herb production and harvest activities. The program should address the following:[29]

- Appropriate clothing, hair restraints, protective outer garments, gloves, visible jewelry, etc.
- Removal of all objects from upper pockets.
- Foreign objects in the field – glass, hard plastics, or metal containers, or other objects should not be brought into the field or areas bordering the field.

6.4 The Best Practices Are: Health

- Establish a health practices program (i.e., an SOP) that addresses the following issues:
  - Persons who present symptoms of diarrheal disease or other infectious disease (e.g., vomiting, diarrhea, jaundice, sore throat with a fever) are prohibited from handling fresh culinary herbs or being within the harvest fields or crews prior to or during harvesting.
  - Workers with open cuts or lesions are prohibited from handling fresh culinary herbs without specific measures to prevent cross-contamination of product.

- Training for supervisors on recognizing symptoms of diarrheal and infectious diseases and appropriate actions to take in the event of worker injury or illness.
- A policy describing procedures for handling / disposing of fresh culinary herbs or food contact surfaces that have come into contact with blood or other bodily fluids.
- First aid kits should be readily available and maintained in accordance with prevailing regulation with materials kept in sanitary and usable condition.

6.5 The Best Practices Are: Toilet Facilities and Hand Washing Stations

- A field sanitary facility program (i.e., an SOP) should be implemented to address the following issues:
  - A response plan for leaks or spills.
  - The number, condition, and placement of field sanitation units and accessibility to the work area
    - The location of worker hygiene facilities should maximize accessibility and use while minimizing the potential for the facility to serve as a source of contamination.
    - Toilet facilities should be placed such that the location minimizes the impact from potential leaks and / or spills while allowing access for cleaning and service.
    - Under OSHA regulations, sanitary facilities are required to be within a ¼ mile walk of each laborer's position in the field with at least one toilet facility and one hand washing facility provided for each 20 workers or a fraction thereof.[4]
    - The location and sanitary design of toilets and hand washing stations should be optimized to facilitate the control, reduction and elimination of human pathogens from hands.
    - Hand washing stations must be supplied with potable running water (e.g., meets local, state, or US EPA microbial standards for drinking water).
  - Facility supplies
    - Toilet facilities should be stocked with toilet paper.
    - Hand washing stations should have hand soap, water, paper towels, and covered towel disposal container.
  - Facility signage
    - Signage requiring hand washing after use of toilet facilities should be visible and posted in applicable languages and/or pictures.
  - Facility maintenance, cleaning and servicing
    - Establish the frequency and specific protocols of toilet and hand washing facility maintenance / sanitation.
    - Establish equipment and supply storage and control procedures when not in use.
    - Remove trash receptacles from the harvest area at the end of the work shift. Instructions should be provided on where to empty them and how to clean them.
    - All portable units should have a tank that captures used hand wash water. Develop an SOP for the appropriate disposal of the waste water.
    - Maintain documentation of maintenance and sanitation schedules and any corrective practices for a period of 2 years.

4 OSHA. 1987. Field Sanitation – 1928-110. http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10959

Documentation List:

- ☐ Attendance log for worker training sessions
- ☐ SOP – Worker practices
- ☐ SOP – Physical hazard prevention
- ☐ SOP – Health program practices
- ☐ SOP – Field sanitary facility
- ☐ SSOP – Field sanitary facility

7.0 Issue: Equipment Facilitated Cross-Contamination

When farm equipment has had direct contact with raw untreated manure, untreated compost, waters of unknown quality, crop damaged from animals, fecal contamination, and animal carcasses, or other potential human pathogen reservoirs it may be a source of cross-contamination. Such equipment should not be used in proximity to or in areas where it may contact edible portions of fresh culinary herbs without proper cleaning and sanitation.

7.1 The Best Practices Are:

- Identify any field operations that may pose a risk for cross-contamination. These include vehicles and farm equipment utilized in the fields, vehicles used to transport workers, as well as many other possibilities.
- Segregate equipment used in high-risk operations or potentially exposed to high levels of contamination (e.g., actively manipulating compost, animal-related operations).
- If equipment was previously used in a high-risk operation, use effective means of equipment cleaning and sanitation before subsequent use in fresh culinary herb production.
- Develop appropriate means of reducing and controlling the possible transfer of human pathogens to soil and water that may directly contact fresh culinary herbs through use of designated equipment.
- Maintain appropriate records related to equipment cleaning and possible cross-contamination issues for a period of 2 years.

Documentation List:

- ☐ SSOP – Equipment for high-risk operations
- ☐ Cross-contamination event log

When farm equipment has had direct contact with raw untreated manure, untreated compost, waters of unknown quality, crop damaged from animals, fecal contamination, and animal carcasses, or other potential human pathogen reservoirs it may be a source of cross-contamination.

If flood waters contain microorganisms of significant public health concern and/or other contaminants, fresh culinary herbs, which are in close proximity to soil, may be contaminated if there is direct contact between flood water or contaminated soil and the fresh culinary herb plants

8.0 Issue: **Flooding**

For purposes of this document, flooding is defined as the flowing or overflowing of a field with water outside of a grower's control that is reasonably likely to contain microorganisms of significant public health concern and/or other contaminants and is reasonably likely to cause adulteration of fresh culinary herbs in that field. Pooled water (e.g., rainfall, irrigation leaks) that is not reasonably likely to cause contamination of the edible portions of fresh culinary herbs should not be considered flooding. However, persistent pooled water (i.e., persisting for several days) may also present potential risk of contamination and is addressed in 1.0 Issue: Environmental Assessments.

If flood waters contain microorganisms of significant public health concern and/or other contaminants, fresh culinary herbs, which are in close proximity to soil, may be contaminated if there is direct contact between flood water or contaminated soil and the fresh culinary herb plants (Casteel et al. 2006; Wachtel et al. 2002a; 2002b). Areas that have been flooded can be separated into three groups: 1) fresh culinary herbs that have come into contact with flood water, 2) fresh culinary herbs that are in proximity to a flooded field but have not been contacted by flood water, and 3) production ground that was partially or completely flooded in the past before fresh culinary herbs were planted. The considerations for each situation are described below and presented in Table II-6.

8.1 The Best Practices: General Items[5]

- Prevent cross-contamination between flooded and non-flooded areas:
  - If personnel enter a field that was flooded, they should wear protective clothing such as rubber boots and rubber gloves. Discard or thoroughly clean and disinfect this clothing after use.
  - During production and harvest of non-flooded areas in close proximity to flooded areas, prohibit contact of production or harvesting equipment with the flooded area (also see section 7.0 Issue: Equipment Facilitated Cross-Contamination).
  - Observe appropriate turn-around buffer zones when using vehicles and equipment in close proximity to flooded areas. Create a buffer zone by placing markers that identify both the high-water line of the flooding and an interval of 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. Do not harvest fresh culinary herbs within any established buffer zones.

5 FDA. 2011. Guidance for Industry: Evaluating the safety of flood-affected food crops for human consumption. http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm274683.htm

- Clean and sanitize any equipment that had contact with flooded areas or crops before subsequent use.

- If a well head is under flood water, complete a sanitary survey including water quality testing to ensure the integrity of the well before using.
- Document all flooding events and activities related to mitigating flooding events (i.e. take photographs of the area and activities).

8.2 The Best Practices for Fresh Culinary Herbs That Have Come into Contact with Flood Waters Are:

- FDA considers any crop that has come into contact with floodwater to be an "adulterated" commodity that cannot be sold for human consumption.[6], [7]
- See Table II-6 for criteria for fresh culinary herb production fields that have possibly come into contact with flood waters. The Appendix B describes in more detail the process used to develop these metrics.
- Fresh culinary herbs that are adulterated by flood waters should be disposed of in a manner to ensure that they do not contaminate unaffected crops during harvesting, storage or distribution.

8.3 The Best Practices for Fresh Culinary Herbs in Proximity to a Flooded Area but Where Edible Portions Have Not Been Contacted by Flood Waters Are:

- Evaluate whether fresh culinary herbs in a field under these conditions should be harvested. Factors to consider include: [32]
  - The source of flood waters and potential upstream contributors of human pathogens and/or chemical contaminants.
  - Type of crop and stage of growth of the edible portion of the crop including how far above the ground the lowest edible portion of the crop grows.
  - Conditions such that the crop may have been exposed to prolonged periods of moisture and stress that could foster fungal and pathogen growth, and possible development of mycotoxins.
- For flood-affected fresh culinary herbs for which the growers have not yet determined whether they have been contaminated (i.e., the edible portion of crops are not exposed to flood waters), clearly identify and sufficiently segregate these herbs to prevent them from contaminating non-flood-affected crops and from entering the food supply inadvertently, pending determination of their disposition.

8.4 The Best Practices For Formerly Flooded Production Ground Are:

- Prior to replanting or soil testing, the designated food safety professional for the grower should perform a detailed food safety assessment of the production field for potential hazards (see Appendix E for an example a pre-planting food safety assessment of formerly flooded production ground). 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 (drainage canal, river, irrigation canal, elevated water table, etc.)

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6 FDA. 2009. A Notice from the Food and Drug Administration to Growers, Food Manufacturers, Food Warehouse Managers, and Transporters of Food Products About the Safety of Food Affected by Hurricanes, Flooding, and Power Outages. http://www.fda.gov/Food/FoodDefense/Emergencies/FloodsHurricanesPowerOutages/ucm112723.htm

7 FDA. 2009. Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens; Draft Guidance.

for potential significant upstream or subsurface contributors of other contaminants and/or human pathogens at levels that pose a significant threat to human health.

- 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 (e.g. fecal coliforms) have occurred within this time interval. Comparative soil samples may be between a baseline (e.g. soil not affected by floodwaters) and post-flooding samples for a given field or between a flooded field and a nearby field that is managed similarly to the flooded field but unaffected by floodwaters.
- Do not plant fresh culinary herbs in formerly flooded production ground for at least 60 days following the receding of floodwaters (unless the ground meets the 30-day testing requirement detailed in the next bullet and Table II-6). In addition to a waiting period before planting, actively tilling the soil provides additional protection against the survival of pathogenic organisms.
- If flooding has occurred on the property, soil testing may be conducted prior to planting fresh culinary herbs. Soil testing may be used to shorten the waiting period to 30 days. If performed, testing should be negative for Enterohemorrhagic *E. coli* (EHEC) or Shiga toxin-producing *E. coli* (STEC) and *Salmonella* as outlined in Table II-6. Representative samples should be collected for the entire area suspected to have been exposed to flooding. See Appendix D for a microbial soil sampling protocol.
- Allow soils to dry sufficiently prior to planting subsequent fresh culinary herbs on formerly flooded production ground.
- Formerly flooded production ground should not lie stagnant. Rework the soil (e.g. aerating, tilling, disking) which helps to reduce the survival of pathogenic organisms.

Documentation List:

- ☐ Flooding event – date of flooding and date when equipment are able to enter field, high water mark, photographs, etc.
- ☐ A pre-planting food safety assessment of formerly flooded ground
- ☐ Soil sampling test results

Table II-6. Flooding

For use when evidence of flooding in a fresh culinary herb production block occurs.

Practice	Metric / Rationale
Flooding Defined	The flowing or overflowing of a field with water outside a grower's control that is reasonably likely to contain microorganisms of significant public health concern and is reasonably likely to cause adulteration of fresh culinary herbs 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 fresh culinary herbs within 30 ft. of the flooding. • 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 should 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 (See Appendix E for an example food safety assessment).
Verification	• Documentation should be archived for a period of 2 years following the flooding event. Documentation may include photographs, sketched maps, or other means of delineating affected portions of fresh culinary herb fields.
Time Interval Before Planting Can Commence Following the Receding of Floodwaters	• Planting can commence 60 days after the flood waters have receded to the point where water is not visible in the areas that are to be planted and the soil should be at a moisture level at which the grower can get equipment into the field for preparation.[1] • Appropriate soil testing can be used to shorten this period to 30 days prior to planting. This testing should be performed in a manner that accurately represents the production field and indicates soil levels of microorganisms lower than the acceptance criteria listed below. 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, see the example soil sampling protocol in Appendix D and consult the "Soil Screening Guidance: Technical Background Document," specifically Part 4 that provides guidance for site investigations (US EPA 1996). 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.

1 Soil moisture test results can also be used to demonstrate moisture levels. Methods typically used by growers to determine soil moisture content include, but are not limited to, tensiometers, electric resistance blocks, oven drying analysis, or other methods that are measurable and repeatable. The grower should have historical information available regarding typical moisture content of the soil so there is comparison data available if it is needed.

Practice	Metric / Rationale
Soil Testing Criteria and Test Methods	**Target Organisms:** • *Salmonella* spp. • Enterohaemorrhagic *E. coli* (EHEC) or Shiga toxin-producing *E. coli* (STEC) **Acceptance Criteria:** • *Salmonella* spp.: Negative or < DL (<1/ 30 grams) • Enterohaemorrhagic *E. coli* (EHEC) or Shiga toxin-producing *E. coli* (STEC): Negative or < DL (<1/ 30 grams) **Preferred Test Methods**: • *Salmonella* spp.: U.S. EPA Method 1682 • Enterohaemorrhagic *E. coli* (EHEC) or Shiga toxin-producing *E. coli* (STEC): Any laboratory validated method for soil sampling. • Other U.S. EPA, FDA, or AOAC-accredited methods may be used as appropriate.
Rationale	The basis for the 30 foot distance is the turn-around distance for production equipment to prevent cross-contamination of non-flooded ground or crops in the fields.

9.0 Issue: Field Packing Operations

Sometimes fresh culinary herbs are packed directly in the field after harvest. Field packing includes any practice that involves grading, sorting, cleaning, bunching or packing of herbs into containers for commerce while in the field. Product-contact containers and tools may be a source of microbiological, chemical or physical contamination if they are not handled and stored in a sanitary manner.

9.1 The Best Practices Are:

- Establish a written procedure for personal hygiene in field packing operations that incorporates the guidelines in Issue 6.0 Field and Harvest Personnel.
- Exclude damaged or decayed fresh culinary herbs.
- Discard foreign objects and debris in an appropriate location.
- Remove soil from product prior to packing.
- Field packing containers:
  - If stored in the field, protect them from potential contamination.
  - Distinguish field packing containers from containers serving other purposes.
  - Prohibit the re-use of single-use containers (e.g. corrugated boxes) for the field packing of herbs.
  - Properly label field packing containers with information for traceability.
- Any surface that touches harvested fresh herbs should be considered a food contact surface and should be treated in a manner so as to not be a source of contamination.
- Packing materials:
  - Inspect packing material upon arrival.
  - Store packing materials so it does not pose a risk of contamination.

Documentation List:

- ☐ SOP – Personal hygienic practices
- ☐ SOP – Packing materials handling and storage

Water used in harvest operations may be a source of contamination if water containing human pathogens has direct contact with fresh culinary herbs.

10.0 Issue: **Water Usage to Prevent Fresh Culinary Herb Dehydration**

Fresh culinary herbs may be sprayed with small amounts of water during harvest or in the field container just after harvest to reduce water loss. Water used in harvest operations may be a source of contamination if water containing human pathogens has direct contact with fresh culinary herbs.

10.1 The Best Practices Are:

- Due to the timing of application of water that directly contacts fresh culinary herbs, assure the water is of appropriate microbial quality (i.e., meets the US EPA's microbial standards for drinking water).
- Test the water source to demonstrate that it meets the post-harvest water acceptance criteria or that it has appropriate disinfection potential as described in Table II-2 "Water Use" under Post-Harvest – Direct Product Contact or Food Contact Surfaces.

SECTION III:

Post-Harvest Unit Operations

SECTION III

Fresh culinary herb food safety programs should focus on preventing adulteration by microbial contamination because these herbs are often eaten raw and without a "kill step" to reduce or eliminate human pathogen levels.

1.0 Issue: GAPs and cGMPs for Packinghouse and Cooling Facilities

Raw agricultural commodities are defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act (FFDCA) as "any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing." This section covers fresh culinary herbs, which are not considered to be ready-to-eat (RTE) because 1) their natural form is not altered, 2) they do not enter a processing facility, and 3) they require washing before being consumed.

While operations engaged solely in the harvesting, storage, or distribution of fresh culinary herbs as a raw agricultural commodity are not subject to cGMPs, operations that alter the form of fresh culinary herbs by cutting or chopping are considered processors or manufacturers and are subject to follow cGMPs. Raw agricultural commodities as defined by the FFDCA are regulated by the FDA under the adulteration provision of the FFDCA (Section 402). Therefore, while packinghouses and cooling facilities that handle fresh culinary herbs as a raw agricultural commodity may not be subject to cGMPs under Code of Federal Regulations Title 21, Part 110 (21 CFR 110), cGMPs serve as a useful tool in assessing whether raw agricultural products are handled under conditions that may adulterate the food.

Fresh culinary herb food safety programs should focus on preventing adulteration by microbial contamination because these herbs are often eaten raw and without a "kill step" to reduce or eliminate human pathogen levels. For that reason, as a general practice these products should be handled according to the FDA's "Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables" ("Fresh-cut Guide") and packinghouse facilities operate under cGMPs as an extra precautionary measure. This set of best practices is primarily based on cGMPs put forward in 21 CFR 110 and the FDA's "Fresh-cut Guide."

2.0 Issue: Transportation to Packinghouses and Cooling Facilities

Conditions of transport from the field to cooler and packinghouse may provide opportunities for microbial contamination. Fresh culinary herbs may be transported to the packinghouse / cooling facilities by numerous modes of transportation. Transportation of fresh culinary herbs should be managed to reduce, control, or eliminate the risk of contamination.

2.1 The Best Practices Are:

- Prepare an SOP for loading and unloading procedures that addresses the following:
  - Inspection / evaluation management programs for field transport vehicles / trailers to verify that food safety needs are being met. Items that may be evaluated include (but

are not limited to) the vehicle / trailer condition, overall cleanliness, good structural condition, etc.

- Procedures to assure that prior loads hauled by transport equipment do not potentially contaminate fresh culinary herbs during transport from the field to the packinghouse or cooling facility.

- Perform periodic maintenance and inspections on transport vehicles (e.g., inspect for any evidence of fluid leaks). Document findings and actions taken to fix the problem. Do not use equipment that is actively leaking fluids in transporting fresh culinary herbs.
- Prepare an SSOP for transport vehicles and equipment that addresses the following:
  - Use of a written sanitation procedure for cleaning transport vehicles that includes frequency and method of cleaning.
  - Use of a routine sanitation schedule that outlines the frequency of sanitation procedures for vehicles transporting fresh culinary herbs to the packinghouse or cooling facility.
  - Maintain truck beds (an indirect food contact surface) in clean condition.
  - If harvested herbs are covered during transport, materials used to cover herbs should be in good condition with established procedures for cleaning and sanitizing them.
- Follow the Best Practices under the SSOP for product containers in Section 5.0 to avoid cross contamination during transportation activities.

Documentation List:

- ☐ SOP – Transport trailer inspection
- ☐ SSOP – Transport vehicles and equipment

3.0 Issue: **Receiving**

When fresh culinary herbs are received at the packinghouse there are important items to consider regarding time intervals between harvest and cooling and the transfer of information. Because some microbes multiply rapidly under warm, moist conditions, the time from harvest to cooling should be minimized. Keep track of the product (traceability) as it is received – during inspections and handling. During receiving it is critical that all essential field information is appropriately maintained and transferred to packinghouse operations for recordkeeping.

During receiving it is critical that all essential field information is appropriately maintained and transferred to packinghouse operations for recordkeeping.

3.1 The Best Practices Are:

- Obtain fresh culinary herbs from suppliers that follow GAPs and the best practices in this guidance.
- Establish a procedure for inspecting and accepting or rejecting incoming loads of fresh culinary herbs.
- Establish procedures to ensure fresh culinary herbs are held and stored in designated areas and handled under proper conditions.
- When fresh culinary herbs first arrive at the packinghouse, they should be cooled to remove the field heat. Warm product put immediately into cold storage without cooling may result in condensation formation that may enable microbial growth.
- Ensure that incoming documentation provides sufficient information to facilitate product traceability and establish a system to maintain that documentation.

Documentation List:

- ☐ SOP – Product inspection
- ☐ SOP – Product holding/storage
- ☐ Product tracing paperwork

4.0 Issue: Water Used in Packinghouse and Cooling Operations

Packinghouses use a variety of practices in handling fresh culinary herbs. Fresh culinary herbs may or may not be washed and/or cooled before packing. When used appropriately with water of adequate quality, disinfectants help minimize survival and growth of microorganisms in the wash water and the subsequent cross contamination of the product. For a list of chemicals that may be safely used to wash fruits and vegetables, see 21 CFR 173.315.[1]

The effectiveness of a disinfectant and the amount that should be used depends on the type of product and the treatment conditions, such as water temperature, acidity (pH), water hardness, contact time, amount and rate of product throughput, water to product ratio, amount of organic material, and the resistance of pathogens to the particular disinfectant. If fresh culinary herbs are washed before being packed, packers should consider options for disinfectants and wash systems that are most appropriate for their operation and verify the washing process by documenting the levels of sanitizers, water changes, pH control, exposure time, and mass-to-volume ratios in their wash water.

Ice and / or ice slurries may also be used to cool fresh culinary herbs thus providing another possible contamination source if ice is not handled appropriately or if contaminated water is used to make the ice. Ice used on fresh culinary herbs should be included in routine water quality testing as described in the Best Practices below.

If pathogens are present in the wash water, they may contaminate the produce, and subsequent washing will not reduce levels of these pathogens. Therefore, water used for washing or cooling fresh culinary herbs should contain sufficient levels of disinfectant to reduce the potential for pathogens to persist in such water. Such practices may include using antimicrobial chemicals in the wash water or using spray type wash treatments instead of submerging. Alternatively, fresh herbs may be cooled by means other than hydrocooling.

1 FDA. 2009. CFR – Code of Federal Regulations Title 21. http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=173.315&SearchTerm=chemicals

4.1 The Best Practices Are: Water Quality

Assuring the microbial quality of water used in cooling and packinghouse operations is critical as water provides a means for spreading contamination to and among product. Evaluate all washing or cooling operations (including ice) where water directly contacts fresh culinary herbs. Water used in post-harvest operations may contaminate fresh culinary herbs if there is direct contact of water containing pathogenic microorganisms with fresh culinary herbs. To ensure better microbial quality, water used in washing and cooling operations should come from wells or municipal sources.

Sanitation of equipment used in washing and cooling operations is critical. If not properly maintained, washing and cooling equipment may acquire a build-up of soil, organic materials and microbial loads that could serve as a source of contamination. In addition, because the structure of some fresh culinary herbs is a hollow leaf tube, special care should be taken if dump tanks or immersion washes are used to minimize microbial contamination.

- The source of water used in cooling and packinghouse operations that directly contacts fresh culinary herbs must meet US EPA microbial standards for drinking water.
  - The water source should be tested as specified in Table III-1. If a municipal water source is used, microbial water quality information from the respective municipal water authority may be obtained and archived if it is reported as total coliforms. Facilities using municipal water should periodically test water at the point of use to verify the integrity of the facility water distribution system.
  - Develop an action plan in case municipal water authorities issue a water quality alert or warning such as "boil water warning." Document and archive any warning or alerts issued by the water authority as well as corrective actions taken by your firm to address this issue.
- If fresh culinary herbs are washed before being packed, operators should verify the washing process by documenting wash water system parameters (e.g., the levels of sanitizers, water changes, pH control, exposure time, and mass-to-volume ratios) that are effective in controlling microbial levels in their system.
- Water used on fresh herbs or food contact surfaces in the packinghouse must have sufficient levels of disinfectant so as not to result in adulteration of the product by cross-contamination as specified in Table III-1.[2]
- If water disinfectants are used, levels should be monitored and

Assuring the microbial quality of water used in cooling and packinghouse operations is critical as water provides a means for spreading contamination to and among product.

2 Water quality criteria are primarily based on recreational water use criteria established by US EPA. The use of this type of information is necessitated by science that is not clear on appropriate agricultural water standards. For further information, please see Appendix B, which provides the technical basis for these guidelines.

maintained throughout the process by testing the water disinfectant concentration and pH or ORP (oxidation reduction potential). Active disinfectant levels should be measured and documented (i.e., free chlorine and not total chlorine). Continuous monitoring of disinfectant levels is preferred.

- Follow manufacturer's directions for mixing of disinfectant chemicals to obtain effective concentrations; a manufacturer's suggested or allowable level in washing and cooling water should not be exceeded.
- All disinfectant measurement devices should be calibrated daily. Disinfectant measurements and equipment calibrations should be documented.
- The person monitoring the water disinfectant levels should know when to add disinfectant based on values obtained.
- Any other substance (e.g., processing aids or organic acids for pH control) used to treat the wash water should be approved by the US EPA or FDA for use in the manner that it is applied and monitored to verify correct concentration. Monitoring activities should be documented.
- To ensure efficient operation, routinely inspect and maintain facility water distribution system and equipment designed to assist in maintaining water quality such as chlorine injectors, filtration systems, and backflow devices. Inspections and maintenance should be documented.
- All monitoring equipment should be adequately maintained and periodically calibrated. Maintain a log of maintenance and calibration events.
- Water holding tanks used at the facility should be kept clean and sanitary. All cleaning and sanitation verification activities should be documented. For more on the care of finished water storage tanks see the Sanitary Survey in Appendix A.

4.2 The Best Practices Are: Recirculated Water

Water in packinghouse or cooling operations may be recirculated. Water quality is especially important at the end of the process when sequential washing is used. If recirculated water is used with fresh culinary herbs, then this water should meet drinking water quality standards and disinfectant levels outlined in Table III-1 throughout all processes.

- When washing or cooling fresh culinary herbs in recirculated water, disinfectant should be present at sufficient levels and the levels monitored to reduce the potential risk of cross contamination (see Table III-1). All monitoring activities should be documented.
- When washing or cooling fresh culinary herbs in recirculated water, procedures must be established to determine when and how often water should be refreshed or completely changed out.
- Water disinfectants levels must be monitored and maintained throughout the process by testing the water disinfectant concentration and pH or ORP (oxidation reduction potential) as follows:
  - Any disinfectants used must be used according to the manufacturer's specifications.
  - When disinfectants are used in a recirculation system, active disinfectant levels (i.e., free chlorine and not total chlorine) and pH or ORP (oxidation reduction potential) should be measured and documented.
  - Continuous monitoring of disinfectant levels is preferred.
  - All disinfectant measurement devices should be calibrated daily. Disinfectant measurements and equipment calibrations should be documented.
  - The person monitoring the water disinfectant levels should know when to add disinfectant based on values obtained.
  - Any other substance (e.g., organic acids for pH control) used to treat the wash water must be monitored to verify correct concentration. These checks should be documented.

- Establish an SOP that outlines corrective actions if system is not operating within the limits and document them.
- All monitoring equipment should be adequately maintained and periodically calibrated. Maintain a log of maintenance and calibration events.

- Filtering devices should be used to minimize the buildup of organic material in recirculated wash water. Filters should be back-flushed and sanitized as part of the master sanitation schedule for packing equipment.
- Appropriate measures should be taken for waste water disposal.
- Any water additive used to wash fresh culinary herbs should be food-grade and compliant with federal, state or local regulations for the intended use. Copies of MSDS for water additives should be maintained on file.

4.3 The Best Practices Are: Ice and Ice Slurry

Fresh culinary herbs may be "iced" or slurry iced to cool product or as a means of keeping the product cold during distribution. Whether ice is manufactured on-site or purchased from outside vendor, it should be handled, stored, and transported in a sanitary manner.

- Water used to make ice that directly contacts product and is used in cooling and packinghouse operations must meet US EPA microbial standards for drinking water.
- The water source used to make ice and ice slurry should be tested periodically at a frequency sufficient to assure that it is of appropriate microbial quality for its intended use (see Table III-1 on Post-Harvest Water Use).
  - Ice used on product should contain an approved water disinfectant at sufficient concentration to reduce the potential for cross contamination.
- Ice must be handled like a food ingredient. Establish an SOP for transporting, handling, and storing ice so that it does not become contaminated. The SOP should address the following:
  - Use of a sanitary underlay when placing unpackaged, block ice on any surface.
  - Clean and sanitize all equipment that holds or transports ice daily.

  - Drip pans should be used to collect condensation under augers and conveyors on ice-conveying systems; drip pans should be emptied directly into the facility drainage system and not onto floor.
  - Ice should not be stored in close proximity to raw product or chemical storage.
  - If ice is manufactured and delivered by an outside vendor, ensure the vendor follows your company's SOP for handling, storing, and transporting ice.
- If iced product is placed in storage racks above pallets of other product, plastic pallet shrouds should be used to protect product beneath from potential cross contamination.

Documentation List:

- ☐ Source water test schedule and results
- ☐ SOP – Chemicals added to wash water
- ☐ SOP – Water disinfectant monitoring
- ☐ Water monitoring equipment calibration logs
- ☐ MSDS for water disinfectant chemicals
- ☐ SOP – Ice transporting, handling, and storage

Table III-1. Post-Harvest Water Use

Use	Metric	Rationale / Corrective Actions
Direct Product Contact or Food Contact Surfaces	**<u>Microbial Testing</u>** **Target Organism:** Total coliforms **Sampling Procedure:** 1 L sample collected aseptically at the point of use **Sampling Frequency:** One sample per water source should be collected and tested prior to use if >60 days since last test of the water source. Additional samples should be collected at intervals of no less than 18 hours and at least monthly during use. **Municipal & Well Exemption:** For wells and municipal water sources, if total coliform levels are below detection limits for five consecutive samples, the sampling frequency may be decreased to once every six months and the 60 and 30 day sampling are waived. This exemption is void if there is a significant source or distribution system change. **Test Method:** FDA BAM method or any US EPA-approved or AOAC-validated method for quantitative monitoring of water for total coliforms.	For any given water source (e.g. municipal, well), samples for microbial testing should be taken as close to the point of use as practical (as determined by the sampler to ensure the integrity of the sample) using sampling methods as prescribed in this table where the water contacts fresh culinary herbs, so as to test both the water source and the water distribution system. There is only one sample per month per distribution system under these metrics. If there are multiple potential point-of-use sampling points in a distribution system, then samples should be taken from different point-of-use locations each subsequent month (randomize or rotate sample locations). Water that directly contacts harvested fresh culinary herbs or is used on food contact surfaces such as equipment or utensils, should come from a source that meets the Maximum Contaminant Level Goal of zero or no detection for total coliforms in drinking water as specified by US EPA and once in use, contain an approved disinfectant at sufficient concentration to prevent cross-contamination.[1] Microbial and physical / chemical testing should be performed, as appropriate to the specific operation, to demonstrate that the disinfectants and corresponding concentrations used are sufficient for the wash system and that acceptance criteria for total coliforms have been met. Always follow your contracting laboratory's protocol for the collection of water samples. **Single Pass and Recirculated Water Systems** • Single pass use – Source water should have non-detectable levels of total coliform and sufficient disinfectant to ensure water has no detectable total coliform (e.g., a minimum of 10 ppm chlorine). • Recirculated use – Source water should have non-detectable levels of total coliform. Water used to wash product should have sufficient disinfectant to ensure returned water has no detectable total coliform (e.g., a minimum of 10 ppm chlorine). * Single pass and recirculated water treated with chlorine-based disinfectants should be tested for free chlorine concentration (ppm) and pH OR for oxidation reduction potential (mV). The selected method should be verified periodically with the alternative process verification method AND by ensuring that established microbial acceptance criterion for water is being met.

Use	Metric	Rationale / Corrective Actions
	Acceptance Criteria: **Negative or Below DL for All Samples** **<u>Physical / Chemical Testing</u>** **Target Variable:** Water disinfectant (e.g. chlorine or other disinfectant compound) **Acceptance Criteria for Disinfectants:** • US EPA-**approved treatments** per product label for human pathogen reduction in water and used in accordance with a wash water system-specific protocol that has been validated to show that active disinfectant is present throughout the wash process. • **Chlorine-based disinfectants** ≥10 ppm free chlorine after application and pH 6.5 – 7.0 • ORP ≥ 725 mV* **Testing Procedure:** • Chemical reaction based colorimetric test, or • Ion specific probe, or • ORP,* or • Other as recommended by disinfectant supplier. **Testing Frequency:** Continuous monitoring (preferred) with periodic verification by titration OR routine monitoring if the system can be shown to have a low degree of variation.	**Corrective Actions**: If any one sample exceeds the acceptance criteria for total coliforms, then the water should not be used for this purpose unless appropriate disinfectants have been added or until corrective actions have been completed and total coliform levels are within acceptance criteria: • Conduct a Sanitary Survey of the water source and distribution system to determine if a contamination source is evident and can be eliminated. Eliminate identified contamination source(s) if applicable. • For wells, perform a Sanitary Survey and / or treat as described in the Sanitary Survey (Appendix A). • Retest the water at the same sampling point after conducting the Sanitary Survey and / or taking corrective actions to determine if it meets the outlined microbial acceptance criteria for this use. For example, if a water sample for water used to clean food contact surfaces has detectable total coliforms, STOP using that water system, examine the distribution line, source the inlet as described in the Sanitary Survey (Appendix A), and retest from the same point of use. Continue testing daily for five days at the point closest to use, and do not use the water system until it consistently delivers water that is safe, sanitary, and meets the acceptance criteria outlined in this table. If any of the five samples taken during the intensive sampling period after corrective actions have detectable total coliforms, repeat corrective actions and DO NOT use that water system until the source of contamination can be corrected. **Records**: All test results and corrective actions should be documented and available for verification from the user of the water for a period of 2 years.

5.0 Issue: Post-Harvest Product Containers, Packaging Materials, Finished Product Containers and Pallets

Fresh culinary herbs are generally harvested into containers and may be field-packed before being transported to a customer or harvested in bulk before being transported to a packinghouse for further trimming, washing, sorting, and packing. At the packinghouse fresh culinary herbs may be packed for shipping in bulk or packaged in market-ready packaging. Post-harvest product containers, packaging materials, finished product containers, and pallets may be a source of microbial contamination if they are not handled and stored in a sanitary manner. In addition, the reuse of containers and pallets that previously may have been used for other products provides the potential for cross-contamination if they have not been transported and stored in a sanitary manner. Finally, pallets used to transport empty containers, packing materials, and finished product should be kept clean and in good condition.

Post-harvest product containers, packaging materials, finished product containers, and pallets may be a source of microbial contamination if they are not handled and stored in a sanitary manner.

5.1 The Best Practices Are: Post-Harvest Product Containers

- Post-Harvest product containers should be distinguishable from field containers (e.g., by color, design, or label). Field containers should be used, maintained, and inventoried separately from post-harvest product containers.
- Wood containers should not be used due to potential for contamination and the inability for cleaning and sanitizing.
- Develop SSOPs for cleaning and sanitizing reused post-harvest product containers. Topics addressed should include (but are not limited to):
  - Cleaning frequency, sanitizer type and concentration, and specific cleaning procedure.
  - Documentation should include the concentration of sanitizer used, date and time of cleaning, and the initials of the employee performing the task.

5.2 The Best Practices Are: Finished Product Containers, Packaging Materials and Pallets

- Establish an SOP for inspecting all incoming finished product packing materials and shipping containers to ensure that they are in sanitary condition and suitable for use. The inspection procedure should also include an inspection of vehicles that transport these containers to ensure no foreign material, pests, or pest contamination exists.
- Store finished product containers in a designated area on clean pallets in a controlled area with coverings to protect them from potential contamination and prevent the intrusion of foreign material including wind-blown dust and debris.
- Include finished product container storage areas in the

company's pest control program.

- The finished product containers' storage area should be maintained with an 18-inch perimeter to facilitate inspection, cleaning, and placement of pest control devices.
- Any finished product containers that are identified as potentially contaminated and not suitable for use in storing food products should be discarded.
- Establish a pallet inspection and repair program (SOP). Pallets used with post-harvest and finished product containers should be in good condition (i.e., free from loose pieces such as nails or staples) and not used for production and harvesting activities. Damaged wood pallets should not be used.

Although there may be multiple strategies for effectively dealing with individual hazards, the overall goal of an effective packinghouse and cooling facility food safety program is to minimize risk of contamination.

Documentation List:

- ☐ Container identification key
- ☐ SSOP – Product containers
- ☐ SOP – Finished product and packing materials inspection
- ☐ SOP – Pallet inspection and repair

6.0 Issue: Packinghouse and Cooling Facilities Construction, Design and Maintenance

A well designed and managed packinghouse and its corresponding food safety program can reduce the risk of microbial contamination. The needs of each packinghouse and cooling facility may vary due to location, environment, the volume of fresh culinary herbs handled, local requirements, and many other variables. Although there may be multiple strategies for effectively dealing with individual hazards, the overall goal of an effective packinghouse and cooling facility food safety program is to minimize risk of contamination.

Although a packinghouse is not considered a manufacturing or processing facility, facilities that pack and cool fresh culinary herbs should follow the requirements for buildings and grounds, packing and holding of foods, equipment and utensils, toilet facilities and controls, and sanitary operations as provided for under 21 CFR Part 110, as appropriate to the facility, especially when wet conditions are present. Packinghouse and cooling facilities that are used seasonally may be dormant for many months leaving them susceptible to pest infestations and microbial contamination. Physical design, product flow, construction materials, facility traffic, and airflow can play a role in direct contamination and cross-contamination of fresh culinary herbs. Facilities and staging areas should be designed to facilitate maintenance and good sanitation practices so that the potential for contamination may be controlled throughout receiving, cooling, packing, and storage operations.

6.1 The Best Practices Are: Facility Grounds

The grounds around the packinghouse and cooling facility should be kept in a condition that will control, reduce, or eliminate the risk of fresh culinary herb contamination. Grounds maintenance includes, but is not limited to:

- Properly store equipment, remove litter and waste, and cut weeds or grass around the buildings or structures that may constitute an attractant, breeding place, or harborage for pests.
- Maintain roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed. Roads should be paved or otherwise managed to prevent dust.
- Evaluate adjacent land use to ensure that it does not pose a significant risk of product cross-contamination.
- Adequately drain areas that may contribute contamination to food by seepage, transfer to facility via foot traffic, or providing a breeding place for pests.
- Operate systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

6.2 The Best Practices Are: Construction and Design

Packinghouse and cooling facilities and equipment should be designed, constructed and maintained to facilitate cleaning and sanitization. Buildings, fixtures, and equipment should be maintained in a sanitary condition and should be kept in repair sufficient to prevent food from becoming adulterated.

- The building structure should be maintained such that pests are excluded from gaining entrance to the facility.
- All exterior doors should have an adequate seal.
- To provide adequate drainage and prevent accumulation of water, floors should be sloped to drains, and kept in good repair.
- Floor drains should be designed to be accessible for cleaning and capable of preventing pest entry.
- Food contact surfaces should be constructed of materials that are smooth, nonabsorbent, smoothly bonded, without niches, and sealed so that they are easily cleaned and sanitized and do not serve as harborage of microbial pathogens.
- Avoid use of hollow structures such as table legs, conveyer rollers, and racks because they may collect water and debris, and thus, harbor pathogens.
- Equipment lubrication should be managed so as to not contaminate fresh culinary herbs. Food grade lubricants should be used on packing equipment where food contact may occur. Food-grade and non-food-grade lubricants are to be stored separately.
- Sufficiently elevate food contact surface above the floor to prevent contamination from floor splashes.
- Raw and finished product storage areas should be separated to reduce the potential for cross-contamination.
- All lights should be adequate for sufficient visibility and designed to prevent the potential for broken glass contamination of the product (i.e., contain shatter-proof bulbs or be sealed in a protective covering).
- Cooling systems' condensation units should drain directly into drainage systems. Emptying of this water into floor drains should be prohibited.
- Overhead equipment, structures or fixtures, catwalks, walls, pipelines, etc. should be designed to avoid the potential to be a contamination source for product and packaging (i.e., condensation formation, dirt).

- Facility water systems should be equipped with back-flow prevention devices to prevent potential contamination of the water supply.
- Waste water collection areas should be designed to prevent product and equipment contamination.
- Provide a designated area not in a food handling area for employees to store personal items.

6.3 The Best Practices Are: Toilets and Hand-Washing Stations Construction and Design

Operations with poorly designed and constructed facilities for toilets and hand-washing stations may provide direct or indirect contamination of fresh culinary herbs and water sources used on the herbs.

- The design and construction of toilet facilities and hand-washing stations including number and location should be in compliance with applicable local, state, and federal regulations.
- The number of toilets and hand-washing stations should meet OSHA requirements as outlined in 29 CFR 1910.141.[3]
- Evaluate the location of toilet facilities and hand-washing stations to maximize accessibility and use, while minimizing the potential for contamination.
- Toilets and hand-washing stations should be constructed of materials that can be easily cleaned and sanitized using cleaners and / or oxidizing agents.
- If the toilets and hand-washing stations have any openings to the outside (e.g. windows, vents), these openings should have proper screens to exclude vermin.
- Toilet facilities and hand-washing stations should be constructed with properly designed drainage systems.
- Doors to the toilet facilities:
  - Should not open directly into areas where product is located
  - Should be self-closing
  - If entry is to a single-person facility, should be lockable from the inside.
- Each individual toilet stall should have doors that are self-closing and lockable from the inside and toilet paper in a proper holder.
- Hand-washing units where employees wash their hands before returning to their work stations should be located so that hand-washing can be observed. All hand-washing units should be equipped with:
  - Potable, hot and cold running water. The quality of the water should be verified by testing to assure its microbial quality is acceptable according to local standards for potable water.
  - Soap or other suitable cleansing agents in dispensers.
  - Single-use paper towels.
  - Hands-free "on / off" switches for water (i.e., workable without using potentially soiled hands).
  - Trash containers with covers
  - Signs indicating that *the water is only for hand-washing purposes* (in appropriate languages).
  - Sealed waste water catch basins with plumbing free of leaks.

3 OSHA. Sanitation. 29 CFR 1910.141. http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9790

7.0 Issue: **Packinghouse and Cooling Facilities Sanitary Operations**

Contamination by location and / or flow of humans, product, equipment, and air can be prevented by adequate food safety controls, operating practices, and facility design. A packinghouse or cooling facility should be designed so that fresh culinary herbs arriving from the field never cross paths with, or are commingled with, finished product. Operators should be aware of and operate in accordance with all relevant laws and regulations that describe facility sanitation practices. [4, 5]

7.1 The Best Practices Are: General Items

- Each facility should have a flow diagram of the packinghouse and / or cooling operation and should perform a hazard analysis for the operation. This analysis should be documented and available for review. If the operator should change the process (e.g., updated equipment), then the analysis should be updated and revised.
- Fresh culinary herbs should not come into contact with the floor or any other non-food contact surface. Herbs that fall on the floor must be discarded.
- Floors in packing or storage areas should have proper drainage to avoid water build-up and reduce the potential for cross-contamination.
- Protect food contact surfaces from contact with non-potable water.
- Avoid practices that cause condensation to form in the facility. Condensation provides conditions optimal for microbial growth and may potentially serve as a source of cross-contamination. If condensation forms in any part of the facility, it should be cleaned and the area sanitized.
- Appropriate measures should be taken for waste water disposal.
- Garbage should be placed in appropriate receptacles with serviceable lids and removed from the facility on a regularly scheduled basis.
- Receptacles should be clearly designated for their intended use (e.g., trash, recyclable materials or product that might be re-worked). Employees should be trained to recognize and use material receptacles appropriately.
- All packinghouse or cooling facility tools should be clearly designated to denote those tools that are only used for food

Contamination by location and / or flow of humans, product, equipment, and air can be prevented by adequate food safety controls, operating practices, and facility design.

4 OSHA. Sanitation 1910.141 http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9790

5 Code of Federal Regulations, Title 21, Part 110 – Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=fe4d3406434fbb5824f74776dadefb66&rgn=div5&view=text&node=21:2.0.1.1.10&idno=21

contact and those that are used for general cleaning and may contact non-food contact surfaces.

- Old, unused equipment should be removed from the packing and cooling areas and stored in a manner that does not present a food safety hazard.
- Appropriate signage should be displayed throughout packinghouse and cooling facility to remind employees to adhere to company policies related to food safety (e.g. use of equipment, hygiene).

7.2 The Best Practices Are: Pest Control

Packinghouse and cooling operation facilities may be dormant for many months and should be appropriately protected from pest infestations. Appropriate cleaning, sanitation, and pest removal / exclusion measures should occur before operations commence. Effective measures should be taken to exclude pests from the packinghouse and cooling areas and to protect against the contamination of food on the premises by pests.

Effective measures should be taken to exclude pests from the packinghouse and cooling areas and to protect against the contamination of food on the premises by pests.

- All pesticides, traps, bait, and chemicals used in pest control must be acceptable for use in and around a food packing facility and used in accordance with local, state, and federal regulations.
  - Permit the use of insecticides or rodenticides inside the facility only under precautions and restrictions that will protect against the contamination of fresh culinary herbs, food-contact surfaces, and food-packaging materials. Rodent bait materials are not to be used within production areas or packaging material storage areas.
  - These materials must only be used by properly trained and accredited personnel. A record of use should be kept available for inspection along with the appropriate applicators licenses and documentation. Applicators should also show records of training, continuing education, etc.
  - If rodent traps are deployed around the inside of the facility and bait stations along the outside perimeter of the facility, detailed maps demonstrating the location of each trap and bait station should be available for review. Traps and bait stations should be inspected routinely and any corrective actions (e.g., cleaning out traps, replacing damaged traps) documented.
  - Pest control chemicals and baits should be securely stored if kept on-site.
  - A procedure should be in place for the disposal of waste pest control chemicals and empty containers and for cleaning of application equipment that protects against product and production area contamination.
- Measures should be taken to protect packaging materials

from rodents or other pests. The storage area or carton yard should be kept clean and should be included in the facility pest control program. All packaging should be covered so as to mitigate contamination by rodents, birds, wind-blown dirt, or chemical sprays.

- Open windows, vents, fans, and similar features should be adequately screened to prevent pest entry.
- Doors or entrances to the facility should remain closed during operation to prevent pest entrance. Strip curtains or similar devices may be used for high traffic areas.
- An inspection buffer of 18 inches should be maintained on both the inside and outside perimeters of the physical facility (e.g., pallets, raw product and equipment may not be stored flush against the wall of the facility).
- If pest control is performed internally or by a third-party pest control company, a copy of the applicator's license, any chemicals used, MSDS, and a schedule of the applicator's activities and actions should be maintained and available for review.

Documentation List:

- ☐ Product flow diagram
- ☐ Hazard analysis for packinghouse and cooling facilities
- ☐ Trap and bait station location maps
- ☐ Trap and bait station inspection log
- ☐ MSDS for pest control chemicals
- ☐ Pest control applicator's license(s)
- ☐ Pest control chemical application/activities log

Cleaning and sanitizing of facilities and equipment should be conducted in a manner that protects against contamination of fresh culinary herbs, herb-contact surfaces, or packaging materials.

8.0 Issue: **Packinghouse and Cooling Facility Sanitation**

Sanitation programs are critical to ensuring that fresh culinary herbs exiting the packinghouse and / or cooling operations have not been contaminated with pathogens. Pathogenic microorganisms may be found on floors, in drains, and on equipment surfaces and components. Operators should be aware of and operate in accordance with all relevant laws and regulations that describe facility sanitation practices including the handling of processing and sanitation chemicals such as the posting of MSDS.

When fresh culinary herbs arrive at the packinghouse, they are routinely cooled to remove field heat. Cooling operations may spread product contamination if cooling equipment is not cleaned and sanitized regularly. In addition to cooling equipment, critical control points in the packinghouse and cooling facilities include any surface that comes into contact with fresh culinary herbs, toilet facilities for employees, and control of pests. Without appropriate sanitation practices, packinghouse and cooling facilities may be

a source of microbial contamination. Cleaning and sanitizing of facilities and equipment should be conducted in a manner that protects against contamination of fresh culinary herbs, herb-contact surfaces, or packaging materials.

8.1 The Best Practices Are: General Facility Sanitation

- The non-food contact components of the facility (e.g., walls, ceilings, floors, drains, cooling equipment, mezzanines, storage areas) should be cleaned and sanitized on a routine basis. Establish a master sanitation schedule for these areas that clearly identifies cleaning frequency, sanitizers to be used, precautions, etc.
- A pre-operative inspection of the packinghouse and cooling facility operations should be conducted daily to verify that sanitation has been satisfactorily completed, the equipment is safe and ready for use, pest control measures are in place and functioning, and all food safety protocols are being followed. Use a checklist and document any corrective actions taken to address deficiencies.
- Cleaning compounds and other chemicals used in a fresh culinary herb operation should be approved for their intended use.[6]
- Use a secure, vented storage area for storing facility sanitizing chemicals and cleaning tools. This storage area should be away from the food handling area and any storage areas for raw or finished product packaging.
- Use floor cleaning techniques that do not pose a risk of cross-contamination of product or food contact surfaces. Workers should be trained about the potential for cross-contamination from splashing when using water to clean the floors.
- Personnel with cleaning and sanitation duties should be trained:
  - To understand the principles and methods required for effective cleaning and sanitation, especially as they relate to food safety.
  - To use, handle, and store cleaning and sanitizing chemicals safely.
  - Personnel with cleaning duties should be trained in the proper cleaning and sanitizing steps of the equipment and facility.
  - In the proper use of cleaning equipment.
- Document employee training and keep records for at least 2 years.
- All chemicals used in cleaning operations should be used and labeled in accordance with the manufacturer's instructions and in accordance with relevant federal, state, and local government regulations.
- A procedure should be in place for the disposal of waste sanitation chemicals and empty containers and for cleaning of equipment used in cleaning and sanitation that protects against product and production area contamination.
- An MSDS should be kept on file for each cleaning and sanitizing chemical.
- Verify the efficacy of the facility cleaning and sanitation with routine environmental testing (e.g., conventional or rapid microbiological methods such as total count or bioluminescence testing). Testing data should be maintained on file.

6 Appropriate chemical use can be verified in NSF's White Book™ – Nonfood Compounds Listings Directory available at http://www.nsf.org/usda/Listings.asp

8.2 The Best Practices Are: Cooling Facility Sanitation

- The cooling facility should have a written sanitation program and master sanitation schedule covering equipment, refrigeration units, icing equipment, forced air rooms, floors, drains, and the storage / distribution area.
- Sanitation should be conducted by personnel trained for handling sanitation chemicals and knowledgeable in sanitation practices.
- The cooling / distribution operation should have a documented environmental microbial testing program screening for *Listeria* spp. with testing targeted to areas where moisture, soil or debris may accumulate (e.g., spray vacuum and icing rooms). If test results are positive for *Listeria* spp., then follow-up tests for *Listeria monocytogenes* should be conducted. [7]
- Bins, shovels, and other equipment used to contain and / or move ice should be clean and sanitary, used only with ice, and stored in a sanitary manner when not in use.

8.3 The Best Practices Are: Equipment Sanitation

All sorting, grading, and packing equipment that makes contact with fresh culinary herbs may serve as a vehicle for spreading microbial contamination. Packinghouse and cooling facility equipment should be maintained clean and free from debris.

- Packinghouse and cooling facility equipment should be inspected for cleanliness before packing and / or cooling operations begin each day.
- At minimum all food-contact surfaces should be cleaned and sanitized daily.
- A master sanitation schedule should be developed for all packinghouse and cooling facility equipment. This schedule should clearly indicate the name or ID number of the piece of equipment, the frequency with which it is to be cleaned (e.g., daily, weekly, monthly or seasonally) and the process to be used for cleaning (e.g., wash, sanitize and rinse if necessary).
- Each piece of packinghouse and cooling facility equipment should have written procedures for cleaning (SSOPs).
- Cleaning and sanitizing of utensils and equipment should be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.
- Equipment filters should be back-flushed and sanitized as part of the master sanitation schedule for packing equipment.
- Avoid cleaning and sanitizing equipment during packing operations.
- Verify the efficacy of the equipment cleaning and sanitation with routine environmental testing (e.g., conventional or rapid microbiological methods such as total count or bioluminescence testing). Testing data should be kept on file.
- All equipment inspection, maintenance, cleaning, and sanitizing activities should be documented.

8.4 The Best Practices Are: Toilets and Hand-Washing Stations Sanitation

Individual toilet and hand-washing units should be properly maintained in a clean and sanitary condition for the worker's health, safety, and comfort. Inadequately supplied or improperly maintained restrooms and hand washing facilities may provide direct or indirect contamination of fresh culinary herbs and / or water sources used on fresh culinary herbs.

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7 FDA. 2008. Guidance for Industry: Control of Listeria monocytogenes in Refrigerated or Frozen Ready-to-Eat Foods; Draft Guidance. http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodProcessingHACCP/ucm073110.htm

- Establish a written cleaning and sanitation schedule for toilet and hand-washing facilities.
- Establish SSOPs for toilet and hand-washing facilities including a checklist of facility supplies.
- Maintain written documentation of service and maintenance of toilet facilities and hand-washing stations that demonstrates compliance with applicable worker health and safety regulations.

8.5 The Best Practices Are: Toilets and Hand-Washing Stations Waste Disposal

Operations with poor management of wastes in the packinghouse or cooling facility can significantly increase the risk of contaminating fresh culinary herbs.

- Maintain a written waste collection service schedule.
- All waste from sanitation facilities should be disposed of according to applicable laws and regulations.
- Disposal of used hand-washing water should not cause unsanitary conditions or contamination of the packinghouse / cooling facility.
- Used toilet paper should be disposed of in a sanitary manner that prevents cross contamination, specifically flushing it down the toilet. In some areas or countries, the plumbing and waste disposal system can't handle toilet paper, in these cases, toilet or waste baskets must be used and managed so as not to allow the waste paper to spill onto the floor.

Documentation List:

- ☐ SSOP – Non-food contact surface
- ☐ Non-food contact surface master sanitation schedule
- ☐ SSOP – Cooling facility
- ☐ Cooling facility master sanitation schedule
- ☐ SSOP – Toilet and hand-washing facilities
- ☐ Toilet and hand-washing facilities master sanitation schedule
- ☐ SSOP – Equipment
- ☐ Equipment master sanitation schedule
- ☐ Pre-operative inspection checklist
- ☐ Corrective action log
- ☐ Employee SSOP training records
- ☐ MSDS for cleaning chemicals
- ☐ Environmental testing schedule and results
- ☐ Toilet and hand-washing facilities service and maintenance log
- ☐ Waste collection schedule

9.0 Issue: Employee Hygiene and Food Safety Training

Fresh culinary herbs are often extensively handled by employees at the packinghouse and possibly by persons working with fresh culinary herbs at the cooler or cold storage facility. Handling by employees may transfer microorganisms of significant public health concern, therefore employee hygiene and sanitary procedures are appropriate in all environments where fresh culinary herbs and people are in proximity. The importance of employees, supervisors, and senior management understanding and practicing proper hygiene cannot be overemphasized.

Employees can transmit human pathogens to fresh culinary herbs, water supplies, and other employees, if they do not understand and follow basic hygienic principles. Employees should be trained regularly in an appropriately comprehensible language regarding food safety and worker health and hygiene. Training programs should emphasize employees' roles and responsibilities in producing a safe product and sanitation principles and practices including appropriate and effective hand-washing, glove use and replacement, health-related policies, etc. Training should be designed to help employees understand what is expected of them and why these practices are important.

9.1 The Best Practices Are: Training

- Mandatory training for every employee in the company's food safety policy and plan, food safety procedures, risk recognition and reporting requirements, sanitation, and personal hygiene appropriate to their job responsibilities at hire with refresher training at prescribed frequencies.
- Document all training sessions with a general description of the subject matter, the trainer's name, the date of training, a list of all employees invited to the training and the signatures of employees attending the training indicating that they understood the information presented.

9.2 The Best Practices Are: Hygiene

- Train employees on how, when, and why they must properly wash their hands and exposed portions of their arms. Employees must wash their hands:
  - Before beginning work.
  - Before putting on a new pair of gloves.
  - After touching human body parts or anything other than fresh culinary herbs or food contact surfaces.
  - After using the toilet.
  - After using tobacco, eating, or drinking.
  - After any activity that may contaminate hands, such as handling garbage, coughing, sneezing, or using a handkerchief or tissue, cleaning chemicals, or incoming herbs before they are washed.
  - After caring for or touching animals.
  - Before returning to a workstation.
- Instruct employees to inform the supervisor of any issues with the hand-washing or toilet units.
- If a company requires or allows employees to wear gloves when handling product, a procedure for glove use should be established, followed, and documented.
  - Employees must wear gloves provided by their employer.

The importance of employees, supervisors, and senior management understanding and practicing proper hygiene cannot be overemphasized.

  - If gloves are reusable, they should be washed and sanitized daily or changed as necessary after any event that may cause gloves to become contaminated.
  - If gloves are disposable, they should be changed as necessary during the work day and after any event that may cause gloves to become contaminated. Powdered disposable gloves should not be used.
  - Gloves should not be worn in or taken into the toilet facilities, break areas, or when handling unsafe or non-food grade materials.
- Employees should wear head and facial hair coverings.
- Employees should wear appropriate, clean protective outer garments when beginning work each day. Heavily soiled and / or damaged reusable protective outer garments should be replaced.
- Protective outer garments such as aprons and gloves should be hung on racks or in a designated area and not placed on top of product, work surfaces, equipment or packaging material.
- Employees should not take packing-related tools or protective outer garments outside the designated areas or inside the toilet facilities and employee break areas.
- Prohibit eating, drinking, smoking, or chewing tobacco outside of designated areas to reduce the potential for product contamination.
- In areas where fresh culinary herbs are present, prohibit employees from activities such as chewing gum or spitting.

9.3 The Best Practices Are: Physical Hazard Prevention

- Employees must remove all jewelry and other objects that might fall into food, equipment, or containers.
- When handling product, employees must remove or cover all hand jewelry that cannot be adequately sanitized.
- Establish storage and control procedures for employee equipment, supplies and personal belongings when not in use. These items should be stored in areas other than where food is exposed or where equipment or utensils are washed.

9.4 The Best Practices Are: Health

- Establish a health practices program that addresses the following issues:
  - Persons who present symptoms of diarrheal disease or other infectious disease (e.g., vomiting, diarrhea, jaundice, sore throat with a fever) are prohibited from handling fresh culinary herbs and being in the production area.
  - Employees should report illnesses to supervisors before beginning work. Train supervisors to know the typical signs and symptoms of infectious disease (e.g. vomiting, nausea, diarrhea, and abdominal cramps), and appropriate action to take in the event of worker injury or illness.
  - Cuts and wounds should be covered with a suitable waterproof dressing when employees with injuries are permitted to continue working.
  - Employees with wounds or cuts that cannot be covered to prevent contact with the product should not perform tasks that require contact with fresh culinary herbs, processing equipment, packaging materials or tools until the wound has healed.
  - A policy describing procedures for handling / disposing of fresh culinary herbs or food contact surfaces that have come into contact with blood or other bodily fluids.
  - First aid kits should be readily available and maintained in accordance with prevailing regulation with materials kept in sanitary and usable condition.

Documentation List:

- ☐ Employee attendance log for food safety policy/plan training
- ☐ SOP – Worker hygienic practices
- ☐ SOP – Employee personal effects storage and control
- ☐ SOP – Worker health practices
- ☐ SOP – Glove use

10.0 Issue: Cold Storage and Warehousing

In post-harvest unit operations, cold storage and warehouse facilities are often the last area that house fresh culinary herbs before they are shipped to the next point of the supply chain. The conditions and sanitation programs of these facilities are critical in maintaining the integrity of the finished product before it exits the facility.

10.1 The Best Practices Are:

- Product placement and storage should not facilitate cross-contamination (e.g., pallets placed on top of bins, iced containers placed above containers with non-iced product).
- Storage and warehousing of finished fresh culinary herbs should be under conditions that will protect them against physical, chemical, and microbial contamination as well as against deterioration of the product and the container.
- The packing facility should have a cold storage area with refrigeration that is appropriate for the product.
- Refrigeration units should be inspected on a regular basis and kept in good operating condition.
- Temperature monitoring devices should be placed in the warmest area of the refrigerator unit and calibrated on a regular basis.
- Avoid practices that cause condensation to form in the facility (i.e. putting product into storage before it is properly cooled).
- Condensate / water from evaporator-type refrigeration systems should be contained in catchments designed to assure that it does not become a source of contamination. Water from refrigeration catchments should be drained into a drainage line and not onto the floor.
- The storage area should be included in scheduled cleaning and sanitation operations. If finished product is present during cleaning of ceiling, floors or drains and equipment such as pressure washer/sprayers, steam or foam cleaners are being used, ensure that water does not splash on product.
- The storage area should be included in the facility pest control program.
- Forklifts and other pallet moving equipment should be included in the master sanitation schedule and should be cleaned on a regular basis.
- Verify the efficacy of the cold storage and warehouse cleaning and sanitation with routine environmental testing (e.g., conventional microbiological methods or rapid methods for total bacterial count or bioluminescence testing). Testing data should be maintained on file.
- Cleaning and sanitation activities should be documented.

Documentation List:

- ☐ SOP – Refrigeration unit inspection
- ☐ Refrigeration unit inspection log
- ☐ Temperature monitoring device calibration log
- ☐ SSOP – Warehouse/cold storage area

11.0 Issue: Transportation from Packinghouse or Cooling Facility

Fresh culinary herb products may be transported from cold storage or distribution facilities by numerous modes of transportation. Conditions of transport may provide opportunities for microbial contamination. Transportation of fresh culinary herb products should be managed to reduce, control or eliminate the risk of contamination.

Implement inspection/ evaluation management programs of shipping trailers to verify that food safety needs are being met.

11.1 The Best Practices Are:

- Vehicles used to transport fresh culinary herbs from the packinghouse and cooling facility should be clean. Implement inspection / evaluation management programs of shipping trailers to verify that food safety needs are being met. Items that may be evaluated include (but are not limited to) the trailer condition, overall cleanliness, good structural condition, etc.
- Establish procedures to assure that prior loads hauled by transport vehicles do not potentially contaminate fresh culinary herb products during transport from the packinghouse or cooling facility.
- The vehicle operator should have a written sanitation procedure (type and frequency of cleaning and sanitizers) for cleaning transport vehicles and schedule / log of cleaning activity.
- Ensure that equipment in refrigerated vehicles is functioning properly and designed to circulate cold air uniformly throughout the vehicle while taking the load layout into consideration.
- The operator should pre-cool and maintain a temperature in the shipping trailer that is appropriate for the particular herb product throughout transportation. Develop and implement an SOP for when and how temperature in the shipping trailer should be measured and maintain records that document the temperature.
- Load and unload in a manner that minimizes damage and contamination.

Documentation List:

- ☐ SOP – Vehicle inspection
- ☐ SSOP – Transport vehicle
- ☐ Vehicle temperature log

SECTION IV:

Processing Unit Operations

SECTION IV

1.0 Issue: **Important Considerations About Processed Fresh Culinary Herbs**

Fresh culinary herbs are primarily sold as raw and processed ready-to-use (RTU) and ready-to-eat (RTE) product. RTU and RTE fresh culinary herbs save preparation time for the customer because they are minimally processed – cleaned, trimmed, and possibly cut before being packed in some form of plastic, protective packaging. RTU and RTE products differ from fresh culinary herbs that are field-packed or packed at a packinghouse where herbs are not trimmed and are primarily packed in bulk. RTU fresh culinary herbs differ from RTE because they require washing and further preparation prior to consumption. RTE products are washed during processing while RTU products may not be washed during processing. For purposes of this section we are addressing processing operations that supply minimally processed RTE and RTU fresh culinary herbs. RTU fresh culinary herbs require washing and further preparation before being consumed, while RTE fresh culinary herbs do not require washing or further preparation before being consumed. This section does not address best practices for handling herbs in a packinghouse (covered in Section II).

Each fresh produce processor is advised to assess the best practices in this document and in the Fresh-cut Guide, and then tailor its food safety practices to its particular operation.

Fresh culinary herb food safety programs should focus on preventing adulteration by microbial contamination because these herbs may be eaten raw and without thermal treatment to reduce human pathogen levels. For that reason, even though RTU fresh culinary herbs are not considered RTE, as a general practice processing facilities should operate under cGMPs and handle these products according to the FDA's "Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables" (Fresh-cut Guide).[1] This set of best practices are primarily based on cGMPs from the Code of Federal Regulations Title 21, Part 110 (21 CFR 110) and the FDA's Fresh-cut Guide.[43]

GMPs are the commonly agreed upon and scientifically based standards by which industry and regulators effectively and harmoniously communicate the standards of performance and conduct whenever food products are being prepared, packed, or held (Gorny, 2006). As such, the cGMPs are centrally important in reducing the risk of product adulteration and food safety risk to consumers. FDA's Fresh-cut Guide is not a set of binding requirements nor does it identify all possible preventive measures to minimize microbial food safety hazards. Each fresh produce processor is advised to assess the best practices in this document and in the Fresh-cut Guide, and then tailor its food safety practices to its particular operation. Alternative approaches that minimize microbial food safety hazards may be used so long as they are consistent with applicable laws and regulations.

The food safety program for a processing facility is generally built upon a number of foundation programs such as: cGMPs, SSOPs, SOPs, traceback

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1 FDA. 2008. Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables. http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064458.htm#ch8

and recall processes, maintenance procedures, employee training and pest control. It is important that management plans or programs verify through documentation (i.e., general evidence of conformity) that processing facility sanitation practices are addressed and preventive or corrective measures are taken to reduce or eliminate the risk of any potential contamination.

2.0 Issue: HACCP/HARPC Plan Development and Operation

A critical step in developing an effective food safety program is to assess the food safety risks for an operation and develop preventative measures to control the identified risks. Hazard Analysis and Critical Control Point (HACCP) and Hazard Analysis and Risk-Based Preventive Controls (HARPC) are systematic preventative approaches to food safety designed to prevent, reduce to acceptable levels, or eliminate the microbial, chemical, and physical hazards associated with food production. The HARPC requirements are similar to HACCP requirements but incorporate preventive controls to address hazards that do not have critical control points. As one component of a comprehensive food safety program, HACCP and HARPC are proactive approaches to prevent food contamination rather than trying to identify and control contamination after it has occurred. Awareness of common risk factors discussed in this document and implementation of either critical control points or preventive controls determined by a firm to be appropriate to its individual operations will enhance the safety of fresh culinary herbs.[2]

As one component of a comprehensive food safety program, HACCP and HARPC are proactive approaches to prevent food contamination rather than trying to identify and control contamination after it has occurred.

2.1 The Best Practices Are:

- Develop a flow diagram of the processing operation.
- Conduct a hazard analysis for the operation.
- Establish critical control points (CCPs) or preventive controls (PCs) to significantly minimize or prevent the occurrence of the identified hazard.
- Establish parameters or critical limits around the CCPs or PCs.
- Establish procedures for monitoring the effectiveness of CCPs or PCs.
- Establish corrective actions to mediate any breach or violation of established parameters / critical limits.

2 Resources for developing HACCP plans are available at the FDA, the USDA, and the FAO:
FDA. 1997. Hazard Analysis and Critical Control Point Principles and Application Guidelines. http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/HACCPPrinciplesApplicationGuidelines/default.htm#princ
USDA. 2010. HACCP. http://foodsafety.nal.usda.gov/nal_display/index.php?info_center=16&tax_level=1&tax_subject=177
FAO. 1998. Food Quality and Safety Systems – A Training Manual on Food Hygiene and the Hazard Analysis and Critical Control Point (HACCP) System. http://www.fao.org/docrep/w8088e/w8088e00.htm

- The hazard analysis, monitoring records, corrective actions, and testing results and any accompanying HACCP/HARPC plan should be documented and available for review.
- Reanalyze your HACCP/HARPC plan at least every 3 years and whenever your facility makes a significant change that may affect your hazard analysis.
- Prepare and review documentation for all CCPs or PCs daily, including corrective actions when warranted, in accordance with the HACCP/HARPC plan.

Documentation List:

- ☐ HACCP/HARPC Plan
- ☐ SOP – CCP/PC inspections
- ☐ Corrective action logs

During receiving it is critical that all essential field information is appropriately maintained and transferred to packinghouse operations for recordkeeping.

3.0 Issue: **Receiving**

When fresh culinary herbs are received at the packinghouse there are important items to consider regarding time intervals between harvest and cooling and the transfer of information. Because some microbes multiply rapidly under warm, moist conditions, the time from harvest to cooling should be minimized. Keep track of the product (traceability) as it is received – during inspections and handling. During receiving it is critical that all essential field information is appropriately maintained and transferred to packinghouse operations for recordkeeping.

3.1 The Best Practices Are:

- Obtain fresh culinary herbs from suppliers that follow GAPs and the best practices in this guidance.
- Establish a procedure for inspecting and accepting or rejecting incoming loads of fresh culinary herbs.
- Establish procedures to ensure fresh culinary herbs are held and stored in designated areas and handled under proper conditions.
- Ensure that incoming documentation provides sufficient information to facilitate product traceability and establish a system to maintain that documentation.

Documentation List:

- ☐ Approved supplier list
- ☐ SOP – Product inspection
- ☐ SOP – Product holding/storage
- ☐ Product tracing paperwork

4.0 Issue: **Water Used in Processing**

Some processing operations supply RTE fresh culinary herb products to the marketplace. Unlike RTU fresh culinary herbs, RTE herbs have been washed and are therefore ready for consumption. When used appropriately with water of adequate quality, disinfectants help minimize survival and growth of microorganisms in the wash water and the subsequent cross contamination of the product. Processors should consider options for disinfectants and wash systems that are most appropriate for their operation. For a list of chemicals that may be safely used to wash fruits and vegetables, see 21 CFR 173.315.[3]

The effectiveness of a disinfectant and the amount that should be used depends on the type of herb and the treatment conditions, such as water temperature, acidity (pH), water hardness, contact time, amount and rate of product throughput, water to product ratio, amount of organic material, and the resistance of pathogens to the particular disinfectant. Some studies have shown that pathogens may become internalized in the herb plants in which case disinfectants would have limited effectiveness of inactivating pathogens (Erickson, 2010; Girardin, 2005; Golberg, 2011). If fresh culinary herbs are washed during processing, processers should consider options for disinfectants and wash systems that are most appropriate for their operation and verify the washing process by documenting the levels of sanitizers, water changes, pH control, exposure time, and mass-to-volume ratios in the water.

If pathogens are present in the wash water, they may contaminate the produce, and subsequent washing will not reduce levels of these pathogens. Therefore, water used for washing or cooling produce should contain sufficient levels of disinfectant to reduce the potential for pathogens to persist in such water. Such practices include using antimicrobial chemicals in the wash water or using spray type wash treatments instead of submerging produce.

Water used for washing or cooling produce should contain sufficient levels of disinfectant to reduce the potential for pathogens to persist in such water.

4.1 The Best Practices Are: Wash Water

- Source water used for washing product in processing operations must meet US EPA drinking water standards.
  - The wash water source should be tested as specified in Table IV-1. If a municipal water source is used, microbial water quality information from the respective municipal water authority may be obtained and archived if it is reported as total coliforms. Facilities using municipal water should periodically test water at the point of use to verify the integrity of the facility water distribution system.
  - Develop an action plan in case municipal water authorities issue a water quality alert or warning such as "boil water

3 Code of Federal Regulations Title 21, Part 173.315. http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=6977748defb77117b2dc3d97d085c4aa&rgn=div5&view=text&node=21:3.0.1.1.4&idno=21#21:3.0.1.1.4.4.1.3

warning." Document and archive any warning or alerts issued by the water authority as well as corrective actions taken by your firm to address this issue.

- If fresh culinary herbs are washed during processing, operators should verify the washing process by documenting wash water system parameters (e.g., the levels of sanitizers, water changes, pH control, amount and rate of product throughput, exposure time, and mass-to-volume ratios) that are effective in controlling microbial levels in their system.
- Process wash water should have sufficient levels of disinfectant so as not to result in adulteration of the product by cross-contamination as specified in Table IV-1. Establish an SOP for monitoring and maintaining wash water disinfectant levels throughout processing operations. Continuous monitoring of disinfectant levels is preferred.
  - *Active* disinfectant levels (i.e., free chlorine and not chlorine concentration) and pH or ORP (oxidation reduction potential) should be measured and documented.
  - Follow manufacturer's directions for mixing of disinfectant chemicals to obtain effective concentrations; manufacturer's suggested or allowable levels in washing and cooling water should not be exceeded.
  - All measurement devices (e.g., free chlorine probes, ORP or pH monitoring equipment) should be calibrated daily. Disinfectant measurements and equipment calibrations should be documented.
  - The person monitoring the water disinfectant levels should know when to add disinfectant based on values obtained.
  - Any other substance (e.g., organic acids for pH control) used to treat water used in processing operations should be monitored to verify correct concentration. These checks should be documented.
  - If the disinfectant level should fall outside the parameters established in the HACCP program, corrective actions as outlined in the HACCP program should be followed and documented.
- Any water additive used to wash fresh culinary herbs should be food-grade and compliant with federal, state or local regulations for the intended use. Copies of MSDS should be maintained on file.
- To ensure efficient operation, routinely inspect and maintain facility water distribution system and equipment designed to assist in maintaining water quality such as chlorine injectors, filtration systems, and backflow devices. Inspections and maintenance should be documented.
- All monitoring equipment should be adequately maintained and periodically calibrated. Maintain a log of maintenance and calibration events.
- Water holding tanks used at the facility should be kept clean and sanitary. All cleaning and sanitation verification activities should be documented. For more on the care of finished water storage tanks see the Sanitary Survey in Appendix A.

4.2 The Best Practices Are: Recirculated Water

Water in processing operations may be continuously recirculated. Water quality is especially important at the end of the process when sequential washing is used. If recirculated water contacts fresh culinary herbs, water should meet drinking water quality standards and disinfectant levels as outlined in Table IV-1 throughout all processes.

- If water is recirculated in a series of processes, water flow should be arranged to be counter to the movement of fresh culinary herbs through different operations so that as the herbs are further processed, they are exposed to the cleanest water.
- When washing or cooling fresh culinary herbs in recirculated water:

  - Disinfectant must be present at sufficient levels and the levels monitored to reduce the potential risk of cross contamination as described in Table IV-1. All monitoring activities should be documented.
  - Procedures must be established to determine when and how often water should be refreshed or completely changed out.
- Water disinfectants levels must be monitored and maintained throughout the process by testing the water disinfectant concentration and pH or ORP (oxidation reduction potential) as follows:
  - Any disinfectants used must be used according to the manufacturer's specifications.
  - *Active* disinfectant levels should be measured and documented (i.e., free chlorine and not chlorine concentration).
  - Continuous monitoring of disinfectant levels is preferred.
  - All disinfectant measurement devices should be calibrated daily. Disinfectant measurements and equipment calibrations should be documented.
  - The person monitoring the water disinfectant levels should know when to add disinfectant based on values obtained.
  - Any other substance (e.g., organic acids for pH control) used to treat the wash water must be monitored to verify correct concentration. These checks should be documented.
  - Establish an SOP that outlines corrective actions if system is not operating within the limits and document them.
  - All monitoring equipment should be adequately maintained and periodically calibrated. Maintain a log of maintenance and calibration events.
- Filtering devices should be used to minimize the buildup of organic material in recycled wash water. Filters should be back-flushed and sanitized as part of the master sanitation schedule for packing equipment.
- Appropriate measures should be taken for waste water disposal.
- Any water additive used to wash fresh culinary herbs must be food-grade and compliant with federal, state or local regulations for the intended use. Copies of MSDS should be maintained on file.

Water in processing operations may be continuously recirculated. Water quality is especially important at the end of the process when sequential washing is used.

4.3 The Best Practices Are: Ice and Ice Slurry

Ice or ice slurry may be used in the processing of fresh culinary herbs to cool product or as a means of keeping the product cold during distribution. Whether ice is manufactured on-site or purchased from outside vendor, it should be handled, stored, and transported in a sanitary manner.

Whether ice is manufactured on-site or purchased from outside vendor, it should be handled, stored, and transported in a sanitary manner.

- Water used to make ice that directly contacts product must meet US EPA drinking water standards.
- The water source used to make ice and ice slurry should be tested periodically at a frequency sufficient to assure that it is of appropriate microbial quality for its intended use (see Table IV-1 on Water Use in Processing Operations).
  - Ice used on product should contain an approved water disinfectant at sufficient concentration to reduce the potential for cross contamination.
- Ice must be handled like a food ingredient. Establish an SOP for transporting, handling, and storing ice so that it does not become contaminated. The SOP should address the following:
  - Clean and sanitize all equipment that holds or transports ice daily.
  - Drip pans should be used to collect condensation under augers and conveyors on ice-conveying systems; drip pans should be emptied directly into the facility drainage system and not onto floor.
  - Ice should not be stored in close proximity to raw product or chemical storage.
  - If ice is manufactured and delivered by an outside vendor, ensure the vendor follows your company's SOP for handling, storing, and transporting ice.
- If iced product is placed in storage racks above pallets of other product, plastic pallet shrouds should be used to protect product beneath from potential cross contamination.

Documentation List:

- ☐ Source water test schedule and results
- ☐ SOP – Chemicals added to wash water
- ☐ SOP – Water disinfectant monitoring
- ☐ Water monitoring equipment calibration logs
- ☐ MSDS for water disinfectant chemicals
- ☐ SOP – Ice transporting, handling, and storage

Table IV-1. Water Use in Processing Operations

Use	Metric	Rationale / Corrective Actions
Direct Product Contact or Food Contact Surfaces	**Microbial Testing** **Target Organism:** Total coliforms **Sampling Procedure:** 1 L sample collected aseptically at the point of use **Sampling Frequency:** One sample per water source should be collected and tested prior to use if >60 days since last test of the water source. Additional samples should be collected at intervals of no less than 18 hr. and at least monthly during use. **Municipal & Well Exemption:** For wells and municipal water sources, if total coliform levels are below detection limits for five consecutive samples, the sampling frequency may be decreased to once every six months and the 60 and 30 day samplings are waived. This exemption is void if there is a significant source or distribution system change. **Test Method:** FDA BAM method or any US EPA-approved or AOAC-validated method for quantitative monitoring of water for total coliforms.	For any given water source (e.g. municipal, well), samples for microbial testing should be taken as close to the point of use as practical (as determined by the sampler to ensure the integrity of the sample) using sampling methods as prescribed in this table where the water contacts fresh culinary herbs, so as to test both the water source and the water distribution system. There is only one sample per month per distribution system under these metrics. If there are multiple potential point-of-use sampling points in a distribution system, then samples should be taken from different point-of-use locations each subsequent month (randomize or rotate sample locations). Water that directly contacts harvested fresh culinary herbs or is used on food contact surfaces such as equipment or utensils, should come from a source that meets the Maximum Contaminant Level Goal of zero or no detection for total coliforms in drinking water as specified by US EPA and once in use, contain an approved disinfectant at sufficient concentration to prevent cross-contamination.[1] Microbial and physical / chemical testing should be performed, as appropriate to the specific operation, to demonstrate that the disinfectants and corresponding concentrations used are sufficient for the wash system and that acceptance criteria for total coliforms have been met. Always follow your contracting laboratory's protocol for the collection of water samples. **Single Pass and Recirculated Water Systems** • Single pass use – Water should have non-detectable levels of total coliform and sufficient disinfectant to ensure water has no detectable total coliform (e.g., a minimum of 10 ppm chlorine). • Recirculated use – Water should have non-detectable levels of total coliform and sufficient disinfectant to ensure returned water has no detectable total coliform (e.g., a minimum of 10 ppm chlorine). * Single pass and recirculated water treated with chlorine-based disinfectants should be tested for free chlorine concentration (ppm) and pH OR for oxidation reduction potential (mV). The selected method should be verified periodically with the alternative process verification method AND by ensuring that established microbial acceptance criterion for water is being met.

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Use	Metric	Rationale / Corrective Actions
	Acceptance Criteria: **Negative or Below DL for All Samples** **<u>Physical / Chemical Testing</u>** **Target Variable:** Water disinfectant (e.g., chlorine or other disinfectant compound) **Acceptance Criteria for Disinfectants:** • US EPA-**approved treatments** per product label for human pathogen reduction in water and used in accordance with a wash water system-specific protocol that has been validated to show that active disinfectant is present throughout the wash process. • **Chlorine-based disinfectants** ≥10 ppm free chlorine after application and pH 6.5 – 7.0 • ORP ≥ 725 mV* **Testing Procedure:** • Chemical reaction based colorimetric test, or • Ion specific probe, or • ORP,* or • Other as recommended by disinfectant supplier. **Testing Frequency:** Continuous monitoring (preferred) with periodic verification by titration OR routine monitoring if the system can be shown to have a low degree of variation.	If any one sample exceeds the acceptance criteria for total coliforms, then investigation and corrective actions should be taken to ensure it can meet acceptance criteria under those operational conditions. then the water should not be used for this purpose unless appropriate disinfectants have been added or until corrective actions have been completed and total coliform levels are within acceptance criteria: • Conduct a Sanitary Survey of the water source and distribution system to determine if a contamination source is evident and can be eliminated. Eliminate identified contamination source(s) if applicable. • For wells, perform a Sanitary Survey and / or treat as described in the Sanitary Survey (Appendix A). • Retest the water at the same sampling point after conducting the Sanitary Survey and / or taking corrective actions to determine if it meets the outlined microbial acceptance criteria for this use. For example, if a water sample for water used to clean food contact surfaces has detectable total coliforms, STOP using that water system, examine the distribution line, source the inlet as described in the Sanitary Survey (Appendix A), and retest from the same point of use. Continue testing daily for five days at the point closest to use, and do not use the water system until it consistently delivers water that is safe, sanitary, and meets the acceptance criteria outlined in this table. If any of the five samples taken during the intensive sampling period after corrective actions have been taken, have detectable total coliforms, repeat corrective actions and DO NOT use that system until the source of contamination can be corrected. **Records**: All test results and corrective actions should be documented and available for verification from the user of the water for a period of 2 years.

5.0 Issue: Facility Construction, Design and Maintenance

Well designed and maintained processing facilities and equipment can reduce the potential for contamination by using appropriate location and / or flow of humans, product, equipment, and air. Facilities that process and pack fresh culinary herbs should follow the requirements for buildings and grounds, packing and holding of foods, equipment and utensils, toilet facilities and controls, and sanitary operations as provided for under 21 CFR Part 110. Buildings, fixtures, and equipment should be constructed and kept in repair sufficient to prevent product from becoming adulterated. The processing facility should be equipped with adequate toilet facilities and hand-washing stations relative to the number of employees working at the site. The operator should follow all applicable federal, state, and / or local regulations regarding the number of individual units and their location within the processing building.

Well designed and maintained processing facilities and equipment can reduce the potential for contamination by using appropriate location and / or flow of humans, product, equipment, and air.

5.1 The Best Practices Are: Facility Grounds

The grounds around the facility should be under the control of the operator and should always be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

- Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the buildings or structures that may constitute an attractant, breeding place, or harborage for pests.
- Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed. Roads should be paved or otherwise managed to prevent dust.
- Adequately draining areas that may contribute contamination to food by seepage, transfer to facility via foot traffic, or providing a breeding place for pests.
- Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.
- Evaluate adjacent land use to ensure that it does not pose a significant risk of product cross-contamination.

5.2 The Best Practices Are: Construction and Design

- Facility design and construction should be in compliance with applicable local, state, and federal regulations.
- External/Internal structures – the following practices are suggested to reduce the potential for contamination:
  - The integrity of the building structure should be maintained such that pests can be excluded from gaining entrance to the facility. Holes, openings, and foundation cracks should be patched and secured.

  - Construct wall, ceiling, and floor surfaces with materials that are easily cleaned and sanitized with chemical cleaners.
- Facility layout – the following practices are suggested to reduce the potential for contamination:
  - Raw and finished product cooling and storage facilities should be clearly separated to reduce the potential for cross-contamination.
  - Locate the maintenance shop close to the process area but well separated so that cross-contamination cannot occur.
  - Have rest rooms open into a location other than a processing area.
  - If a microbiology lab is in the building, it should be operated under the FDA's Good Laboratory Practices.[4]
  - Any designated employee break area should be physically separate from the processing area.
- The flow of personnel, product, equipment, or air – the following practices are suggested to reduce the potential for contamination:
  - Use short direct routes for both product and personnel flow.
  - Design the plant for one direction of personnel traffic, product, and air flow.
  - Design product areas to have traffic patterns that separate raw and finished product using either linear product flow (i.e., raw to finished product) or by physical partition.
  - Use an air filtration system for central air distribution and airflow that is counter to product flow, so that filtered air moves with a positive pressure from the cleanest areas (e.g., from packaging and finished product storage) toward less clean areas (e.g., the receiving area).
  - Restricting the movement of lift trucks, bins, totes, maintenance tools, cleaning implements, and people from receiving and storage zones to processing and packaging areas.
  - Code bins, totes, clothing, cleaning implements, maintenance tools, and other items (e.g., blue aprons for receiving zones and red aprons for processing and packaging areas) to help achieve separation of traffic and thereby minimize cross-contamination.
- Entryways – the following practices are suggested to reduce the potential for contamination:
  - Design all entrances and exits to the process floor to be closable or to provide a barrier so that outside air cannot enter the plant directly.
  - Keep the number of entrances and exits to the processing areas to a minimum to reduce the potential for contamination of intake air.
  - Locate hand dip and foot bath stations at each employee entrance so that employees must pass through them to enter the processing and packing area. The hand dip and foot bath stations should contain an appropriate sanitizer to prevent tracking of microbes from outside into the processing area.
  - Locate the door to the outside in an area other than into a processing area.
- Water delivery and drainage systems – to reduce the potential for contamination, design and construct:
  - Floors so that water drains well.
  - Floor drains in processing or storage areas to prevent pest entry, water accumulation in or around the drain and to be accessible for cleaning.
  - Under-floor drains to carry waste water out of processing areas.

4 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=58

  - Cooling systems' condensation units to drain directly into drainage systems. Emptying of this water into floor drains should be prohibited.
  - Waste water collection areas to prevent product and equipment contamination.
  - Facility water systems equipped with back-flow prevention devices.
  - Overhead equipment, structures or fixtures, catwalks, walls, pipelines, etc. should be designed to avoid the potential to be a contamination source for product and packaging (i.e., condensation formation, dirt).
- Food contact surfaces (FCS) – the following practices are suggested to reduce the potential for contamination:
  - Construct FCS with materials that are smooth, nonabsorbent, smoothly bonded, without niches, and sealed so that they are easily cleaned and sanitized and do not serve as harborage of microbial pathogens.
  - Protect FCS from contact with non-potable water.
  - Avoid use of hollow structures such as table legs, conveyer rollers and racks because they may collect water and debris, and thus, harbor pathogens.
  - Equipment lubrication should be managed so as to not contaminate fresh culinary herbs. Food grade lubricants should be used on packing equipment where food contact may occur. Food-grade and non-food-grade lubricants are to be stored separately.
  - Sufficiently elevate FCS above the floor to prevent contamination from floor splashes.
- All lights should be adequate for sufficient visibility and designed to prevent the potential for broken glass contamination of the product (i.e., contain shatter-proof bulbs or be sealed in a protective covering).
- Provide a designated area separate from food handling areas for employees to store personal items.

5.3 The Best Practices Are: Toilets and Hand-Washing Stations Construction and Design

Operations with poorly designed and constructed toilet facilities and hand-washing stations may provide direct or indirect contamination of the fresh culinary herbs and water sources used on fresh culinary herbs.

- The design and construction of toilet facilities and hand-washing stations, including number and location, should be in compliance with applicable local, state, and federal regulations. [5]
- The number of toilet facilities and hand-washing stations should meet OSHA requirements as outlined in 29 CFR 1910.141. [6]
- Evaluate the location of toilet facilities and hand-washing stations to maximize accessibility and use, while minimizing the potential for the facility to serve as a source of contamination.
- Toilet facilities should be constructed of materials that can be easily cleaned and sanitized using cleaners and / or oxidizing agents.
- If the toilet facilities have any openings to the outside (e.g. windows, vents), these openings should have proper screens to exclude vermin.
- Toilet facilities and hand-washing stations should be constructed with properly designed drainage systems.

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5 The number of toilet and hand-washing stations should meet OSHA requirements as outlined in 29 CFR 1910.141.

6 OSHA. Sanitation. 29 CFR 1910.141. http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9790

A processing facility should be designed so that fresh culinary herbs arriving at the facility will never cross paths or commingle with finished product.

- Doors to the toilet facilities:
  - Should not open directly into areas where product is located
  - Should be self-closing
  - If entry is to a single-person facility, should be lockable from the inside.
- Each individual toilet stall should have doors that are self-closing and lockable from the inside and toilet paper in a proper holder.
- Hand-washing units where employees wash their hands before returning to their work stations should be located so that hand-washing can be observed. All hand-washing units should be equipped with:
  - Potable, hot and cold running water. The quality of the water should be verified by testing to assure its microbial quality is acceptable according to local standards for potable water.
  - Soap or other suitable cleansing agents in dispensers.
  - Single-use paper towels.
  - Hands-free "on / off" switches for water (i.e., workable without using potentially soiled hands).
  - Trash containers with covers
  - Signs indicating that *the water is only for hand-washing purposes* (in appropriate languages).
  - Sealed waste water catch basins with plumbing free of leaks.
- Post cGMP signage that shows employees proper hand-washing procedures.

6.0 Issue: **Processing Facility Sanitary Operations**

Contamination by location and / or flow of humans, product, equipment, and air can be prevented by adequate food safety controls, operating practices, and facility design. A processing facility should be designed so that fresh culinary herbs arriving at the facility will never cross paths or commingle with finished product. Operators should be aware of and operate in accordance with all relevant laws and regulations that describe facility sanitation practices.[7,8]

7 OSHA. Sanitation 1910.141 http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9790

8 Code of Federal Regulations, Title 21, Part 110 – Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=fe4d3406434fbb5824f74776dadefb66&rgn=div5&view=text&node=21:2.0.1.1.10&idno=21

6.1 The Best Practices Are: General Items

- Develop a pre-operative check list that can be used for a daily inspection of the processing plant to verify that sanitation has been satisfactorily completed, the equipment is safe and ready for use, pest control measures are in place and functioning, and all food safety protocols are being followed. Retain the checklist as documentation along with a corrective action section that identifies food safety infractions and assigns responsibility to correct the infraction.
- Fresh culinary herbs should not come into contact with the floor or any other non-food contact surface. Herbs that fall on the floor must be discarded.
- Inspect fresh culinary herbs throughout the processing stream for field contaminants that may not have been noticed in the packinghouse or during the incoming inspection. Remove from the processing stream damaged or decomposed fresh culinary herbs, extraneous matter, and herbs that appear to be contaminated (e.g. by animal feces, fuel, machine grease, or oil).
- Avoid practices that cause condensation to form in the facility. Condensation provides conditions optimal for microbial growth and may potentially serve as a source of cross-contamination. If condensation forms in any part of the facility, it should be cleaned and the area sanitized.
- Appropriate measures should be taken for waste water disposal.
- Garbage should be placed in appropriate receptacles with serviceable lids and removed from the facility on a regularly scheduled basis.
- Garbage receptacles should be clearly designated for their intended use (e.g., trash, recyclable materials or product that might be re-worked). Employees should be trained to recognize and use material receptacles appropriately.
- All processing facility tools should be clearly designated to denote those tools that are only used for food contact and those that are used for general cleaning and may contact non-food contact surfaces.
- Old, unused equipment should be removed from the processing area and stored in a manner that does not present a food safety hazard.
- The employee break area should be equipped with trash receptacles that are emptied and cleaned daily.
- Appropriate signage should be displayed throughout the processing facility to remind employees to adhere to company policies related to food safety (e.g. use of equipment, hygiene).

6.2 The Best Practices Are: Pest Control

A pest control program should be implemented throughout the entire processing facility to eliminate and exclude pests (such as rodents, birds, reptiles, and insects) that may harbor or be a vector for a variety of pathogens. As part of the plant's pest control program, consider frequent monitoring of affected and treated areas to assess accurately the effectiveness of the program.

- All pesticides, traps, bait, and chemicals used in pest control must be acceptable for use in and around a food processing facility and used in accordance with local, state, and federal regulations.
  - Permit the use of insecticides or rodenticides inside the facility only under precautions and restrictions that will protect against the contamination of fresh culinary herbs, food-contact surfaces, and food-packaging materials. Rodent bait materials are not to be used within production areas or packaging material storage areas.
  - These materials must only be used by properly trained and accredited personnel. A record of use should be kept available for inspection along with the appropriate applicators licenses and documentation. Applicators should also show records of training, continuing education, etc.
  - Rodent traps should be deployed around the inside of the facility and bait stations along the outside

A pest control program should be implemented throughout the entire processing facility to eliminate and exclude pests (such as rodents, birds, reptiles, and insects) that may harbor or be a vector for a variety of pathogens.

perimeter of the facility. Detailed maps demonstrating the location of each trap and bait station should be available for review. Traps and bait stations should be inspected routinely and any corrective actions (e.g., cleaning out traps, replacing damaged traps) documented.

  - Pest control chemicals and baits should be securely stored if kept on-site.
  - A procedure should be in place for the disposal of waste pest control chemicals and empty containers and for cleaning of application equipment that protects against product and production area contamination.

- Open windows, vents, fans, and similar features should be adequately screened to prevent pest entry.
- Measures should be taken to protect packaging materials from rodents or other pests. The storage area or carton yard should be kept clean and should be included in the facility pest control program. All packaging should be covered so as to mitigate contamination by rodents, birds, wind-blown dirt, or chemical sprays.
- Doors or entrances to the facility should remain closed during operation to prevent pest entrance. Strip curtains or similar devices may be used for high traffic areas. An inspection buffer of 18 inches should be maintained on both the inside and outside perimeters of the physical facility (i.e., pallets, raw product and equipment may not be stored flush against the wall of the facility).
- If pest control is performed internally or by a third-party pest control company, a copy of the applicator's license, any chemicals used, MSDS, and a schedule of the applicator's activities and actions should be maintained and available for review.

Documentation List:

- ☐ Product flow diagram
- ☐ Hazard analysis for processing facilities
- ☐ Trap and bait station location maps
- ☐ Trap and bait station inspection log
- ☐ MSDS for pest control chemicals
- ☐ Pest control applicator's license(s)
- ☐ Pest control chemical application/activities log

7.0 Issue: Facility and Equipment Sanitation

Operators should be aware and operate in accordance with all relevant laws and regulations that describe facility sanitation practices. Operators should be aware and operate in accordance with all relevant laws and regulations with regard to handling processing and sanitation chemicals including the posting of MSDS. Cleaning and sanitizing of utensils and equipment should be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All food-contact surfaces, including work utensils and food-contact surfaces of equipment, should be cleaned and sanitized on a regularly scheduled basis to protect against contamination of the food. All chemicals used in cleaning operations should be used and labeled in accordance with the manufacturer's instructions and in accordance with relevant federal, state, and local government regulations.

Cleaning and sanitizing of utensils and equipment should be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

7.1 The Best Practices Are: General Items

- All facility and equipment inspection and maintenance activities should be documented.
- Cleaning compounds and other chemicals used in a fresh culinary herb operation should be approved for their intended use.[9]
- An MSDS should be kept on file for each sanitizing chemical.
- Use a secure, vented storage area for storing sanitizing chemicals and cleaning tools. This storage area should be away from the process area and any storage areas for raw or finished product packaging.
- A procedure should be in place for the disposal of waste sanitation chemicals and empty containers and for cleaning of equipment used in cleaning and sanitation that protects against product and production area contamination.
- Personnel with cleaning and sanitation duties should be trained:
  - To understand the principles and methods required for effective cleaning and sanitation, especially as they relate to food safety.
  - To use, handle, and store cleaning and sanitizing chemicals safely.
  - Personnel with cleaning duties should be trained in the proper cleaning and sanitizing steps of the equipment and facility.
  - In the proper use of cleaning equipment.
  - Employee training records should be archived for at least 2 years.
- Code cleaning and sanitizing implements, equipment, tools, etc. according to use to help minimize cross-contamination.

9 Appropriate chemical use can be verified in NSF's White Book™ – Nonfood Compounds Listings Directory available at http://www.nsf.org/usda/Listings.asp

7.2 The Best Practices Are: Processing Facility Sanitation (Non-Food Contact Components of the Facility)

- The non-food contact components of the facility (e.g., walls, ceilings, floors, drains, cooling equipment, mezzanines, storage areas, employee break areas) must be cleaned and sanitized on a routine basis. Establish a master sanitation schedule and written procedures (SSOPs) for these areas that clearly identify cleaning frequency, sanitizing methods, sanitizing agents, precautions, etc. Document all facility cleaning and sanitizing activities.
- Verify the efficacy of the facility cleaning and sanitation with routine environmental testing (e.g. conventional or rapid microbiological methods such as total count or bioluminescence testing). Retain all testing data and related documentation in company records.
- The facility should have a documented environmental microbial testing program screening for *Listeria* spp. with testing targeted to areas where moisture, soil or debris may accumulate (e.g., equipment exterior, floor drains). If test results are positive for *Listeria* spp., then follow-up tests for *Listeria monocytogenes* should be conducted. [10]

7.3 The Best Practices Are: Processing Equipment

- Processing equipment must be maintained clean and free from debris and should be inspected for cleanliness before operations begin each day.
- Develop a master sanitation schedule for all processing equipment. This schedule should clearly indicate the name or ID number of the piece of equipment and the frequency with which it is to be cleaned (e.g., daily, weekly, monthly, or seasonally). Document all equipment cleaning and sanitizing activities.
- Each piece of processing equipment should have written procedures for cleaning and sanitizing (SSOPs) that addresses the following:
  - At a minimum, all food-contact surfaces should be cleaned and sanitized daily.
  - Cleaning and sanitizing of utensils and equipment should be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.
- Equipment filters should be back-flushed and sanitized as part of the master sanitation schedule for packing equipment.
- Avoid cleaning and sanitizing equipment during packing operations.
- Verify and document the efficacy of equipment cleaning and sanitation with routine environmental testing (e.g., conventional or rapid microbiological methods such as total count or bioluminescence testing). Special attention should be given to grooves and niches in equipment. Testing data should be kept on file.
- All equipment inspection, maintenance, cleaning, and sanitizing activities should be documented.

7.4 The Best Practices Are: Toilets and Hand-Washing Stations Sanitation

Individual toilet and hand-washing units should be properly maintained in a clean and sanitary condition for the worker's health, safety, and comfort. Inadequately supplied or improperly maintained restrooms and hand-washing facilities may provide direct or indirect contamination of the fresh culinary herbs and water sources used on fresh culinary herbs.

- Establish a written cleaning and sanitation schedule for toilet and hand-washing stations.

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10 FDA. 2008. Guidance for Industry: Control of Listeria monocytogenes in Refrigerated or Frozen Ready-to-Eat Foods; Draft Guidance. http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodProcessingHACCP/ucm073110.htm

- Establish cleaning and sanitation procedures (SSOP) including a checklist of facility supplies.
- Maintain written documentation of service and maintenance of toilet facilities and hand-washing stations that demonstrates compliance with applicable worker health and safety regulations.

7.5 The Best Practices Are: Toilets and Hand-washing Stations Waste Disposal

Operations with poor management of human and other wastes in the processing facility can significantly increase the risk of contaminating fresh culinary herbs.

- Maintain a written waste collection service schedule.
- All waste from sanitation facilities should be disposed of according to applicable laws and regulations and not contaminate the environment of the processing facility.
- Used toilet paper should be disposed of in a sanitary manner that prevents cross contamination, specifically flushing it down the toilet. In some areas or countries, the plumbing and waste disposal system can't handle toilet paper; in these cases, toilet or waste baskets must be used and managed so as not to allow the waste paper to spill onto the floor.
- Disposal of used hand-washing water should not cause unsanitary conditions or contamination of the processing facility.

Documentation List:

- ☐ SSOP – Non-food contact surface
- ☐ Non-food contact surface master sanitation schedule
- ☐ SSOP – Toilet and hand-washing facilities
- ☐ Toilet and hand-washing facilities master sanitation schedule
- ☐ SSOP – Processing equipment
- ☐ Processing equipment master sanitation schedule
- ☐ Pre-operative inspection checklist
- ☐ Corrective action log
- ☐ Employee SSOP training records
- ☐ MSDS for cleaning chemicals
- ☐ Environmental testing schedule and results
- ☐ Toilet and hand-washing facilities service and maintenance log
- ☐ Waste collection schedule

Operations with poor management of human and other wastes in the processing facility can significantly increase the risk of contaminating fresh culinary herbs.

8.0 Issue: Employee Practices / cGMPs

Fresh culinary herbs greens are often extensively handled by employees at the processing facility. Handling by employees may transfer microorganisms of significant public health concern, therefore employee hygiene and sanitary procedures are appropriate in all environments where produce and people are in proximity. The importance of employees understanding and practicing proper hygiene cannot be overemphasized. People can transmit human pathogens to fresh produce, water supplies, and other people if they do not understand and follow basic hygienic principles. Employees should be trained regularly, in an appropriately comprehensible language, regarding basic cGMPs, food safety, and worker health and hygiene.

Training programs should emphasize employee roles and responsibilities in producing a safe product, sanitation principles and sanitary practices including appropriate and effective hand-washing, glove use and replacement, health-related policies, etc. Training should be designed to help employees understand what is expected of them and why these practices are important. This training should be documented and kept on file for review.

8.1 The Best Practices Are: Training

- Mandatory training for every employee in the company's food safety policy and plan, food safety procedures, risk recognition and reporting requirements, sanitation, and personal hygiene appropriate to their job responsibilities at hire with refresher training at prescribed frequencies.
- Document all training sessions with a general description of the subject matter, the trainer's name, the date of training, a list of all employees invited to the training and the signatures of employees attending the training indicating that they understood the information presented
- A supervisor or quality assurance personnel should conduct a daily inspection to ensure that all cGMPs are being followed. Those employees that fail to follow cGMPs should be notified and trained. Continued failure to follow cGMPs should result in dismissal.
- Use systems which aid in employee management to minimize employee traffic and minimize potential for cross contamination between work areas (e.g., color coded bump caps).
- Train employees in the proper use of hand dip and footbath stations and why it is important for the overall safety of the product. Sanitizer levels should be monitored and adjusted throughout the day.

8.2 The Best Practices Are: Hygiene

- Train employees on how, when, and why they must properly wash their hands and exposed portions of their arms. Employees must wash their hands:
  - Before beginning work.
  - Before putting on a new pair of gloves.
  - After touching human body parts or anything other than fresh culinary herbs or food contact surfaces.
  - After using the toilet.
  - After using tobacco, eating, or drinking.
  - After any activity that may contaminate hands, such as handling garbage, coughing, sneezing, or using a handkerchief or tissue, cleaning chemicals, or incoming produce before it has been washed.
  - After caring for or touching animals.
  - Before returning to a workstation.
- Instruct employees to inform the supervisor of any issues with the hand-washing or toilet units.
- If a company requires or allows employees to wear gloves when handling product, a procedure for glove

use should be established, followed, and documented

- Employees must wear gloves provided by their employer.
- Gloves should not be worn in or taken into the restroom or break areas.
- If gloves are reusable, they should be washed and sanitized daily or changed as necessary after any event that may cause gloves to become contaminated.
- If gloves are disposable, they should be changed as necessary during the work day and after any event that may cause gloves to become contaminated. Powdered disposable gloves should not be used.

- Employees should wear head and facial hair coverings.
- Employees should wear appropriate, clean protective outer garments when beginning work each day. Heavily soiled and / or damaged reusable protective outer garments should be replaced.
- Protective outer garments such as aprons and gloves should be hung on racks or in a designated area and not placed on top of product, work surfaces, equipment or packaging material.
- Employees should not take processing-related tools or protective outer garments outside the designated areas or inside the toilet facilities or employee break areas.
- Prohibit eating, drinking, or smoking outside of designated areas to reduce the potential for product contamination.
- In areas where fresh culinary herbs are present, prohibit employees from activities such as chewing gum or spitting.

8.3 The Best Practices Are: Physical Hazard Prevention

- Employees must remove all jewelry and other objects that might fall into food, equipment, or containers.
- When handling product, employees must remove or cover all hand jewelry that cannot be adequately sanitized.
- Establish storage and control procedures for employee equipment, supplies and personal belongings when not in use. All personal items should be stored in the area designated for personal items outside the processing area and in areas other than where food is exposed or where equipment or utensils are washed.
- Employees must comply with the company's glass and brittle plastic control policy for the processing areas.

8.4 The Best Practices Are: Health

- Establish a health practices program that addresses the following issues:
  - Persons who present symptoms of diarrheal disease or other infectious disease (e.g., vomiting, diarrhea, jaundice, sore throat with a fever) are prohibited from handling fresh culinary herbs and being in the production area.
  - Employees should report illnesses to supervisors before beginning work. Train supervisors to know the typical signs and symptoms of infectious disease (e.g. vomiting, nausea, diarrhea, and abdominal cramps), and appropriate action to take in the event of worker injury or illness.
  - Cuts and wounds should be covered with a suitable waterproof dressing when employees with injuries are permitted to continue working.
  - Employees with wounds or cuts that cannot be covered to prevent contact with the product should not perform tasks that require contact with fresh culinary herbs, processing equipment, packaging materials or tools until the wound has healed.

- A policy describing procedures for handling / disposing of fresh culinary herbs or food contact surfaces that have come into contact with blood or other bodily fluids.
- First aid kits should be readily available and maintained in accordance with prevailing regulation with materials kept in sanitary and usable condition

Documentation List:

- ☐ Employee attendance log for food safety policy/plan training
- ☐ SOP – Worker hygienic practices
- ☐ SOP – Employee personal effects storage and control
- ☐ SOP – Worker health practices
- ☐ SOP – Glove use
- ☐ SOP – Glass and brittle plastic policy

Storage and transportation of finished food should be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

9.0 Issue: Cold Storage and Warehousing

Cold storage and warehouse facilities are often the last area that house fresh culinary herbs before they are shipped to the next point of the supply chain. The conditions and sanitation programs of these facilities are critical in maintaining the integrity of the finished product before it exits the facility. Storage and transportation of finished food should be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

9.1 The Best Practices Are:

- Product placement and storage should not facilitate cross-contamination (e.g., pallets placed on top of bins, iced containers placed above containers with non-iced product).
- Storage and warehousing of finished fresh culinary herbs should be under conditions that will protect them against physical, chemical, and microbial contamination as well as against deterioration of the product and the container.
- The packing facility should have a cold storage area with refrigeration that is appropriate for the product.
- Refrigeration units should be inspected on a regular basis and kept in good operating condition.
- Monitor and document temperatures in the cold storage using calibrated temperature sensors.
- Temperature monitoring devices should be placed in the warmest area of the refrigerator unit and calibrated on a regular basis.
- Measures should be taken to prevent condensate and defrost water from evaporator-type cooling systems from dripping onto finished product.

- Avoid practices that cause condensation to form in the facility (i.e. putting product into storage before it is properly cooled).
- Condensate / water from evaporator-type refrigeration systems should be contained in catchments designed to assure that it does not become a source of contamination. Water from refrigeration catchments should be drained into a drainage line and not onto the floor.
- The storage area should be included in scheduled cleaning and sanitation operations. If finished product is present during cleaning of ceiling, floors or drains and equipment such as pressure washer/sprayers, steam or foam cleaners are being used, ensure that water does not splash on product.
- The storage area should be included in the facility pest control program.
- Forklifts and other pallet moving equipment should be included in the master sanitation schedule and should be cleaned on a regular basis.
- Verify the efficacy of the cold storage and warehouse cleaning and sanitation with routine environmental testing (e.g., conventional microbiological methods or rapid methods for total bacterial count or bioluminescence testing). Testing data should be maintained on file.
- Cleaning and sanitation activities should be documented.

Documentation List:

- ☐ SOP – Refrigeration unit inspection
- ☐ Refrigeration unit inspection log
- ☐ Temperature monitoring device calibration log
- ☐ SSOP – Warehouse/cold storage area

10.0 Issue: Finished Product Containers and Packaging Materials

Any material including packaging material that comes into contact with fresh culinary herbs might result in contamination. Maintaining a program that inspects packaging materials throughout their use (e.g., at arrival, during use, and after packaging) in a processing operation helps to reduce the potential for these materials to contaminate products.

10.1 The Best Practices Are:

- Establish an SOP for inspecting all incoming finished product packing materials and shipping containers to ensure that they are in sanitary condition and suitable for use. The inspection procedure should also include an inspection of vehicles that transport these containers to ensure no foreign material, pests, or pest contamination exists.
- Store finished product containers in a designated area on clean pallets in a controlled area with coverings to protect them from potential contamination and prevent the intrusion of foreign material, including wind-blown dust and debris.
- Include finished product container storage areas in the company's pest control program.
- The finished product containers' storage area should be maintained with an 18-inch perimeter to facilitate inspection, cleaning, and placement of pest control devices.
- Any finished product containers that are identified as potentially contaminated and not suitable for use in storing food products should be discarded.

- Establish a pallet inspection and repair program (SOP). Pallets used with finished product containers should be in good condition (i.e., free from loose pieces such as nails or staples) and not used for anything other than processing activities. Damaged wood pallets should not be used.

Documentation List:

- ☐ SOP – Finished product and packing materials inspection
- ☐ SOP – Finished product containers and packing materials storage and handling
- ☐ SOP – Pallet inspection and repair

11.0 Issue: Metal Detection

Fresh culinary herb processors may utilize metal detection to control a significant metal hazard identified in their HACCP plan, to collect data to verify that metal is not a significant hazard, or to comply with a customer's requirements. The following Best Practices apply if metal detection is used.

11.1 The Best Practices Are:

- All finished product containers should pass through metal detection. The metal detector should operate within the parameters established in the company's Food Safety Plan.
- The metal detector should be calibrated daily using ferrous, non-ferrous and stainless steel standards. Calibration should be documented.
- Check metal detector operation according to the company's HACCP plan by placing a standard in a sample product container and running it through the detector. Proper operation would result in a container being rejected. Operational tests should be documented.
- If a metal detector alarm is activated, quality control personnel should follow the company's HACCP plan in evaluating any rejected product to determine the cause.

Documentation List:

- ☐ Metal detection program
- ☐ Metal detection calibration records
- ☐ SOP – Metal detector activation

12.0 Issue: Labeling of Ready-To-Eat (RTE) and Ready-To-Use (RTU) Products

End-users, including consumers, may have difficulty in quickly and easily differentiating RTU and RTE products. RTU products require washing before consumption, and RTE products do not require washing before consumption. Clearly label products to avoid end-user confusion regarding whether or not a product needs to be washed before consumption.

12.1 The Best Practices Are:

- Clearly label RTE packages with language to indicate that the product does not require washing before consumption.
- Clearly label RTU packages with language to indicate that the product needs to be washed before consumption.

13.0 Detailed Background Guidance Information and Resources

Bioterrorism Act of 2002.
(http://www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm)
Food Facility Registration
(http://www.fda.gov/Food/FoodDefense/Bioterrorism/FoodFacilityRegistration/default.htm)
Prior notice of imported food shipments
(http://www.fda.gov/Food/FoodDefense/Bioterrorism/PriorNotice/default.htm)

Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Human Food, Code of Federal Regulations, Title 21, Part 110.
(http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=455b9bcf4b981f8e40db32e79d48356f&rgn=div5&view=text&node=21:2.0.1.1.10&idno=21)

FDA's Reportable Food Registry
(http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/default.htm)

"Food Safety Auditing Guidelines: Core Elements of Good Agricultural Practices for Fresh Fruits and Vegetables." United Fresh Produce Association, 2001.
(http://www2.unitedfresh.org/forms/store/ProductFormPublic/)

"Food Safety Begins on the Farm: A Grower Self Assessment of Food Safety Risks," National GAPs Program Cornell University, 2003.
(http://www.gaps.cornell.edu/farmassessmentws.html)

"Food Safety Guidelines for the Fresh-Cut Produce Industry," United Fresh Produce Association, 2001.
(http://www2.unitedfresh.org/forms/store/ProductFormPublic/)

"Food Security Guidelines and Questionnaire for Fresh Fruits and Vegetables," United Fresh Produce Association, 2001.
(http://www2.unitedfresh.org/forms/store/ProductFormPublic/) "Guide to Federal Food Safety and Security Inspections: Guidance on Preparing for and Successfully Directing Regulatory Inspections by FDA and other Food Authorities," United Fresh Produce Association, 2005.
(http://www2.unitedfresh.org/forms/store/ProductFormPublic/)

"Fresh-cut Produce Handling Guidelines," United Fresh Produce Association, 2001.
(http://www2.unitedfresh.org/forms/store/ProductFormPublic/)

"Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," U.S. Food and Drug Administration, 1998.
(http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064574.htm)

"Guide to Minimize Microbial Food Safety Hazards for Fresh-cut Fruits and Vegetables," U.S. Food and Drug Administration, 2008.
(http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/produceandplanproducts/ucm064458.htm)

"Guide to Traceback of Fresh Fruit and Vegetables Implicated in Epidemiological Investigations," U.S. Food and Drug Administration, 2001.
(http://www.fda.gov/downloads/ICECI/Inspections/InspectionGuides/ucm109502.doc)

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APPENDICES

for the

Commodity Specific Food Safety Guidelines for the Production, Harvest, Post-Harvest, and Processing Unit Operations of Fresh Culinary Herbs

APPENDICES

Appendices Table of Contents

These appendices are resources created to supplement the *Commodity Specific Food Safety Guidelines for the Production, Harvest, Post-Harvest, and Processing Unit Operations of Fresh Culinary Herbs*.

APPENDIX A

Sanitary Survey and Remediation Guidelines
for Water Resources

APPENDIX A

Appendix A Table of Contents

1.0 Introduction

The Sanitary Survey and Remediation Guidelines described below are to be used as follow-up to situations encountered while using the *Commodity Specific Food Safety Guidelines for the Production, Harvest, Post-Harvest, and Processing Unit Operations of Fresh Culinary Herbs*. This report provides an action plan when a water sample taken closest to the point-of-use has levels of generic *E. coli* (production) or total coliforms (packinghouse or processing facility) above acceptance criteria.

For purposes of this report:

- A sanitary survey is an inspection of the entire water system, including water source, facilities, and equipment, for the purpose of identifying conditions that may result in contamination.
- Remediation guidelines describe corrective actions corresponding to the conditions observed in the sanitary survey.

A sanitary survey of water systems should also be conducted periodically to prevent contamination. Sanitary surveys:

- Reduce the risk of waterborne disease.
- Provide an opportunity to enhance your knowledge of your water system.
- Identify and document system deficiencies.

This document prescribes a sanitary survey be performed prior to the start of the growing season on water supplies and distribution systems used in the production of fresh herbs. There are also some remediation approaches in this document that require that a Sanitary Survey be performed such as when source water used in packing and processing facilities exceeds the acceptance criteria for total coliforms. In addition, a sanitary survey is a useful tool for packing and processing facilities in managing their food safety and HACCP programs.

In the Production and Harvest Unit Operations section, Figures 3A and 3B have certain "red-box" situations when water samples taken closest to the point-of-use result in generic *E. coli* levels above an action level. In these situations, a sanitary survey is initiated to determine any potential sources of contamination. In general, when conducting a sanitary survey the reliability, quality, and vulnerability of your water system are being investigated. To get started:

While irrigating herb production areas, irrigation water tests are above acceptance criteria (this situation brings you to a red box in a decision tree in Figure 3A or 3B). Continue the investigative process as stated in the blue-box instructions in the decision tree:

1. Perform a generic *E. coli* test on a water sample taken at or as close to the source as possible. This result of this test will help to determine where the source of the contamination might reside. Depending on the results of this test, additional tests may be used to further narrow the exact location of the contamination entering the distribution system.
2. Initiate a sanitary survey of your water system:
    - Begin the sanitary survey process at the water source and continue surveying the water system between the water source and the site of the positive sample.
    - For specific water sources, follow the guidelines for conducting Sanitary Surveys and corresponding remediation outlined below.

1.1 Water sources

Whenever possible the sanitary survey should begin at the water system source as this is the first opportunity for controlling microbial contaminants. When investigating your water system source, you should identify the characteristics and activities that may lead to microbial contamination.

1.1.1 Wells

1.1.1.1 Sanitary Survey and Remediation Guidelines for Wells

Sanitary surveys of wells should focus on the integrity (meaning the state of repair) of the well components and the condition of the area surrounding the well. Inspect your wellhead on a regular basis and keep records of inspections and repairs. Issues to consider when surveying the surrounding area are:
Proximity to:

- Livestock – including animal burial grounds, feedlots, manure pits/lagoons
- Sewers and septic systems
- Irrigation systems

Tables 1 and 2 below provide guidelines for doing surveys of a well's components and the condition of the surrounding area.

Table 1. Survey of Well Components

Well Component	Survey Guidelines	Remediation Guidelines
Well casing	Listen for water running down into the well. If you can hear water, there could be a crack or hole in the casing. If you can move the casing by pushing against it, you may also have a problem with the integrity of the casing. Well casing should extend at least 18 inches above the ground.	*Contact a well contractor or other trained individual for well casing repair or construction of a new well.
Annular space (The space between two well casings or between the casing and the wall of the drilled hole.)	The annular space of the well should have a minimum of 25 feet of sealing material.	*Contact a contractor or other trained individual for correction of a deficient annular space seal or construction of a new well.
Well cap or seal	Well should be completely sealed against surface water, insects, or other foreign matter. Look for holes, missing plugs, leaking water. If artesian flow install appropriate check valve.	Replace any missing plugs and seal any openings, gaps or cracks. *Contact a well contractor or other trained individual to install a new cap and/or wellhead gasket.
Well vent	Check the cleanliness & integrity of the well vent screen. Look for tears or holes.	Vents must be covered with a screen. Replaced damaged vent screen.
Concrete well pad	Look for cracks that would allow water to enter well casing.	Seal cracks or re-pour a new concrete pad. Ground should slope away from well so that surface water cannot collect near the well.
Well pump	Make sure pump is operating properly; check for corrosion.	Clean, repair or replace pump

*Many California counties' Departments of Environmental Health have listings of licensed contractors.

Information taken from *A Guide For The Private Well Owner, Santa Clara Valley Water District, County of Santa Clara, Department of Environmental Health* and *Preparing for a Sanitary Survey: Information to Help Small Water Systems, WA State Dept of Health, DOH Pub.#331-238.*

Table 2. Survey of the Area Surrounding the Well

Issue	Survey Guidelines	Remediation Guidelines
Cleanliness	Look for debris.	Manually remove debris.
Gradient	There is standing water around the well or water draining toward the well. Well is downstream from a potential contaminant source.	Re-grade around the well so the ground slopes away from your well. Move either the well or potential contaminant source.
Potential contaminant source	Minimum horizontal distance from: Any sewer 50 ft. Watertight septic tank or subsurface sewage leaching field 100 ft. Cesspool or seepage pit 150 ft. Animal enclosure 100 ft.	Move potential contaminant source to meet the minimum guidelines.
Information taken from *DWR – Southern District Water Well Standards, Part II, Section 8* and *A Guide For The Private Well Owner, Santa Clara Valley Water District, County of Santa Clara, Department of Environmental Health*		

1.1.1.2 Remediation: Well Disinfection

If generic *E. coli* (production) or total coliforms (packinghouse or processing facility) level in well water sample is above corresponding action levels, wells must be disinfected in order to remove the contamination. Follow the disinfection steps outlined below and keep records of when, why and how disinfection was done.

Table 3. Disinfection Steps

Steps	Detailed Disinfection Instructions	Step Summary
1.	A chlorine solution containing at least 50 mg/l (or ppm – parts per million) available chlorine, is added to the well. Tables A-F in Appendices 1.1-1.5 lists quantities of various chloride compounds required to dose 100 feet of water-filled casing at 50 mg/l for diameters ranging from 2 to 24 inches. If bringing the well back into service quickly is desired (such as when wells have been repaired or when a pump has been repaired or replaced), the solution should contain at least 100 mg/l available chlorine. To obtain this concentration, double the amounts shown in Tables A-F.	Using Tables A-F to make a 50 ppm (mg/L) chlorine solution and add it to the well.
2.	To prevent contamination of the well during disinfection, first clean the work area around the top of the well. Remove grease and mineral deposits from accessible parts of the well head and flush the outside surfaces with chlorine solution (1/2 cup of laundry bleach in 5 gal of water). Turn off the pump. Remove the cap or the well plug on the rubber seal. There are many types of well caps and plugs. If you have questions, you should contact a licensed well driller. If you have a submersible pump, you may also want to contact a licensed well driller for advice on disinfection procedures. Wash the pump column, drop pipe, or anything inserted into the well with chlorine solution. Try to coat the sides of the casing as you pour. NOTE: To prevent later corrosion, thoroughly flush sensitive pump parts such as wiring with fresh water after disinfection process is completed.	Clean surrounding area & disinfect well head. Turn off the pump. Remove well cap. Wash sides of well casing, pump column, and anything inserted into the well with chlorine solution.
3.	After it has been placed into position, turn the pump on and off several times so as to thoroughly mix the disinfectant with the water in the well. Repeat this procedure **3-5x** at 1-hour intervals. Test for the presence of chlorine in well discharge with a residual chlorine test; if chlorine is not detected, the disinfection process should be repeated. NOTE: Inexpensive color comparator residual chlorine test kits can be purchased from most large department stores and swimming pool supply companies.	Mix well water by turning pump on and off several times until discharge tests positive for residual chlorine. Repeat 3-**5x** at 1 hr intervals.
4.	The well shall be allowed to stand without pumping for 24 hours.	Let pump/well rest for 24 hours.

Steps	Detailed Disinfection Instructions	Step Summary
5.	The waste water shall then be pumped to land and contained. Avoid all water conveyance features such as swales, ditches, canals, creeks or streams. Do not allow overland flow to reach surface waters. Pump until presence of chlorine is not detectable. The absence of chlorine is best determined by testing for available chlorine residual (Inexpensive color comparator residual chlorine test kits can be purchased from most large department stores and swimming pool supply companies.). NOTE: Heavily chlorinated water should not be discharged into any plumbing system that utilizes individual sewage disposal systems (septic tanks). Such strong disinfectants could neutralize the bacteria needed to stabilize the sewage and also could damage the soil adsorption system.	Pump water to a safe waste location until chlorine is no longer detected.
6.	A bacteriological sample shall be taken and submitted to a laboratory for examination. For individual wells, technical advice regarding the collection of bacteriological samples may be obtained from your local health departments or from the laboratories that will examine the sample. If no technical assistance is available, use the following procedure: Use a new sterile sample collection container (it can be a collection bag i.e. Whirl-Pak®) preferably a bottle provided by the laboratory to ensure the integrity of the sample, but before sampling ensure that the sample container is properly labeled with location, date, and time of sampling. It is extremely important that nothing except the water to be analyzed come in contact with the inside of the bottle or the cap; the water must not be allowed to flow over an object (such as the hands) and into the container while it is being filled. If the water is collected from a sample tap, turn on the tap and allow the water to flow for 2 or 3 minutes before collecting the sample. Do not rinse the sample container. The sample should be delivered to the laboratory as soon as possible and in no case more than 30 hours after its collection. It is recommended to chill samples in an ice chest or refrigerator immediately after collection. During delivery, the sample should be kept as cool as possible. Do not freeze samples. U.S EPA recommends holding water samples below 50°F during transit when testing for total coliforms; however, there is evidence this is also valid for *E.coli*.	Take a water sample using sanitary techniques and submit it to a lab for testing.

Steps	Detailed Disinfection Instructions	Step Summary
7.	Testing should be performed and results interpreted. Testing for total coliforms is currently approved by U.S. EPA to verify drinking water disinfection with "zero" as the Maximum Contaminant Level Goal (MCLG). If the laboratory analysis indicates microbial contamination, the disinfection procedure should be repeated. Depending on the level of contamination, it may be necessary to use a higher concentration chlorine solution (several times that shown in Tables A-F in Appendices 1.1-1.5) and re-test the water. If repeated attempts to disinfect the well are unsuccessful, a detailed investigation to determine the cause of the contamination should be undertaken.	If testing shows microbial levels are still above acceptable action levels, repeat the disinfection process.

Information taken from *DWR –Southern District, Water Well Standards, Appendix C.*
Additional resources:

WHO. 2011a. Technical notes on drinking-water, sanitation and hygiene in emergencies: Cleaning and disinfecting wells. Geneva: World Health Organization.
CGA. 1995. Article 500 – Well disinfection. Santa Rosa: California Groundwater Association. Adopted July 15, 1995.

See Tables A-F in Appendices 1.1 – 1.5 for the amount of chlorine compound required to dose specific volumes of water-filled well casing at 50 milligrams per liter (mg/L) [1]

- Appendix 1.1 – 65% Calcium Hypochlorite[2] (Dry Weight) [3]
- Appendix 1.2 – 70% Calcium Hypochlorite[2] (Dry Weight) [3]
- Appendix 1.3 – 25% Chloride of Lime [3]
- Appendix 1.4 – 5.25% Sodium Hypochlorite [4]
- Appendix 1.5 – 12.5% Sodium Hypochlorite

1. Some authorities recommend a minimum concentration of 100 mg/L. See instructions given in Appendices to calculate higher concentrations.
2. HTH, Perchloron, Pittchlor, etc.
3. Where dry chlorine is used, it should be mixed with water to form a chlorine solution prior to placing it into the well. Note that dry chlorine should always be added to water, not vice versa. Further, the chemical should be added slowly. These precautions are necessary to lessen the possibility of a violent chemical reaction.
4. Household bleaches such as Clorox, etc.
5. Review Material Safety Data Sheets (MSDS) and labels before performing disinfection activities.

1.1.2 Surface Water in Canals, Laterals, and Ditches

1.1.2.1 Sanitary Survey and Remediation Guidelines for Surface Water

Sanitary surveys of canals, laterals, and ditches should focus on the integrity of surrounding bank systems focusing on potential point source and non-point source confluences (e.g. drainage into these systems). Inspections should occur on a regular basis. Keep records of the date of inspection and any observations made.

Table 4. Guidelines for Assessment of Surface Water

Issues	Survey Guidelines	Remediation Guidelines
Evidence of animal intrusion around the water source	Look for evidence of animal intrusion (observed animal in canal, fecal deposits, or animal carcasses).	Remove animal debris; if animal intrusion is a regular occurrence, investigate the potential cause for intrusion and re-test the source.
Contaminating waters	Look for dirty/contaminated water that may be draining into the canal.	Redirect contaminating water with diversion dikes, gradients, inlet/outlet control structures, etc.
Cleanliness	Look for trash and debris accumulation.	Remove and dispose of items away from water.

1.1.2.2 Remediation by Disinfection

Management of microbial contamination in flowing water is difficult. If water source is not from a managed irrigation district, disinfection is not an option. If water source is from a managed irrigation district, contact the irrigation district manager. It may also be possible to treat (disinfect) water between pump and filter or after filter.

1.1.3 Well Reservoirs

1.1.3.1 Sanitary Survey and Remediation Guidelines for Well Reservoirs

Sanitary surveys of well reservoirs should focus on the condition of the source water, the integrity of the reservoir's surrounding bank system, and potential for contamination from both point source (e.g. animal feces) and non-point sources (e.g. influent). Inspections should occur on a regular basis. Keep records of the date of inspection and any observations made.

Table 5. Guidelines for Assessment of Well Reservoirs

Issues	Survey Guidelines	Remediation Guidelines
Contaminated well (source) water	Biannual or pre-production testing of source or well water as described in Decision Tree for Well Head reveals contamination.	Options: • Drain reservoir and allow to dry. Disinfect connection system before refilling reservoir with disinfected well water. • Treat water as it is taken from the reservoir.
Evidence of animal intrusion around the water source	Look for evidence of animal intrusion (observed animal in reservoir, fecal deposits, carcasses, etc.).	Remove animal debris. If animal intrusion is a regular occurrence consider isolating reservoir with fences.
Contaminating influent	Look for dirty/contaminated water that may be draining into reservoir. Caution should be exercised when back-flushing filtration systems so that this water does not return directly to the source.	Redirect water with diversion dikes, gradients, drainage pipes, inlet control structures, etc. A managed grassed buffer zone around reservoir (but not on banks) helps prevent contamination.
Overflow pipe	Observe whether opening is clean and free of weeds and debris.	Cover opening with a mesh screen.

1.2 Irrigation Systems

Contamination of irrigation systems can be avoided with proper maintenance and storage. Documented inspections should occur on a routine basis, and additionally when microbial levels of irrigation water are above acceptable levels.

1.2.1 Sanitary Survey for Irrigation Systems

- Mechanical components (Clark 1996; Benham 2002)
  - Check primary and secondary filtration equipment for cleanliness and proper function.
  - Check for leaks on seals, gaskets, and fittings.
- Water lines
  - Check water lines for visual evidence of microbial growth (Clark 1996).
    - white stringy slime
    - red filamentous sludge
  - For drip irrigation systems, use of chlorination treatment is advised if water source is not chlorinated.[1]
    - Because bacteria can grow in filters, inject chlorine upstream from filter units.
    - Chlorine may be injected continuously (at concentration of 1-2 ppm) or as a shock treatment (at concentrations of 10-30 ppm).
    - A general formula for calculating the amount of chlorine for injection is: (Clark 1996; see footnote for an example) 2

      IR = Q x C x 0.006/S
      Where IR = injection rate (gal/hr); Q = irrigation system flow rate (gal/min); C = the desired chlorine concentration (ppm); and S = strength of chlorine solution used (percent).
    - Chlorine materials commonly used and their corresponding strength (S)

      Sodium hypochlorite (household bleach): 5.25 – 15%
      Calcium hypochlorite (dry): 65 – 70%
      Chlorine gas: 100%
    - It may be necessary to lower the pH during chlorination to increase the effectiveness of the microbial action.3
      - pH should be ≤ 7.0
      - acid and chlorine should be added to the system 2 – 3 feet apart
      - never combine chlorine and acid in the same container
  - Establish a documented regular maintenance schedule of inspection and flushing.

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[2] Example: A grower wishes to use household bleach (NaOC at 5.25% active chlorine) to achieve a 3 ppm chlorine level at the injection point. The flow rate of his irrigation system is 90 gal/min. IR = 90 gal/min x 3 ppm x 0.006/5.25 = 0.31 gallon per hour. At an irrigation flow rate of 90 gal/min, the grower is pumping: 90 gal/min x 60 min = 5400 gal/hr. The goal is to inject 0.31 gallon of bleach into 5400 gallons of water each hour that injection occurs. If the injector is set for a 300:1 ratio, it will inject 5400/300 or 18 gal/hr. Then, 0.31 gallon of bleach should be added to 18 gallons of water in the stock solution. Note: be careful to use the same time units (hours) when calculating the injection rate.

2

3 Note: Chlorine in solution exists as hypochlorus acid (HOC) and hypochlorite (OC-). HOC is 40-80x more effective at killing microorganisms than OC- and water with a lower pH increases the amount of HOC. 1

1.3 Water Holding Tanks

The water holding tank site should be well maintained and properly graded. The tank should be located away from livestock and septic systems.

1.3.1 Sanitary Survey for Water Holding Tank

- Area around the tank:
  - Whether it is on the ground or elevated, the base of the tank should be visible
  - Should be clean and free of debris and weeds
- On a routine basis inspect each water holding tank to ensure:
  - Structural soundness (interior and exterior damage or rust)
  - No vegetation is growing on tank
  - Access hatch lids are properly gasketed and secured
  - If vents are present, they should be adequately screened with a corrosion resistant material
  - The overflow and drain pipes are screened and have proper air gaps
- Tanks should be cleaned and sanitized on a routine basis (WHO 2011b).

1.3.2 Remediation: Disinfection

If water in a holding tank tests positive for generic *E. coli*, contact a water system contractor or other trained individual to clean and disinfect the tank.

1.4 Water Distribution System

Since almost all of the distribution system components are underground, a map of your water distribution system would be helpful. If however, a map is not available, check exposed components for any vulnerability to contaminants. Signs of damaged underground components may include unexplained erosion or patches of lush green grass.

1.4.1 Cross Connections

As part of the Sanitary Survey, check for cross connections in your water system. The EPA defines a cross connection as an actual or potential physical connection between a water system and another water source of unknown or questionable quality. For example, agricultural water systems should not be cross-connected with human or animal waste systems. Water systems intended to convey untreated human or animal waste should be separated from conveyances utilized to deliver agricultural water.

Any physical connection between agricultural water systems and systems with unknown water quality could allow water of questionable quality to backflow into the agricultural water system. An unintentional, potential cross connection can occur in places where proper air gaps between water surfaces and water sources are not maintained and therefore allow flow reversals. An example of an unintentional cross connection is a hose with one end attached to a water line and the other end lying in a tub of water, a fountain base, or a fish pond.

Table 6. Sanitary Survey of Distribution System

Issues	Remediation Guidelines
There are cross-connections in the plumbing system.	Make sure that your plumbing is not connected to another source of water that may be contaminated (e.g. a defunct community water system, animal waste system).
There is not adequate back-flow protection.	Install a back-flow prevention device on every outdoor faucet (available at most hardware and plumbing supply stores).
There are dead-end or unused water lines connected to your plumbing system.	Flush lines regularly or remove any used lines or sections of the water system.
There are abandoned or inactive wells on my property.	When no longer in use, wells must be destroyed to prevent them from functioning as a vertical conduit for contaminants.

2.0 Summary and Conclusions

- Have your entire water system checked annually by a licensed contractor or other trained individual, and as required in the decision trees in the *Commodity Specific Food Safety Guidelines for the Production, Harvest, Post-Harvest, and Processing Unit Operations of Fresh Culinary Herbs*.
- Keep detailed records every time a sanitary survey is conducted. Documentation should include:
  - Date
  - A description of the condition of the water system
  - Location and description of problem areas and the corresponding repairs and/or resolutions.

3.0 References

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How to use tables in Appendices 1:1 – 1:5

Step 1: Determine the pipe diameter of your well in inches.

Step 2: Determine the well depth (or pipe length) of your well in feet (The company that constructed the well should be able to provide you with the well depth if you do not have it in your records).

Step 3: Determine the water level of your well in feet from the top of the well.

Step 4: Subtract the water level from the well depth to determine the length of pipe containing water (ft.).

Step 5: Using the table for the particular disinfectant product listed on the next five pages, match your pipe diameter with your calculated length of pipe containing water to determine the amount of disinfectant (e.g., 70% calcium hypochlorite) required (Example – If you have a well that has a pipe diameter of 6 inches and a length of pipe containing water that is 60 ft., you would use 0.84 oz. or 23.8 grams of (70%) calcium hypochlorite).

Step 6: Decide what concentration of chlorine is required for the well disinfection. If you want to use a 50 mg/L chlorine solution, use the number that you derived in the table. If you want a **100 mg/L chlorine solution,** use the number that you derived in the table **multiplied by 2**. If you want a **200 mg/L chlorine solution,** use the number that you derived in the table **multiplied by 4**.

Step 7: **NOTE** — If you are going to weigh out the disinfectant product in **grams, use the second Table on each page — these numbers are metric**.

Appendix 1.1: Conversion table for calculating the amount of (65%) Calcium Hypochlorite required to dose specific well volumes at 50 mg/L.

Table A

(65%) Calcium Hypochlorite (Dry Weight in ounces)

Pipe Diameter (inches)	Length of Pipe Containing Water (ft.)																		
	100	95	90	85	80	75	70	65	60	55	50	45	40	35	30	25	20	15	10
2	0.17	0.16	0.15	0.14	0.13	0.13	0.12	0.11	0.10	0.09	0.08	0.08	0.07	0.06	0.05	0.04	0.03	0.03	0.02
4	0.67	0.64	0.60	0.57	0.54	0.50	0.47	0.44	0.40	0.37	0.34	0.30	0.27	0.23	0.20	0.17	0.13	0.10	0.07
6	1.51	1.43	1.36	1.28	1.21	1.13	1.06	0.98	0.91	0.83	0.75	0.68	0.60	0.53	0.45	0.38	0.30	0.23	0.15
8	2.68	2.55	2.41	2.28	2.15	2.01	1.88	1.74	1.61	1.48	1.34	1.21	1.07	0.94	0.80	0.67	0.54	0.40	0.27
10	4.19	3.98	3.77	3.56	3.35	3.14	2.93	2.72	2.51	2.30	2.10	1.89	1.68	1.47	1.26	1.05	0.84	0.63	0.42
12	6.03	5.73	5.43	5.13	4.83	4.53	4.22	3.92	3.62	3.32	3.02	2.72	2.41	2.11	1.81	1.51	1.21	0.91	0.60
16	10.73	10.19	9.66	9.12	8.58	8.05	7.51	6.97	6.44	5.90	5.36	4.83	4.29	3.75	3.22	2.68	2.15	1.61	1.07
20	16.76	15.92	15.09	14.25	13.41	12.57	11.73	10.90	10.06	9.22	8.38	7.54	6.71	5.87	5.03	4.19	3.35	2.51	1.68
24	24.14	22.93	21.72	20.52	19.31	18.10	16.90	15.69	14.48	13.28	12.07	10.86	9.66	8.45	7.24	6.03	4.83	3.62	2.41

Table B

(65%) Calcium Hypochlorite (Dry Weight in grams)

Pipe Diameter (inches)	Length of Pipe Containing Water (ft.)																		
	100	95	90	85	80	75	70	65	60	55	50	45	40	35	30	25	20	15	10
2	4.8	4.5	4.3	4.0	3.8	3.6	3.3	3.1	2.9	2.6	2.4	2.1	1.9	1.7	1.4	1.2	1.0	0.7	0.5
4	19.0	18.1	17.1	16.2	15.2	14.3	13.3	12.4	11.4	10.5	9.5	8.6	7.6	6.7	5.7	4.8	3.8	2.9	1.9
6	42.8	40.6	38.5	36.4	34.2	32.1	29.9	27.8	25.7	23.5	21.4	19.2	17.1	15.0	12.8	10.7	8.6	6.4	4.3
8	76.0	72.2	68.4	64.6	60.8	57.0	53.2	49.4	45.6	41.8	38.0	34.2	30.4	26.6	22.8	19.0	15.2	11.4	7.6
10	118.8	112.9	106.9	101.0	95.0	89.1	83.2	77.2	71.3	65.3	59.4	53.5	47.5	41.6	35.6	29.7	23.8	17.8	11.9
12	171.1	162.5	154.0	145.4	136.9	128.3	119.8	111.2	102.6	94.1	85.5	77.0	68.4	59.9	51.3	42.8	34.2	25.7	17.1
16	304.1	288.9	273.7	258.5	243.3	228.1	212.9	197.7	182.5	167.3	152.1	136.9	121.7	106.4	91.2	76.0	60.8	45.6	30.4
20	475.2	451.5	427.7	403.9	380.2	356.4	332.7	308.9	285.1	261.4	237.6	213.8	190.1	166.3	142.6	118.8	95.0	71.3	47.5
24	684.3	650.1	615.9	581.7	547.4	513.2	479.0	444.8	410.6	376.4	342.2	307.9	273.7	239.5	205.3	171.1	136.9	102.6	68.4

Appendix 1.2: Conversion table for calculating the amount of (70%) Calcium Hypochlorite required to dose specific well volumes at 50 mg/L.

Table C

(70%) Calcium Hypochlorite (Dry Weight in ounces)

Pipe Diameter (inches)	Length of Pipe Containing Water (ft.)																		
	100	95	90	85	80	75	70	65	60	55	50	45	40	35	30	25	20	15	10
2	0.16	0.15	0.14	0.13	0.12	0.12	0.11	0.10	0.09	0.09	0.08	0.07	0.06	0.05	0.05	0.04	0.03	0.02	0.02
4	0.62	0.59	0.56	0.53	0.50	0.47	0.44	0.40	0.37	0.34	0.31	0.28	0.25	0.22	0.19	0.16	0.12	0.09	0.06
6	1.40	1.33	1.26	1.19	1.12	1.05	0.98	0.91	0.84	0.77	0.70	0.63	0.56	0.49	0.42	0.35	0.28	0.21	0.14
8	2.49	2.37	2.24	2.12	1.99	1.87	1.74	1.62	1.49	1.37	1.25	1.12	1.00	0.87	0.75	0.62	0.50	0.37	0.25
10	3.89	3.70	3.50	3.31	3.11	2.92	2.72	2.53	2.33	2.14	1.95	1.75	1.56	1.36	1.17	0.97	0.78	0.58	0.39
12	5.60	5.32	5.04	4.76	4.48	4.20	3.92	3.64	3.36	3.08	2.80	2.52	2.24	1.96	1.68	1.40	1.12	0.84	0.56
16	9.96	9.46	8.97	8.47	7.97	7.47	6.97	6.48	5.98	5.48	4.98	4.48	3.98	3.49	2.99	2.49	1.99	1.49	1.00
20	15.57	14.79	14.01	13.23	12.45	11.67	10.90	10.12	9.34	8.56	7.78	7.00	6.23	5.45	4.67	3.89	3.11	2.33	1.56
24	22.41	21.29	20.17	19.05	17.93	16.81	15.69	14.57	13.45	12.33	11.21	10.09	8.97	7.84	6.72	5.60	4.48	3.36	2.24

Table D

(70%) Calcium Hypochlorite (Dry Weight in grams)

Pipe Diameter (inches)	Length of Pipe Containing Water (ft.)																		
	100	95	90	85	80	75	70	65	60	55	50	45	40	35	30	25	20	15	10
2	4.4	4.2	4.0	3.8	3.5	3.3	3.1	2.9	2.6	2.4	2.2	2.0	1.8	1.5	1.3	1.1	0.9	0.7	0.4
4	17.7	16.8	15.9	15.0	14.1	13.2	12.4	11.5	10.6	9.7	8.8	7.9	7.1	6.2	5.3	4.4	3.5	2.6	1.8
6	39.7	37.7	35.7	33.8	31.8	29.8	27.8	25.8	23.8	21.8	19.9	17.9	15.9	13.9	11.9	9.9	7.9	6.0	4.0
8	70.6	67.1	63.5	60.0	56.5	53.0	49.4	45.9	42.4	38.8	35.3	31.8	28.2	24.7	21.2	17.7	14.1	10.6	7.1
10	110.3	104.8	99.3	93.8	88.3	82.7	77.2	71.7	66.2	60.7	55.2	49.6	44.1	38.6	33.1	27.6	22.1	16.5	11.0
12	158.9	150.9	143.0	135.0	127.1	119.1	111.2	103.3	95.3	87.4	79.4	71.5	63.5	55.6	47.7	39.7	31.8	23.8	15.9
16	282.4	268.3	254.2	240.1	225.9	211.8	197.7	183.6	169.4	155.3	141.2	127.1	113.0	98.8	84.7	70.6	56.5	42.4	28.2
20	441.3	419.2	397.1	375.1	353.0	331.0	308.9	286.8	264.8	242.7	220.6	198.6	176.5	154.4	132.4	110.3	88.3	66.2	44.1
24	635.4	603.7	571.9	540.1	508.3	476.6	444.8	413.0	381.3	349.5	317.7	285.9	254.2	222.4	190.6	158.9	127.1	95.3	63.5

Appendix 1.3: Conversion table for calculating the amount of (25%) Chloride of Lime required to dose specific well volumes at 50 mg/L.

Table E

(25%) Chloride of Lime (Dry Weight in ounces)

Pipe Diameter (inches)	Length of Pipe Containing Water (ft.)																		
	100	95	90	85	80	75	70	65	60	55	50	45	40	35	30	25	20	15	10
2	0.44	0.41	0.39	0.37	0.35	0.33	0.31	0.28	0.26	0.24	0.22	0.20	0.17	0.15	0.13	0.11	0.09	0.07	0.04
4	1.74	1.66	1.57	1.48	1.39	1.31	1.22	1.13	1.05	0.96	0.87	0.78	0.70	0.61	0.52	0.44	0.35	0.26	0.17
6	3.92	3.73	3.53	3.33	3.14	2.94	2.75	2.55	2.35	2.16	1.96	1.77	1.57	1.37	1.18	0.98	0.78	0.59	0.39
8	6.97	6.62	6.28	5.93	5.58	5.23	4.88	4.53	4.18	3.84	3.49	3.14	2.79	2.44	2.09	1.74	1.39	1.05	0.70
10	10.90	10.35	9.81	9.26	8.72	8.17	7.63	7.08	6.54	5.99	5.45	4.90	4.36	3.81	3.27	2.72	2.18	1.63	1.09
12	15.69	14.91	14.12	13.34	12.55	11.77	10.98	10.20	9.41	8.63	7.84	7.06	6.28	5.49	4.71	3.92	3.14	2.35	1.57
16	27.89	26.50	25.10	23.71	22.31	20.92	19.53	18.13	16.74	15.34	13.95	12.55	11.16	9.76	8.37	6.97	5.58	4.18	2.79
20	43.58	41.40	39.22	37.05	34.87	32.69	30.51	28.33	26.15	23.97	21.79	19.61	17.43	15.25	13.07	10.90	8.72	6.54	4.36
24	62.76	59.62	56.48	53.35	50.21	47.07	43.93	40.79	37.66	34.52	31.38	28.24	25.10	21.97	18.83	15.69	12.55	9.41	6.28

Table F

(25%) Chloride of Lime (Dry Weight in grams)

Pipe Diameter (inches)	Length of Pipe Containing Water (ft.)																		
	100	95	90	85	80	75	70	65	60	55	50	45	40	35	30	25	20	15	10
2	12.4	11.7	11.1	10.5	9.9	9.3	8.6	8.0	7.4	6.8	6.2	5.6	4.9	4.3	3.7	3.1	2.5	1.9	1.2
4	49.4	47.0	44.5	42.0	39.5	37.1	34.6	32.1	29.7	27.2	24.7	22.2	19.8	17.3	14.8	12.4	9.9	7.4	4.9
6	111.2	105.6	100.1	94.5	89.0	83.4	77.8	72.3	66.7	61.2	55.6	50.0	44.5	38.9	33.4	27.8	22.2	16.7	11.1
8	197.7	187.8	177.9	168.0	158.2	148.3	138.4	128.5	118.6	108.7	98.8	89.0	79.1	69.2	59.3	49.4	39.5	29.7	19.8
10	308.9	293.4	278.0	262.6	247.1	231.7	216.2	200.8	185.3	169.9	154.4	139.0	123.6	108.1	92.7	77.2	61.8	46.3	30.9
12	444.8	422.6	400.3	378.1	355.8	333.6	311.4	289.1	266.9	244.6	222.4	200.2	177.9	155.7	133.4	111.2	89.0	66.7	44.5
16	790.8	751.2	711.7	672.1	632.6	593.1	553.5	514.0	474.5	434.9	395.4	355.8	316.3	276.8	237.2	197.7	158.2	118.6	79.1
20	1235.6	1173.8	1112.0	1050.2	988.4	926.7	864.9	803.1	741.3	679.6	617.8	556.0	494.2	432.4	370.7	308.9	247.1	185.3	123.6
24	1779.2	1690.2	1601.3	1512.3	1423.4	1334.4	1245.4	1156.5	1067.5	978.6	889.6	800.6	711.7	622.7	533.8	444.8	355.8	266.9	177.9

Appendix 1.4: Conversion table for calculating the amount of (12.5%) Sodium Hypochlorite required to dose specific well volumes at 50 mg/L.

Table G

(12.5%) Sodium Hypochlorite (Liquid Measure in fluid ounces)

Pipe Diameter (inches)	Length of Pipe Containing Water (ft.)																		
	100	95	90	85	80	75	70	65	60	55	50	45	40	35	30	25	20	15	10
2	0.84	0.79	0.75	0.71	0.67	0.63	0.58	0.54	0.50	0.46	0.42	0.38	0.33	0.29	0.25	0.21	0.17	0.13	0.08
4	3.34	3.18	3.01	2.84	2.67	2.51	2.34	2.17	2.01	1.84	1.67	1.50	1.34	1.17	1.00	0.84	0.67	0.50	0.33
6	7.52	7.14	6.77	6.39	6.02	5.64	5.26	4.89	4.51	4.14	3.76	3.38	3.01	2.63	2.26	1.88	1.50	1.13	0.75
8	13.37	12.70	12.03	11.36	10.70	10.03	9.36	8.69	8.02	7.35	6.68	6.02	5.35	4.68	4.01	3.34	2.67	2.01	1.34
10	20.89	19.85	18.80	17.76	16.71	15.67	14.62	13.58	12.53	11.49	10.44	9.40	8.36	7.31	6.27	5.22	4.18	3.13	2.09
12	30.08	28.58	27.07	25.57	24.06	22.56	21.06	19.55	18.05	16.54	15.04	13.54	12.03	10.53	9.02	7.52	6.02	4.51	3.01
16	53.48	50.80	48.13	45.46	42.78	40.11	37.43	34.76	32.09	29.41	26.74	24.06	21.39	18.72	16.04	13.37	10.70	8.02	5.35
20	83.56	79.38	75.20	71.02	66.85	62.67	58.49	54.31	50.14	45.96	41.78	37.60	33.42	29.25	25.07	20.89	16.71	12.53	8.36
24	120.32	114.31	108.29	102.28	96.26	90.24	84.23	78.21	72.19	66.18	60.16	54.15	48.13	42.11	36.10	30.08	24.06	18.05	12.03

Table H

(12.5%) Sodium Hypochlorite (Liquid Measure in milliliters)

Pipe Diameter (inches)	Length of Pipe Containing Water (ft.)																		
	100	95	90	85	80	75	70	65	60	55	50	45	40	35	30	25	20	15	10
2	24.7	23.5	22.2	21.0	19.8	18.5	17.3	16.1	14.8	13.6	12.4	11.1	9.9	8.6	7.4	6.2	4.9	3.7	2.5
4	98.8	93.9	89.0	84.0	79.1	74.1	69.2	64.2	59.3	54.4	49.4	44.5	39.5	34.6	29.7	24.7	19.8	14.8	9.9
6	222.4	211.3	200.2	189.0	177.9	166.8	155.7	144.6	133.4	122.3	111.2	100.1	89.0	77.8	66.7	55.6	44.5	33.4	22.2
8	395.4	375.6	355.8	336.1	316.3	296.5	276.8	257.0	237.2	217.5	197.7	177.9	158.2	138.4	118.6	98.8	79.1	59.3	39.5
10	617.8	586.9	556.0	525.1	494.2	463.3	432.4	401.6	370.7	339.8	308.9	278.0	247.1	216.2	185.3	154.4	123.6	92.7	61.8
12	889.6	845.1	800.6	756.2	711.7	667.2	622.7	578.2	533.8	489.3	444.8	400.3	355.8	311.4	266.9	222.4	177.9	133.4	89.0
16	1581.5	1502.4	1423.4	1344.3	1265.2	1186.1	1107.1	1028.0	948.9	869.8	790.8	711.7	632.6	553.5	474.5	395.4	316.3	237.2	158.2
20	2471.1	2347.6	2224.0	2100.4	1976.9	1853.3	1729.8	1606.2	1482.7	1359.1	1235.6	1112.0	988.4	864.9	741.3	617.8	494.2	370.7	247.1
24	3558.4	3380.5	3202.6	3024.6	2846.7	2668.8	2490.9	2313.0	2135.0	1957.1	1779.2	1601.3	1423.4	1245.4	1067.5	889.6	711.7	533.8	355.8

Appendix 1.5: Conversion table for calculating the amount of (5.25%) Sodium Hypochlorite required to dose specific well volumes at 50 mg/L.

Table I

(5.25%) Sodium Hypochlorite (Liquid Measure in fluid ounces)

Pipe Diameter (inches)	Length of Pipe Containing Water (ft.)																		
	100	95	90	85	80	75	70	65	60	55	50	45	40	35	30	25	20	15	10
2	1.99	1.89	1.79	1.69	1.59	1.49	1.39	1.29	1.19	1.09	0.99	0.90	0.80	0.70	0.60	0.50	0.40	0.30	0.20
4	7.96	7.56	7.16	6.76	6.37	5.97	5.57	5.17	4.77	4.38	3.98	3.58	3.18	2.79	2.39	1.99	1.59	1.19	0.80
6	17.91	17.01	16.11	15.22	14.32	13.43	12.53	11.64	10.74	9.85	8.95	8.06	7.16	6.27	5.37	4.48	3.58	2.69	1.79
8	31.83	30.24	28.65	27.06	25.47	23.87	22.28	20.69	19.10	17.51	15.92	14.32	12.73	11.14	9.55	7.96	6.37	4.77	3.18
10	49.74	47.25	44.76	42.28	39.79	37.30	34.82	32.33	29.84	27.36	24.87	22.38	19.89	17.41	14.92	12.43	9.95	7.46	4.97
12	71.62	68.04	64.46	60.88	57.30	53.72	50.14	46.55	42.97	39.39	35.81	32.23	28.65	25.07	21.49	17.91	14.32	10.74	7.16
16	127.33	120.96	114.59	108.23	101.86	95.50	89.13	82.76	76.40	70.03	63.66	57.30	50.93	44.56	38.20	31.83	25.47	19.10	12.73
20	198.95	189.00	179.05	169.11	159.16	149.21	139.26	129.32	119.37	109.42	99.47	89.53	79.58	69.63	59.68	49.74	39.79	29.84	19.89
24	286.49	272.16	257.84	243.51	229.19	214.86	200.54	186.22	171.89	157.57	143.24	128.92	114.59	100.27	85.95	71.62	57.30	42.97	28.65

Table J

(5.25%) Sodium Hypochlorite (Liquid Measure in milliliters)

Pipe Diameter (inches)	Length of Pipe Containing Water (ft.)																		
	100	95	90	85	80	75	70	65	60	55	50	45	40	35	30	25	20	15	10
2	58.8	55.9	53.0	50.0	47.1	44.1	41.2	38.2	35.3	32.4	29.4	26.5	23.5	20.6	17.7	14.7	11.8	8.8	5.9
4	235.3	223.6	211.8	200.0	188.3	176.5	164.7	153.0	141.2	129.4	117.7	105.9	94.1	82.4	70.6	58.8	47.1	35.3	23.5
6	529.5	503.0	476.6	450.1	423.6	397.1	370.7	344.2	317.7	291.2	264.8	238.3	211.8	185.3	158.9	132.4	105.9	79.4	53.0
8	941.4	894.3	847.2	800.2	753.1	706.0	659.0	611.9	564.8	517.8	470.7	423.6	376.6	329.5	282.4	235.3	188.3	141.2	94.1
10	1470.9	1397.4	1323.8	1250.3	1176.7	1103.2	1029.6	956.1	882.5	809.0	735.5	661.9	588.4	514.8	441.3	367.7	294.2	220.6	147.1
12	2118.1	2012.2	1906.3	1800.4	1694.5	1588.6	1482.7	1376.8	1270.9	1165.0	1059.0	953.1	847.2	741.3	635.4	529.5	423.6	317.7	211.8
16	3765.5	3577.2	3389.0	3200.7	3012.4	2824.1	2635.9	2447.6	2259.3	2071.0	1882.8	1694.5	1506.2	1317.9	1129.7	941.4	753.1	564.8	376.6
20	5883.6	5589.4	5295.2	5001.1	4706.9	4412.7	4118.5	3824.3	3530.2	3236.0	2941.8	2647.6	2353.4	2059.3	1765.1	1470.9	1176.7	882.5	588.4
24	8472.4	8048.8	7625.2	7201.5	6777.9	6354.3	5930.7	5507.1	5083.4	4659.8	4236.2	3812.6	3389.0	2965.3	2541.7	2118.1	1694.5	1270.9	847.2

APPENDIX B

Technical Basis Document

APPENDIX B

Appendix B Table of Contents

1.0 Introduction

This document serves as a supplementary source of information to the Commodity Specific Food Safety Guidelines for the Production, Harvest, Post-Harvest, and Processing Unit Operations of Fresh Culinary Herbs (Fresh Culinary Herbs Guide). The document established measurable best practices and guidelines ("metrics") for a variety of process areas judged to be potential contributors to the risk of microbial contamination. The intent of this document is to provide the basis and rationale for the choice of metrics used in the recommended best practices. Metrics for fresh culinary herbs are primarily based on the metrics for green onions and/or lettuce and leafy greens. In those cases, text from the Technical Basis Documents for commodity specific food safety guidelines for lettuce and leafy greens (Leafy Greens Guide) and/or green onions (Green Onions Guide) are provided for context.

In all of these commodity-specific guidelines, a three-tier approach was used to identify appropriate metrics:

1. A comprehensive literature review was conducted to establish whether a scientifically valid basis for establishing a metric has been published.
2. If the literature review did not identify published scientific support for an appropriate metric, existing standards or metrics supported by authoritative or regulatory bodies were adopted.
3. If neither scientific studies nor existing standards or metrics from authoritative bodies supported adoption of a specific metric, consensus among industry representatives and/or other stakeholders was sought.

The Fresh Culinary Herbs Guide relies on supporting scientific research for the best practices that meet the following criteria:

1. Publication in peer-reviewed scientific journals.
2. Research findings are reported in more than one peer-reviewed study.

The following sections provide a detailed explanation of the processes and rationale for derivation of the metrics.

2.0 Water Sources and Uses

2.1 Production and Harvest Unit Operations

Metrics for water sources used in agricultural applications must consider (1) which microorganisms to test for and the test methods, (2) action levels to apply, and (3) appropriate responses. An ideal test method would detect all pathogenic organisms present; however, this is not scientifically or economically feasible for many reasons:

- Concentrations of pathogenic microbes can vary widely in fecal matter. Hence, if testing focuses on specific pathogens at the exclusion of others, the presence of fecal contamination may not be detected even if significant contamination is present (Ashbolt *et al.* 2001; World Health Organization 2008). While continuous monitoring or daily testing might more reliably detect these microbes, this approach is economically unfeasible.
- Existing test methods may not be able to detect the wide variety of pathogenic organisms that might contaminate water (World Health Organization 2008). Even if water is routinely tested for the more common pathogenic organisms, this does not guarantee other pathogens are not present.

Given the statements above, and guidance and/or comments from various regulatory agencies (US EPA 1986; California Department of Health Services (CDHS) and California Department of Food and Agriculture (CDFA

2006; US FDA 2006)), use of an "indicator" microbe was determined to be the most effective and efficient testing approach. Testing for generic *E. coli* is considered the best available indicator for fecal contamination of a water source. Generic *E. coli* is generally non-pathogenic; thus, using this as an indicator organism results in action levels that are not necessarily health risk-based. Although increasing levels of generic *E. coli* in a water source are likely to correlate with increasing health risk, "bright line" levels of generic *E. coli* above which health risks are unacceptable cannot rationally be established. Action levels based on generic *E. coli* concentrations should not be considered as separating "safe" or "unsafe" levels — they should only be considered as indicators of fecal contamination or increasing bacteriological densities.

To set generic *E. coli* action levels for water used in agricultural applications, it was decided that it was not possible to use one set of levels for all uses. For instance, water that is used post-harvest should likely have more stringent standards than water that is used pre-harvest. In order to address this issue, use-specific standards for production and harvest operations were created for two uses determined to be most critical to the safety of fresh culinary herbs during these operations:

- Pre-harvest applications.
- Post-harvest direct contact applications (e.g. re-hydration, harvest equipment cleaning, bin cleaning, product cooling, product washing).

For the pre-harvest use category, a rolling average and single sample maximum metric was set. These metrics were based on water quality standards developed by the US EPA in their risk assessment of *E. coli* in recreational waters (US EPA 1986; 2003). To protect against unacceptable risk of waterborne diseases, US EPA determined that the geometric mean of *E. coli* in recreational water systems should not exceed 126 MPN *E. coli*/100 mL. In addition to this geometric mean value, they also determined single sample maximum values for various beach-use types. These single sample maximums are based on certain confidence levels of the geometric mean value of 126 MPN. For a "Designated Beach," U.S. EPA used the 70% confidence level, which is a value of 235 MPN/100 mL. These two guidelines were used to establish action levels for pre-harvest water uses. All pre-harvest water uses must meet the geometric mean requirement of 126 MPN/100 mL and a single sample maximum of 235 MPN/100 mL. The use of these values is bolstered by the adoption of the 126 MPN/100 mL geometric mean by the state of Arizona as its irrigation water quality standard. These values are also used in the Green Onions Guide and the Leafy Greens Guide as pre-harvest (direct contact) irrigation water quality metrics.

For post-harvest direct contact applications before herbs reach the packinghouse, it was determined that stringent requirements should be met due to the potential high-risk for cross-contamination, as well as the lack of additional steps to remove or reduce contamination for product that goes directly to customers without additional processing in a packinghouse or processing facility. Hence, the metric for this standard has been set at the US EPA's Maximum Contaminant Level Goal for *E. coli* in drinking water, which is zero or no detection and the detection limit is currently 2 MPN/100 mL. This value is also used in the Leafy Greens and Green Onions Guides for post-harvest water quality metrics.

A complete list of the various action levels is outlined in Table II-2 in the Fresh Culinary Herbs Guide, while decision tree explaining their use is shown in Figures 3A and 3B.

When the Leafy Greens Guide was being developed, appropriate locations for water testing were evaluated. Initially, testing the "source" of the water was thought to be most appropriate. However, several stakeholders commented that testing at the source may miss contamination introduced into the distribution systems (US FDA 2006). Hence, this guidance document follows the Leafy Greens Guide in specifying testing as close to the point-of-use as possible. If water is found to be above action levels at this location, then additional testing and the initiation of a sanitary survey are required.

Acceptable methods for testing water are similar to the methods in the Leafy Greens Guide. Since the creation of the Leafy Greens Guide in 2007, newer technologies approved by the US EPA and validated by the AOAC have been developed to provide more rapid results than the MPN methods such as described in the FDA's Bacteriological Analytical Manual. The Leafy Greens Guide has recently been revised to allow for the use of these newer technologies, and these changes have been incorporated into the Fresh Culinary Herbs Guide. However, unlike the Leafy Greens and Green Onions Guides, the Fresh Culinary Herbs Guide does not allow for presence/absence testing. The Fresh Culinary Herbs Industry Working Group recommended that because these methods are not quantitative, they do not represent the "best practices" for preventing potential microbial contamination.

2.2 Post-Harvest (Packing) and Processing Unit Operations

For water use in the packinghouse and processing facility, it was determined that source water must meet US EPA's drinking water microbiological standards. Hence, the metric for this standard has been set at the US EPA's Maximum Contaminant Level Goal for total coliforms in drinking water, which is zero or no detection and the detection limit is currently 2 MPN/100 mL. Guidelines for continuous monitoring of disinfectant in packinghouse and processing facility product washing systems are also provided in the *Commodity Specific Food Safety Guidelines for the Production and Harvest of Fresh Culinary Herbs,* Tables III-1 and IV-1 to facilitate meeting this standard.

3.0 Soil Amendments

Considerably more guidance exists for establishing metrics for soil amendments (SAs) than water sources. Many regulatory bodies have set guidelines for production of soil amendments as well as acceptable levels of microbial organisms in finished products. A complete list of the metrics is provided in Table II-3 of the Fresh Culinary Herbs Guide, and decision trees are found in Figures 4A and 4B.

3.1 Manure

The application of manure to fresh culinary herb production fields is thought to be a high risk practice, and industry discussions have centered on completely disallowing this practice.

The decision to disallow this practice is based on the Leafy Greens and Green Onions Guides, and was discussed in the Technical Basis document for those crops as follows:

> *Initially, allowing use of manure in fields used for production of lettuce and leafy greens with a suitable application interval (120 days as suggested in the National Organic Program guidance) (USDA 2002) was considered; however, this use was prohibited after discussion and comments received from multiple stakeholders. Given the long survival period of bacteria in raw manure (over 120 days in some references), it was determined that the 120 day period was not acceptable, and that raw manure should not be used in the production of lettuce and leafy greens. However, in order not to completely restrict the use of land that has at some point had raw manure applied, a one-year waiting period prior to planting lettuce and leafy greens was considered appropriate.*

The fresh herb industry group discussed reducing the one-year waiting period, but was unable to find unconditional support for a reduction in light of the varying climate and environmental conditions in herb growing areas nationwide.

3.2 Composted Soil Amendments

Due to the existence of California state regulations regarding the production of compost (CCR Title 14 - Chapter 3.1 – Article 7), these guidelines were essentially adopted "as is" for the Fresh Herb Guide, with the addition of E. coli O157:H7 testing as an additional safeguard as was done for both the Leafy Green and Green Onions Guides. These guidelines largely rely upon fecal coliforms as the indicator pathogens.

A three hurdle process was considered to be sufficient for safe application of composted SAs to fresh culinary herbs. The first hurdle recommends use of a validated process for compost production; the second recommends microbial testing, and the third recommends applying an application interval to minimize risk from remaining pathogenic microorganisms.

During the development of the Leafy Greens Guide, the use of the National Organic Program's 120-day waiting period for use of raw manure was suggested for use as an appropriate interval for composted soil amendments. However, because the 120-day period is specific to raw (uncomposted) manure, it was judged reasonable to shorten this period to 45-days for soil amendments that underwent an actively monitored composting process.

The Sampling Plan for composted SAs in the Fresh Herb Guide is the same as the Leafy Greens Guide and is based on practices recommended by compost suppliers.

3.3 Physically Heat Treated Soil Amendments

Due to limited information related to the process and expected microbial populations found in physically heat treated soil amendments, metrics were primarily based on the state of California's composting metrics described above. Some processes are discussed in the literature and this information was used to set some metrics for application intervals (US EPA 1994). Most of these US EPA-based requirements are for biosolids, but are considered to be appropriate for application to raw manure. Because the process for physically heat treating manure is much more controlled than composting, a stricter requirement for fecal coliform concentrations (<10 MPN) was considered reasonable for heat treated soil amendments.

Due to the stricter testing requirements and more tightly controlled process used with heat treated soil amendments, if a validated process is used, no application interval is required for these types of amendments. If the process is not validated, a >45-day application interval was deemed appropriate based on the same decision-making process that was used for Composted Soil Amendments (described above).

The Sampling Plan for physically heat treated SAs containing animal manure in the Fresh Herb Guide is the same as the Leafy Greens Guide and is based on practices recommended by compost suppliers.

3.4 Non-Synthetic Crop Treatments

Due to limited information related to the process and expected microbial populations found in non-synthetic crop treatments, metrics were primarily based on the composting metrics described above. However, due to the foliar application of many of these types of treatments, a more stringent guideline was considered to be appropriate for microbial testing (e.g. negative for *E. coli* O157:H7 and *Salmonella* spp.). Specific metrics are found in Table II-4 of the Fresh Herb Guide, and a decision tree for these treatments can be found in Figure 5.

Due to the stricter testing requirements and used with non-synthetic crop treatments and their intended use as foliar applicants, if a validated process is used no application interval is required for these products. If the process is not validated, a >45-day application interval was deemed appropriate based on the same decision-making process that was used for Composted Soil Amendments (described above).

4.0 Flooding

The definition of flooding used in the Leafy Green Guide was adopted for use as the definition of flooding in *Commodity Specific Food Safety Guidelines for the Production and Harvest of Fresh Culinary Herbs*. Therefore the rationale as provided in the Leafy Greens Guide's Technical Basis document pertains here.

The distance not to be harvested from the high-water mark of any flood event was selected to be 30 feet, based on the turn-around distance of farm equipment to prevent cross-contamination. This distance may be increased if there is the uncertainty about the location of the high-water mark or if some equipment has a greater turning radius— whether to increase this distance is to be determined by an appropriately trained food safety expert, with possible consultation with other experts as necessary.

The required waiting period after flooding prior to planting (60 days) was selected based on comments from regulatory bodies; these comments were consistent with original time periods based on USDA NOP guidance on use of manure (i.e., it was assumed that the worst-case flooding event would be equivalent to use of raw manure on fields) (USDA 2002). This 60-day prior to planting time period is roughly equivalent to 120-days prior to harvest depending on the specific growing season of the crop, and was considered to be easier to implement in the field.

As did the Leafy Green and Green Onions Guides, the Fresh Culinary Herbs Guide provides an option to reduce this time period to 30 days if growers can demonstrate through a valid sampling program that soil microbial levels meet specific acceptance criteria. A soil sampling protocol was developed by the Working Group under the direction of Dr. Trevor Suslow who has significant experience in soil testing following flooding events.

Regardless of the use of the standard 60-day period or the 30-day period, all decisions related to use of flooded land should be made with the consultation of a qualified food safety professional. This person should have the same qualifications as described in the Environmental Assessments section below.

5.0 Environmental Assessments

In order to maintain vigilance over the conditions associated with the production of fresh culinary herbs, periodic monitoring of production fields is required. This monitoring requires visual observation of field conditions with focus on animal activity and neighboring land uses. This monitoring should begin one week prior to planting and continue through the growing cycle. In addition, three formal assessments must also be conducted—approximately one week prior to planting, within one week prior to harvest, and at harvest.

5.1 Animal Activity in Field (Wild or Domestic)

The metrics developed for assessing animal intrusions in production fields were based on best professional judgment about proper assessment and corrective actions. In general, it was assumed that continuous monitoring for this type of event was not feasible, so periodic monitoring as well as pre-harvest and harvest formal assessments were determined to be viable alternatives.

Research has shown that not all animals are of equal risk for spreading pathogenic organism to food crops. In general, due to the likely subjective issues in determining whether or not an animal intrusion is significant and presents a risk of contaminating fresh culinary herbs, the Fresh Culinary Herb Guide recommends that a trained food safety professional be involved in decisions related to animal intrusion. The qualifications for this person are as follows:

- The design and implementation of food safety programs and systems for fresh culinary herb operations from farm to market is a complex task requiring significant knowledge from several fundamental areas of science. Personnel entrusted with management level responsibility for food safety in the fresh produce industry should have training or experience sufficient to establish a solid understanding of the principles of food safety as applied to agricultural production.
- Each fresh produce production operation involved in growing, harvesting, and / or packing fresh culinary herbs should have an appropriately qualified individual whose primary job function is development, implementation, and supervision of a comprehensive food safety program. This person should be

a direct employee; however, for some smaller operations where this is impractical, a continuous, contractual relationship involving at least quarterly direct involvement with the production operation is also an acceptable option.

- It is recommended that the individual should have some training or experience in actual food safety principles related to fresh produce.

These requirements recognize the fact that food safety in the fresh produce industry is an endeavor based on scientific principles and that significant experience and training is required to prepare individuals for food safety management responsibilities in the industry.

Because there are too many subjective situations regarding crop damage by animals it was not feasible to develop metrics for all of them. Food safety professionals should use their best professional judgment to determine whether or not to harvest fresh culinary herbs, how much buffer distance should be assigned for various crop damage incidents, and whether remedial options might reduce or eliminate risk from these events. The best practices recommend a three-foot buffer radius around areas of animal-related crop damage that cannot otherwise be adequately controlled. The only established metric for this area is the recommendation not to harvest fresh culinary herbs when there is evidence of fecal material and if fecal material is found, a minimum 5-foot radius buffer distance from the spot of the contamination should not be harvested. This distance was selected using best professional judgment based on practicality in the field.

5.2 Crop Land & Water Source Adjacent Land Uses

Developing metrics related to acceptable distances from production fields to various adjacent land and water uses was difficult due to a lack of scientific literature on the topic, and the many different environmental factors that might be encountered in the field. In order to provide some basis for determining these distances, the various types of land uses were first characterized according to their relative risk. These initial relative risks and land uses of possible concern were based on those found in the Leafy Greens Guide where they are described as follows:

> *Once the relative risk associated with each type of land or water was agreed upon, acceptable proximate distances from the land/water were determined. The use of a "proximate" metric instead of a defined lower or upper boundary was considered appropriate due to the myriad factors that might be found in a particular environment. A "one size fits all" strategy did not seem reasonable. Due to the lack of suitable science for defining "safe" distances, almost all of the distance metrics were determined by best professional judgment between the authors, growers/producers, and the expert reviewers of the document. These stakeholders also produced a list of factors that might necessitate increasing or decreasing some of the distances. As additional science is brought to bear on this issue, it is anticipated that the metrics will change accordingly.*

The fresh culinary herbs industry group decided that similar metrics were appropriate for fresh culinary herbs.

6.0 References

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USDA. 2002. *U.S. National Standards on Organic Agricultural Production and Handling, Subpart C - Organic Crop, Wild Crop, Livestock, and Handling Requirements, Preamble*. Alternative Farming Systems Information Center, United States Department of Agriculture. http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELDEV3003494

This table is supplied as guidance for testing in the event that irrigation water that exceeds the limits outlined in Table I-2 is applied to fresh herbs. The protocol outlined below is provided as an example. Please check with your laboratory prior to gathering the sample as the number and weight of samples may vary based on the size of the production block that received the irrigation water and their laboratory-specific testing methods. It is important to confirm with your laboratory that they follow AOAC-certified/approved or FDA-approved test methods.

Protocol	Measurement Criteria	Remedial Actions	Timeline
• A composite sample of fresh herbs plants still in the ground will be collected. Collect 75 to 125 g samples using a pattern that covers the irrigated field (e.g., "Z" or "Σ" patterns that are typically used for pesticide residue analysis). The number of samples depends on the size of the irrigated field and individual operation lot definitions but should not exceed 5 ac per sample.[1] Individual samples from 1 ac lots may be combined into a composite sample of at least 375 grams (snap or cut-off a bunch and do not remove with roots or soil attached; do not remove dead and damaged leaves).[2] Sampling should occur at the time of the non-compliant water test result and within 10 days or less before harvest. Care should be taken not to step on plants while traversing the field. • Reasonable aseptic sample collection techniques should be utilized among defined lots and between samples of irrigated fields from the same source. • Tests should include *E. coli* O157:H7 and *Salmonella* as well as any other microorganism deemed appropriate.[3] • Results should be available for review before harvest of the field.	• Negative or < DL (<1/125 grams) for *E. coli* O157:H7 or *Salmonella*. • Negative or <DL for any other human pathogen for which testing was conducted.	• Fresh herbs from blocks which do not pass the measurement criteria will be destroyed before harvest. • All equipment utilized to destroy the fresh herb crop must be cleaned and sanitized upon exiting the field. • The field will not be re-planted for food crop production for at least 60 days following incorporation of the contaminated crop. • This action should be documented and available for verification from the grower responsible party.	• After irrigation water that exceeds generic *E. coli* water quality standards is used on fresh herbs, product from the block must test negative for the presence of *E. coli* O157:H7 and *Salmonella*, and any other pathogen for which testing was conducted. • A compliant 5-sample geometric mean must be re-established in the water source prior to use for irrigation or other soil and crop management purposes.

[1] Maximum lot size of 5 acres is a crop-specific recommendation for fresh culinary herbs and may not be applicable for other fresh produce commodities.

[2] Confirm that your contracted laboratory uses a validated protocol (i.e. standardized temperature, buffer-to-product ratio, etc.).

[3] Individual operations may choose to test for additional target organisms (e.g. EHEC/STEC, generic *E. coli*).

This table is supplied as guidance for taking soil samples for microbial testing prior to replanting after a flooding event. The sampling protocol outlined below is provided as an example. **NOTE: Protocol specifics may vary depending on site-specific conditions and laboratory requirements. Please check with your laboratory prior to gathering the sample as the number and weight of samples may vary based on the size of the production block that was flooded and laboratory-specific testing methods** (AOAC certified/approved technologies are preferred).[1]

Sampling Protocol [2]	Measurement Criteria	Remedial Actions	Timeline
• Collect soil samples from various locations in the potentially contaminated area to assure a representative sample. A map of the flooded field that identifies the sampling locations is recommended. At a minimum, collect no less than 5 individual samples per acre (e.g. soil cores or scooped soil). Individual samples can be combined into a composite sample of at least 500 grams (with a maximum of 5 acres per composite sample). • The following two methods provide examples of how to collect samples: ○ Take soil cores to a depth of 15 cm. Composite five cores per location into one sterile polyethylene bag. ○ Using a sterile scoop, remove top 2-3 cm x 2-3 cm of surface soil from a bed (seed-bed or prepared planting row) or furrow at five locations. Composite per location into one sterile polyethylene bag	• *Salmonella* spp.: Negative or < DL (<1/ 30 grams) • Enterohemorrhagic *E. coli* (EHEC) or Shiga toxin-producing *E. coli* (STEC): Negative or < DL (<1/ 30 grams) • If EHEC/STEC test result is positive, confirm presence of pathogens with further testing.[4] If conducting a comparative analysis:[3] • Fecal coliforms:[5] a significant difference between flooded and non-flooded field(s)	• If test result for any one pathogen is positive, wait 2 weeks and retest for the same pathogen. If initial testing was quantitative and the pathogen levels were near the lower limits of the measurement criteria, than a shorter interval for retesting may be warranted. • Soil preparation such as aerating, tilling, disking, etc. helps to reduce the survival of pathogenic organisms. • All equipment utilized to till contaminated soil should be cleaned and sanitized upon exiting the field.	If test results for pathogens are negative, replant after a minimum of 30 days. The 30-day interval should commence after flood waters have receded to the point where they are not visible in the areas that are to be planted and the soil should be at a moisture level at which the grower can get equipment in to the field for preparation or soil moisture test results are in the normal range for that particular field.[6]

[1] Currently no methods for detecting EHEC/STEC in soil are AOAC-approved.
[2] From an unpublished protocol from the Suslow Lab, UC Davis.
[3] Because the levels and composition of the microbial community in soil often varies widely and "normal" levels, generally speaking, are difficult to define, comparative soil analysis may be useful in evaluating food safety risks related to a flooding event. An optimal comparison would be microbial test results of soil taken concurrently from flooded and non-flooded areas of the same field. Alternatively, post-flooding soil microbial testing results could be compared with 1) pre-flooding soil test results if microbial testing was conducted on the field in the past or 2) concurrent microbial test results from a nearby non-flooded field that has the same soil type and was managed similarly to the flooded field.
[4] Because PCR methods may result in false positives or the detection of non-viable organisms, confirming the presence of EHEC/STEC by culturing is recommended.
[5] Incubation temperature specific for fecal coliforms (also known as thermotolerant coliforms) is 42-44°C; commonly used lower incubation temperatures (e.g. 35°C) provide results for total coliforms.
[6] Methods typically used by growers to determine soil moisture content include, but are not limited to, tensiometers, electric resistance blocks, oven drying analysis, or other methods that are measurable and repeatable.

Sampling Protocol [2]	Measurement Criteria	Remedial Actions	Timeline
• If doing a comparative soil analysis, also collect from appropriate non-flooded areas. [3] • Although working in a non-sterile outdoor environment, reasonable aseptic sample collection techniques should be utilized if taking samples from different fields (i.e. change gloves, use different collection devices or clean devices thoroughly between fields). • Double-bagging of samples is preferred. This practice protects the sample integrity if the bag is damaged and against potential cross-contamination between samples from soil on the first sample bag's lip or exterior. • Samples should be stored on ice during transport and/or shipping to laboratory.		• Observe appropriate turn-around buffer zones when using vehicles and equipment in close proximity to uncontaminated areas.	

[2] From an unpublished protocol from the Suslow Lab, UC Davis.
[3] Because the levels and composition of the microbial community in soil often varies widely and "normal" levels, generally speaking, are difficult to define, comparative soil analysis may be useful in evaluating food safety risks related to a flooding event. An optimal comparison would be microbial test results of soil taken concurrently from flooded and non-flooded areas of the same field. Alternatively, post-flooding soil microbial testing results could be compared with 1) pre-flooding soil test results if microbial testing was conducted on the field in the past or 2) concurrent microbial test results from a nearby non-flooded field that has the same soil type and was managed similarly to the flooded field.

Risk Factor	Area of Observation/ Observation Point	Analysis	Rationale
Extent of flooding	Degree and duration of soil exposure to flood waters and related conditions	Identify the high water mark. What area of the field was flooded? How long was it under water?	Documentation of the flooding event to support replanting decisions.
Source of flood waters	Determine the source of flood waters. Potential sources: • Drainage canal • River • Irrigation canal • High water table • Pond • Reservoir • Catch basin • Saturated water table	Do the flood waters come from: ○ A flowing surface water source such as a river, stream or creek? ○ A pooled surface water source (e.g. pond, reservoir) that overflowed? ○ A saturated groundwater source (e.g. rising water table)? Were the floodwaters flowing over the field? or Were the floodwaters stagnate and pooled on the field?	Knowledge of the sources of flood waters will help evaluate the likelihood of soil contamination by flood waters.
Upstream contaminants	Identify sources of potential chemical contamination	Potential sources include: Manufacturing facility Storage facility Industrial complexes Equipment & automotive service industries Mining Landfills Hazardous waste disposal sites	Flood waters may contain sewage, chemicals, heavy metals, debris, human pathogens, or other contaminants. Knowledge of any possible upstream contributors of microbiological, chemical, or physical contaminants will help evaluate the likelihood of soil contamination by flood waters.

Risk Factor	Area of Observation/ Observation Point	Analysis	Rationale
	Identify sources of potential microbiological contamination	Potential sources include: Septic systems Sewage treatment plants Manure stacks Livestock facilities Barnyard Landfills Composting operations	
	Identify sources of potential contamination from physical hazards	Potential sources include: Manufacturing facility Salvage yards Landfills	
Field conditions	Determine the time interval between the flooding event, crop planting, and crop harvest	Document when water was no longer visible in the field. Was the soil reworked after flooding? If so, how many days after the flooding event was equipment able to gain access to the field?	Helpful for assessing when to begin post-flooding, pre-planting interval.
Soil	Determine the background level of indicator organisms or pathogens in the flooded-affected field	Has the soil in the flooded field been previously tested for coliforms and/or pathogens? Has the soil in a nearby field that has been similarly managed been previously tested for coliforms and/or pathogens?	If testing soil from flooded fields, historical data may be helpful in assessing the test results.

SOP template on the following pages.

Standard Operating Procedure

SOP No. X
Title: Food Safety Assessment – Template
Page 1/192

Effective Date:
Supersedes Date: New
Issued by: Author
Approved by: Supervisor

11.0 Purpose

A food safety assessment is a standardized stepwise process of addressing relevant factors affecting the safe production of fresh culinary herbs. The objective is to assess the risk to herb products from uncertain field conditions and identify appropriate remedial actions to reduce or remove the risk.

12.0 Scope

This SOP deals with food safety assessments that must be completed under the scope of the *Commodity Specific Food Safety Guidelines for the Production, Harvest, Post-Harvest, and Processing Unit Operations of Fresh Culinary Herbs* when flooding field. The goal is to provide assurances, in light of the best available scientific knowledge, that leafy greens are grown and harvested using the safest available technology.

13.0 Responsibility

The company food safety professional is responsible for conducting the actual food safety assessment and also will be responsible for updating and revising this SOP annually or as needed.

14.0 General Requirements

- Anytime a field has been flooded the grower's designated food safety professional should be notified.
- The company food safety professional should receive training in food safety risk assessment and be familiar with the literature on the topic.
- The food safety professional should travel to the impacted field(s) as soon as practical to perform the food safety assessment.
- Planting or harvest operations should stop until the food safety professional has performed the food safety assessment.
- Keep documents of all assessments and all actions that were taken to deal with flooded or past flooded fields.

15.0 Food Safety Assessment – Flooding

- Areas that have been flooded can be separated into three groups: 1) Product that has come in 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.
- If there is evidence of flooding, survey the entire production block and clearly mark and document flooded areas.
- DO NOT harvest any product within at least 30 feet of the flooded portion of the field.
- Prevent cross contamination between flooded and non-flooded areas.

- Do not drive harvest equipment through flooded areas and into non-flooded areas.
- Clean and sanitize any equipment that comes in contact with previously flooded soil.
- Place markers identifying both the high-water line of the flooding and an interval of at least 30 feet beyond this line.

- Resuming planting operations after flooding
  - Following the receding of flood water, wait at least 60 days before beginning planting operations. Or
  - This period could be decreased to 30 days if soil testing indicates soil levels of pathogens lower than the standard (acceptance criteria) outlined in Table II-6 of the Guidelines.
  - After soil has dried sufficiently to allow equipment into the field, rework the soil by aerating, tilling, disking, etc..
  - If it is decided that soil testing will be useful:
    - Call a third-party consultant or laboratory with experience in the area to assist with developing an appropriate sampling strategy. An example soil sampling protocol is provided in Appendix D.
    - In determining if testing for contaminants other than microbiological is necessary, evaluate the source of flood waters (e.g. drainage or irrigation canal, river, etc.) for potential significant upstream contaminants.
    - Document the sampling strategy and the type of sampling plan used for soil testing.
  - If it is decided that soil testing is not useful, return to the field 60 days after the floodwaters have receded and determine whether or not planting may begin based on:
    - The source of flood waters (e.g. drainage or irrigation canal, river, etc.) for potential significant upstream contaminants.
  - Planting operations should begin or resume on previously flooded ground only after the food safety professional has given approval.

California Code of Regulations, Title 14, Division 7, Chapter 3.1 Composting Operations Regulatory Requirements Article 7. Environmental Health Standards

NOTE: The regulations contained in this document may change at any time, for updates check: http://www.calrecycle.ca.gov/Laws/Regulations/Title14/ch31a5.htm#article7

Section 17868.1. Sampling Requirements.

All composting operations that sell or give away greater than 1,000 cubic yards of compost annually, and all facilities shall meet the following requirements:

(a) Operators shall verify that compost meets the maximum acceptable metal concentration limits specified in section 17868.2, and pathogen reduction requirements specified in section 17868.3. Verification of pathogen reduction requirements shall occur at the point where compost is sold and removed from the site, bagged for sale, given away for beneficial use and removed from the site or otherwise beneficially used. This verification shall be performed by taking and analyzing at least one composite sample of compost, following the requirements of this section as follows:

(1) An operator who composts green material, food material, or mixed solid waste shall take and analyze one composite sample for every 5,000 cubic-yards of compost produced.

(2) An operator who composts biosolids shall meet the sampling schedule described in Table 1 below.

Table 1
Frequencies of Compost Sampling for Biosolids Composting Facilities

Amount of Biosolids Compost Feedstock (metric tons per 365 day period)	**Frequency**
Greater than zero but annually fewer than 290	annually
Equal to or greater than 290 but fewer than 1,500	quarterly
Equal to or greater than 1,500 but fewer than 15,000	bimonthly
Equal to or greater than 15,000	monthly

(A) The amount of biosolids compost feedstock shall be calculated in dry weight metric tons.

(3) Composite sample analysis for maximum acceptable metal concentrations, specified in section 17868.2, shall be conducted at a laboratory certified by the California Department of Health Services, pursuant to the Health and Safety Code.

(b) A composite sample shall be representative and random, and may be obtained by taking twelve (12) mixed samples as described below.

(1) The twelve samples shall be of equal volume.

(2) The twelve samples shall be extracted from within the compost pile as follows:

(A) Four samples from one-half the width of the pile, each at a different cross-section;

(B) Four samples from one-fourth the width of the pile, each at a different cross-section; and,

(C) Four samples from one-eighth the width of the pile, each at a different cross-section.

(c) The EA may approve alternative methods of sampling for a green material composting operation or facility that ensures the maximum metal concentration requirements of section 17868.2 and the pathogen reduction requirements of section 17868.3 are met.

Section 17868.2. Maximum Metal Concentrations.

(a) Compost products derived from compostable materials that contains any metal in amounts that exceed the maximum acceptable metal concentrations shown in Table 2 shall be designated for disposal, additional processing, or other use as approved by state or federal agencies having appropriate jurisdiction.

Table 2
Maximum Acceptable Metal Concentrations

Constituent	Concentration (mg/kg) on dry weight basis
Arsenic (As)	41
Cadmium (Cd)	39
Chromium (Cr)	1200
Copper (Cu)	1500
Lead (Pb)	300
Mercury (Hg)	17
Nickel (Ni)	420
Selenium (Se)	36
Zinc (Zn)	2800

(b) Alternative methods of compliance to meet the requirements of Subdivision (a) of this section, including but not limited to sampling frequencies, may be approved by the EA for green and food materials composting operations and facilities if the EA determines that the alternative method will ensure that the maximum acceptable metal concentrations shown in Table 2 are not exceeded.

Section 17868.3. Pathogen Reduction.

(a) Compost products derived from compostable materials, that contains pathogens in amounts that exceed the maximum acceptable pathogen concentrations described in Subdivision (b) of this section shall be designated for disposal, additional processing, or other use as approved by state or federal agencies having appropriate jurisdiction.

(b) Operators that produce compost shall ensure that:

(1) The density of fecal coliform in compost, that is or has at one time been active compost, shall be less than 1,000 Most Probable Number per gram of total solids (dry weight basis), and the density of Salmonella sp. bacteria in compost shall be less than three (3) Most Probable Number per four (4) grams of total solids (dry weight basis).

(2) At enclosed or within-vessel composting process operations and facilities, active compost shall be maintained at a temperature of 55 degrees Celsius (131 degrees Fahrenheit) or higher for a pathogen reduction period of 3 days.

(A) Due to variations among enclosed and within-vessel composting system designs, including tunnels, the operator shall submit a system-specific temperature monitoring plan with the permit application to meet the requirements of Subdivision (b)(2) of this section.

(3) If the operation or facility uses a windrow composting process, active compost shall be maintained under aerobic conditions at a temperature of 55 degrees Celsius (131 degrees Fahrenheit) or higher for a pathogen reduction period of 15 days or longer. During the period when the compost is maintained at 55 degrees Celsius or higher, there shall be a minimum of five (5) turnings of the windrow.

(4) If the operation or facility uses an aerated static pile composting process, all active compost shall be covered with 6 to 12 inches of insulating material, and the active compost shall be maintained at a temperature of 55 degrees Celsius (131 degrees Fahrenheit) or higher for a pathogen reduction period of 3 days.

(c) Alternative methods of compliance to meet the requirements of Subdivision (b) of this section may be approved by the EA if the EA determines that the alternative method will provide equivalent pathogen reduction.

(d) Compost operations and facilities shall be monitored as follows to ensure that the standards in Subdivision (b) of this section are met:

(1) Each day during the pathogen reduction period, at least one temperature reading shall be taken per every 150 feet of windrow, or fraction thereof, or for every 200 cubic-yards of active compost, or fraction thereof.

(2) Temperature measurements for pathogen reduction shall be measured as follows:

(A) Windrow composting processes and agitated bays shall be monitored twelve (12) to twenty-four (24) inches below the pile surface;

(B) Aerated static pile composting processes shall be monitored twelve (12) to eighteen (18) inches from the point where the insulation cover meets the active compost.

Section 17868.5. Green Material Processing Requirements.

In order for a feedstock to be considered green material, as defined in section 17852(a)(21), the following requirements shall be met:

(a) The feedstock shall undergo load checking to ensure that physical contaminants are no greater than 1.0 percent of total weight. Load checking shall include both visual observation of incoming waste loads and load sorting to quantify percentage of contaminating materials.

(1) A minimum of one percent of daily incoming feedstock volume or at least one truck per day, whichever is greater, shall be inspected visually. If a visual load check indicates a contamination level greater than 1.0 percent, a representative sample shall be taken, physical contaminants shall be collected and weighed, and the percentage of physical contaminants determined. The load shall be rejected if physical contaminants are greater than 1.0 percent of total weight.

(b) Upon request of the EA, the operator shall take a representative sample of feedstock, physical contaminants shall be collected and weighed, and the percentage of physical contaminants determined.

(c) Any agricultural material handling operation using this material shall ensure the feedstock meets the metal concentration limits specified in Table 2 of section 17868.2.

(d) Facility personnel shall be adequately trained to perform the activities specified in this section.

(e) Any operation or facility using this feedstock shall maintain records demonstrating compliance with this section.

Note:

Authority cited:

Sections 40502, 43020, and 43021 of the Public Resources Code.

Reference:

Sections 43020 and 43021 of the Public Resources Code.

APPENDIX Z

Land and/or Natural Resource Management Agency Contacts

APPENDIX Z

The following list of permitting agencies and technical service providers is meant as a resource to help growers comply with the metrics in a way that is compatible with environmental protection and permitting requirements.

Permit Issuing Agencies:

California Department of Fish and Game

The California Department of Fish and Game should be contacted for Lake and Streambed Alteration Agreements, Incidental Take Permits and/or Depredation Permits. Please see below for specific program area contact information.

Julie Means
Lake and Stream Alteration Agreement,
Fish and Game Code Section 1602
California Department of Fish and Game
1234 East Shaw Ave.
Fresno, CA 93710
Office: (559) 243-4014 ext. 240
Fax: (559) 243-4020

Contact Julie Means if the project proponent plans to divert or obstruct the natural flow of, or alter the bank (including riparian habitat), bed or channel of a river, stream or lake. The project proponent must submit a written Notification and appropriate fee to the Department. Information is available at www.dfg.ca.gov/1600/. The Department has 30 days to determine a Notification complete and 60 days from the date the Notification is determined complete to issue an Agreement.

Anne Ferranti
Incidental Take Permit for State Listed Species,
Fish and Game Code Section 2081.
California Department of Fish and Game
1234 East Shaw Ave.
Fresno, CA 93710
Office: (559) 243-4014 ext. 222
Fax: (559) 243-4020

Contact Anne Ferranti if there is a potential to take a State threatened, endangered or candidate species under a lawful activity. Take is defined to hunt, pursue, catch, capture, or kill, or attempt to hunt, pursue, catch, or kill. Before an "Incidental Take Permit" will be issued an Environmental Impact Report pursuant to the California Environmental Quality Act (CEQA) is required.

Jeff Cann
Depredation Permits, Wildlife Management,
Fish and Game Code Sections 4181 and 4181.5
California Department of Fish and Game
20 Lower Ragsdale Drive
Monterey, CA 93940
Office: (831) 649-7194
Fax: (831) 649-2894

Contact Jeff Cann if property is being damaged or destroyed by deer, elk, bear, beaver, wild pig, wild turkey, or gray squirrel. The department will determine if actual damage by the above species is occurring and recommend alternative prevention methods before a depredation permit is issued. Department staff are also available to discuss fencing or other wildlife issues.

Regional Water Quality Control Boards

The following Regional Water Boards have agricultural waiver programs. They should be contacted regarding compliance issues with agricultural waivers in the respective regions. The Regional Water Boards should be contacted for all issues that may affect water quality and by growers who need help with well, pond and other irrigation water disinfection procedures.

Jill North
Environmental Scientist
Central Coast Regional Water Quality Control Board
895 Aerovista Place, Suite 101
San Luis Obispo, CA 93401-7906
Office: (805) 542-4762
Fax: (805) 788-3583
jnorth@waterboards.ca.gov

Joe Karkoski
Division Chief, Irrigated Lands Assessment and Planning Office
Central Valley Regional Water Quality Control Board
11020 Sun Center Drive #200
Rancho Cordova, CA 95670
Office: (916) 464-4668
jkarkoski@waterboards.ca.gov

Rebecca Veiga Nascimento
Environmental Scientist
Los Angeles Regional Water Quality Control Board
320 West 4th Street, Suite 200
Los Angeles, CA 90013
Office: (213) 576-6661
rveiga@waterboards.ca.gov

Technical Assistance Agency Contacts:

Environmental Protection Agency

Jovita Pajarillo
Associate Director
Water Division (WTR-1)
(415) 972-3491
pajarillo.jovita@epa.gov

National Marine Fisheries Service

The National Marine Fisheries Service should be contacted for technical assistance about land use activities that could affect steelhead or their habitat, riparian management activities, activities that affect a floodplain or activities that might deliver sediment to streams.

William Stevens
Natural Resource Management Specialist
National Marine Fisheries Service
777 Sonoma Avenue, Room 325
Santa Rosa, California 95404-6528
Office: (707) 575-6066
Fax: (707) 578-3435
William.Stevens@noaa.gov

Natural Resources Conservation Service (NRCS)

The Natural Resources Conservation Service (NRCS) can provide free confidential technical assistance in evaluating the effect of proposed food safety protection measures on other natural resource protection goals such as water quality protection, erosion control, and wildlife management and endangered species protection. The NRCS can help growers develop management plans to comply with the metrics in a way that is compatible with environmental protection.

Luana Kiger
USDA-NRCS California State Office
430 G Street
Davis, CA 95616-4164
(530) 792-5661
Luana.Kiger@ca.usda.gov

Curtis Tarver
USDA-NRCS Central Valley Area Office
4974 E. Clinton Way, Suite 114
Fresno, CA 93727-1520
(559) 252-2191 ext. 115
Curtis.Tarver@ca.usda.gov

Jim Spear
USDA-NRCS Northern California Area Office
1345 Main Street
Red Bluff, CA 96080-2347
(530) 527-2667 ext. 104
Jim.Spear@ca.usda.gov

Kay Joy Barge
USDA-NRCS Central Coast Area Office
318 Cayuga Street, Suite 206
Salinas, CA 93901-2668
(831) 754-1595 ext. 107
Kay.Joy@ca.usda.gov

Jae Lee
USDA-NRCS Southern California/
High Desert Area Office
4500 Glenwood Drive, Bldg. B
Riverside, CA 92501-3042
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