COMMODITY SPECIFIC FOOD SAFETY GUIDELINES FOR THE PRODUCTION, HARVEST, POST-HARVEST, AND VALUED-ADDED UNIT OPERATIONS OF GREEN ONIONS

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Previous Work

The effort to develop commodity specific food safety guidelines for green onions began in the summer of 2006. Greatest appreciation is expressed to the people who contributed to the earlier draft guidance document entitled, *Commodity Specific Food Safety Guidelines for the Green Onion / Herb Supply Chain* (unpublished). Editors of this foundational document were:

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FOREWORD

The diversity of methods in the production of green onions makes a single, universally applicable approach to food safety planning complicated. It is important that each firm 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 green onion product safety for consumers. Whatever the preferred production method for a single producer, green onion producers agree that the following basic principles should serve as the foundation for all food safety programs within their segment of the industry:

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

In the sections that follow, a list of Best Practices was developed to address each identified potential food safety issue. However, it is the responsibility of individuals and companies involved in the field-to-fork green onion 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 green onions and may or may not apply to other specialty crops. Particular recommendations 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 three sections, each one of them includes its own table of contents, background information resources, and references. Reference documents 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 [SOPs]) 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) guidelines for the fresh fruit and vegetable industry.

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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.

aerosolized	The dispersion or discharge of a liquid substance that generates a suspension of fine particles in air or other gas.
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) which are counted.
concentrated animal feeding operation (CAFO)	A lot or facility where animals have been, are, or will be stabled or confined and fed or maintained for a total of 45 days or more in any 12 month period. 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]
coliforms	Gram-negative, non-spore forming, rod-shaped bacteria that ferment lactose to gas. They are

[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

[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

	frequently used as indicators of process control, but exist broadly in nature.
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.
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 harvest. [4]
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 green onions to the packinghouse / processing facility.
finished product container	Containers used to hold green onions that are ready for shipping. Typically waxed fiberboard

[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

	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 that is reasonably likely to contain microorganisms of significant public health concern and is reasonably likely to cause adulteration of green onions in that field.
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-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

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

	10 number.
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.
handler	An individual or entity that receives, acquires, cleans, sells, consigns, or imports green onions in their natural form including both raw agricultural commodities and value-added products.
hepatitis A virus	An RNA virus that, when excreted in feces of infected people, can produce clinical disease in susceptible individuals who consume contaminated water or food; usually causes a mild illness characterized by sudden onset of fever, malaise, nausea, anorexia, and abdominal discomfort followed by several days of jaundice.[7]
human pathogen	Microorganism capable of causing disease or injury to people. This is different from plant pathogens which may cause disease to plants.
iced green onions	Green onions that are trimmed before being packed with ice; considered a raw agricultural commodity
iceless green onions	Green onions that are minimally processed upon arrival and packaged without ice into finished product containers; also considered a raw agricultural commodity.
indicator microorganisms	An organism that when present indicates fecal contamination, a condition that is often associated with the presence of enteric pathogens. For example, coliforms including *E. coli*, are "indicators" of the possible presence of enteric pathogens such as *Salmonella* or *E. coli* O157:H7
microorganism	Yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. [5]
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

[7] FDA. 2009. "Bad Bug Book", accessed November 5, 2009. http://www.fda.gov/Food/FoodSafety/FoodborneIllness/FoodborneIllnessFoodbornePathogensNaturalToxins/BadBugBook/default.htm

	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 green onions 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.[8]
pathogen	A disease causing agent such as a virus, parasite, or bacteria.
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 green onions 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.[9]
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 green onions.
raw agricultural commodity (RAC)	Any food in its raw or natural state, including all fruits that are washed, colored, or otherwise

[8] Centers for Disease Control and Prevention. (http://www.cdc.gov/oralHealth/infectioncontrol/glossary.htm)
[9] OSHA. 1987. Field Sanitation –1928.110.
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10959

	treated in their unpeeled natural form prior to marketing.[10]
Ready-to-eat (RTE) food	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.[11]
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.
Reported 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.
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, motile bacterium – nonmotile exceptions are *S. gallinarum* and *S. pullorum* – non-sporeforming and Gram-negative organism that cause illness (salmonellosis) in humans. Environmental sources include water, soil, insects, manufacturing surfaces, animal feces, and raw meats, poultry or seafood.
sanitize	To adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.
Sanitary Survey	An inspection of the entire water system, including water source, facilities, and equipment, for the purpose of identifying

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

[11] FDA. 2009. Food Code: U.S. Public Health Service.

	conditions that may result in microbial contamination.
soil amendment	Elements added to the soil, such as compost, peat moss, or fertilizer, to improve its capacity to support plant life.
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.
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.[12]
synthetic crop treatments	Any crop inputs that are refined, chemically synthesized, and / or transformed through a chemical process (e.g., gypsum, lime, sulfur, potash).
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, defensible 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, hydraulic appurtenances, and other components used to carry water from its primary source to other areas of the property, building, etc.

[12] 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

ACRONYMS AND ABBREVIATIONS

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
FIFO: First-In, First-Out
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
PPM: Parts Per Million
RAC: Raw Agricultural Commodity
RFR: Reportable Food Registry
RNA: Ribonucleic Acid

RPCs: Returnable Plastic Containers

RTE: Ready-To-Eat

SENASICA: National Service of Agro Alimentary Health, Safety, and Quality

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

WHO: World Health Organization

LIST OF APPENDICES

INTRODUCTION

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, GAPs guidance informs fruit and vegetable growers and shippers about the potential biological, chemical, and physical hazards associated with various aspects of the production pipeline including: land history, adjacent land use, water quality, worker hygiene, pesticide and fertilizer use, equipment sanitation, and product transportation. 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 or external third party GAPs 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 assure 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. Unlike GAPs, cGMPs are regulations and are enforceable by law. cGMPs serve as one basis for FDA inspections. Fresh produce processors are obligated to comply with cGMPs as set forth in 21 CFR 110. In addition to the cGMPs, FDA has published a "Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables" ("Fresh-cut Guide").[13] FDA developed this guidance to complement the cGMPs, to recommend more specific food safety practices relevant to processors of fresh produce.

Commercial fresh produce processors are the most pervasively regulated segment 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.

In addition to food safety efforts for fresh produce in the U.S., the Mexican government, in conjunction with its green onion industry, has developed food safety standards for green onions, and the government / industry in Canada are collaborating on the

[13] 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

development of GAPs for fresh green vegetables. The Mexican government's National Service of Agro Alimentary Health, Safety, and Quality (SENASICA) has issued voluntary GAPs for all green onions grown in Mexico for export. Select states may require SENASICA green onion GAPs as a condition of export. All production, harvesting, packing, and transportation operations that export green onion products to Mexico must register with the Mexican government and have a food safety program with specific requirements to address areas of potential physical, chemical, and microbiological contamination. In Canada, the Canadian Horticultural Council is leading a joint government agencies and industry effort to establish GAPs for leafy green produce, including green onions and other herbs. This document is designed to complement the Mexican and Canadian efforts while making necessary adaptations to meet U.S. requirements.

While the produce industry has an admirable record of providing the general public with safe, nutritious fruits and vegetables, it is also committed to continuous improvement with regard to food safety. In 2004, the FDA promulgated a produce safety action plan that specifically requested produce industry leadership to develop the next generation of food safety guidance for fruit and vegetable production. Additionally, in the summer of 2009, FDA drafted new commodity-specific guidelines for leafy greens, tomatoes, and melons. While green onions were not selected for inclusion in this initial FDA list of commodities, industry has decided that being proactive in this area is important and that moving forward ahead of FDA regulation can help increase the safety and security of the U.S. green onion supply chain. This document is the based on work begun by the industry in the summer of 2006.

PURPOSE

The purpose of this document is to provide green onion growers, packers, and shippers with effective guidelines to reduce the potential of microbial contamination of green onions. The issues identified are based on the core elements of GAPs and cGMPs. The specific recommendations contained herein are intended for green onions only. If these specific recommendations are effectively implemented this would constitute the Best Practices for a comprehensive food safety program for the production, harvest, and processing of green onions. 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."[14]

Human pathogens that are most often associated with produce cause infection and illness by the fecal-oral route of food contamination. Specifically for green onions, hepatitis A, *Shigella flexneri,* and *Salmonella* pathogens that are transmitted via the fecal-oral route, have been linked to green onion contamination. Since 1990 hepatitis A has been the most common organism associated with foodborne disease outbreaks in the U.S. (CDC 2008; Dentinger et al. 2001; Wheeler et al. 2005). An outbreak of *Shigella flexneri* infection in two Midwestern states in 1994 was linked to green onions grown on a single farm in Mexico and distributed through shippers in California (Beuchat 1996; FDA 2001). Even

[14] 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

though CDC does not record any past foodborne illness outbreaks associated with *Salmonella* contamination in green onions, voluntary recalls in late summer of 2009 that were associated with this pathogen have raised concerns in the industry and regulatory communities.[15] Therefore, green onion food safety programs should pay special attention to controlling, reducing, and eliminating potential fecal contamination through water, soil, people, and animals (both domestic and wild).

SCOPE

This document is designed to offer food safety guidance for growers and handlers of green onions during production, harvesting, packing, and shipping operations (see Figure 1). It includes three sections: 1) Production and Harvest Unit Operations, 2) Post-Harvest Unit Operations, and 3) Value-Added Unit Operations.

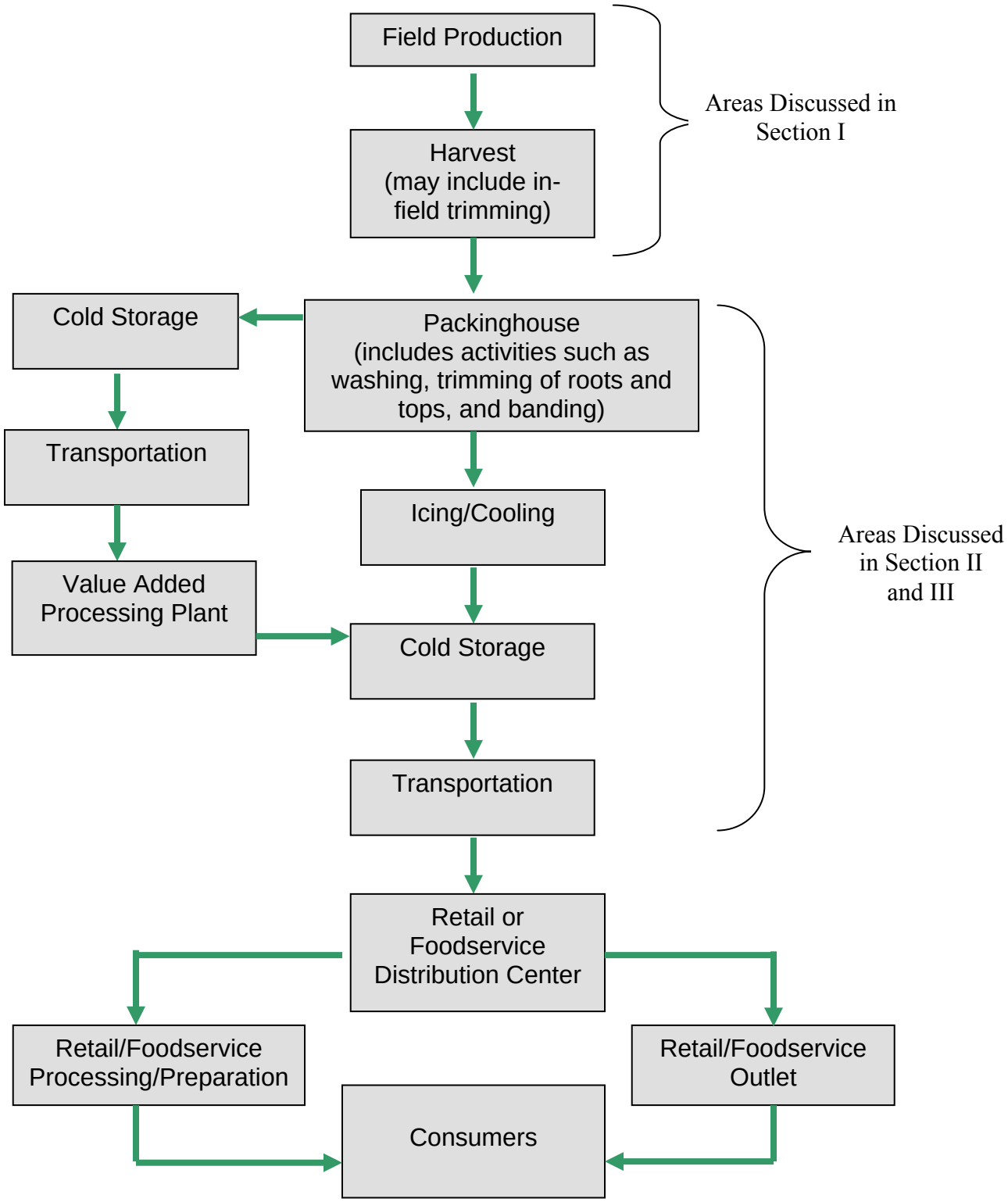
Green onions are generally harvested by hand, and can be packed in the field, in a packinghouse or in a processing plant. Due to harvesting by hand, quality sorting, and the practice of bunching and packing these commodities, there are numerous "touch points" early in the supply chain. Each of these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

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

It is suggested that all companies involved in the green onions' farm-to-table supply chain consider the recommendations contained within these guidelines to ensure the safe production and handling of green onion 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 green onions to the market place.

[15]FDA. 2009. Limited Recall of 772 Cartons of Iced Jumbo Green Onions due to Possible Health Risk. http://www.fda.gov/Safety/Recalls/ucm177114.htm
FDA. 2009. Voluntary Product Recall: Steinbeck Country Green Onions. http://www.fda.gov/Safety/Recalls/ucm180939.htm
FDA. 2009. Ocean Mist Farms Announces Precautionary, Voluntary Recall of 1,746 Cases of Iceless Green Onions. http://www.fda.gov/Safety/Recalls/ucm181061.htm

Figure 1. General Supply Chain Flow for Green Onions



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1.0 ISSUE: GENERAL RECOMMENDATIONS

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

1.1 The Best Practices Are:

- A written comprehensive Green Onions 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 address 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 recommendations may change as new and additional information becomes available.
- Growers should review their Green Onions Food Safety Plan at least annually and make revisions as appropriate to their particular situation based on updated or new guidance, regulations, and / or changes to their operations (e.g., new field location or new season).
- Handlers should have an up-to-date growers list with contact and location information on file.
- Handlers shall comply with the requirements of The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (farms are exempt from the Act) including those requirements for recordkeeping (traceability), imports, and registration.[16]
- Anyone that manufactures, processes, packs, or holds green onions 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 Reportable Food Registry (RFR).[17] Firms that only grow green onions are exempt from reporting.
- 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. Twenty-four hour contact information should be available for these individuals in case of food safety emergencies.

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[16] 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

[17] FDA. 2009. Reportable Food Report. http://rfr.fda.gov/

- Each grower and handler should develop a written plan of action to be taken in the event that a food safety problem occurs.
- Each grower and handler should develop appropriate standard operating procedures (SOPs) and standard sanitation operating procedures (SSOPs) for conducting food safety assessments during production and harvesting activities.

2.0 ISSUE: ENVIRONMENTAL ASSESSMENTS

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

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 issues related to green onion fields, adjacent land uses, or animal intrusion (see Table I-1A) that might impact the safety of green onions.

Green onions 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 green onions 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 green onions are produced.

Green onions are generally grown in rural areas that may have adjacent wetlands, wildlands, and / or parks harboring wildlife. Some wildlife species are known to be potential carriers of various human pathogens (Fenlon 1985; Keene et al. 1997). Uncertainties in the literature about which wildlife species 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 recommendation that if animal intrusion is detected, measures should be taken to prevent the harvest of any potentially contaminated green onions. 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 that should be considered when developing risk assessments.

Finally, it is possible that some land uses may be of greater concern than others when located near production fields. Table I-1B provides a list of these uses and recommended buffer distances.

2.1 The Best Practices Are:

A. Pre-planting Assessment

- Prior to the first seasonal planting perform an environmental assessment of the production field and surrounding area. Focus these assessments on evaluating

the production field for possible animal intrusion or other sources of human pathogens of concern, assessing adjacent land uses for possible sources that might contaminate the production field, and evaluating nearby water sources for the potential of past or present flooding.

- Assessment of Green Onion Fields
  - Evaluate all green onion fields for evidence of animal intrusion and / or feces. See Table I-1A and Figure 2 for numerical criteria and guidance applicable to animal encroachment.
  - When developing strategies to reduce the risk associated with wild animals that are endemic to a particular production area, it is recommended that mitigations are designed to minimize adverse impacts to the environment.
  - Before taking remedial action, producers are advised to check for local, state, and federal laws and regulations that protect riparian habitat, restrict removal of vegetation or habitat, or restrict construction of wildlife deterrent fences in riparian areas or wildlife corridors.
  - Growers 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 recommendations. In addition, growers may wish to consult with their local Natural Resources Conservation Service (NRCS) 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 green onion production block.
  - Document any observed animal intrusion during pre-planting periods.
  - Evaluate the risk to subsequent green onion production on production acreage that has experienced recent post-harvest grazing with or by domesticated animals that used field culls as a source of animal feed.
  - To the degree possible, locate green onion production blocks to minimize potential access by animals and maximize distances to possible sources of microbial contamination. During pre-planting, periodically monitor and assess factors such as proximity to water (i.e., riparian areas), areas where animals may seek harborage, open range lands, non-contiguous blocks, and urban centers as outlined in Tables 1A and 1B. If the designated food safety professional deems that there is the potential for microbial contamination in green onion production areas due to signs of animal intrusion, a risk assessment shall be performed to determine

the risk level as well as to evaluate potential strategies to control or reduce the introduction of human pathogens (see suggestions in Table I-1A and 1B).

- Pooled water (e.g., a seasonal lake) from rainfall may attract animals and should be considered as part of any land use evaluation.

- Assessment of Adjacent Land Use

  - Evaluate all land and waterways adjacent to green onion 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 I-1B for further detail). If any possible uses that might result in green onion contamination are present, follow management practices identified in the sections below related to environmental and land use concerns.

  - See Table I-1B for numerical criteria and guidance applicable to adjacent land uses.

  - Consider controlling risks associated with encroachment by urban development. Risks may include, but are not limited to, domestic animal fecal contamination of production fields and harvest equipment and septic tank leaching.

  - 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 green onions. 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 green onion 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 I-1B, any deviations from the recommended buffer distances due to mitigation factors or increased risk should be documented and explained.

- Assessment of Historical Land Use

  - To the degree practical, determine and document the historical land uses for green onion 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 green onion fields for evidence of flooding. If any evidence is found, follow procedures identified in section 10.0 Flooding.

B. 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.
- Evaluate and monitor animal activity in and around green onion fields and production environments as is appropriate based on the location of your green onion fields. If there are animals present, make particular efforts in accordance with the recommendations in Table I-1A to reduce their access to the green onion crop.

C. Harvest Assessment

- Workers should be trained to monitor environmental conditions of the production field during harvest operations for:
  - Evidence of animal intrusion.
  - DO NOT harvest areas of fields where unusually heavy activity by animals occurs. Examples of animal activities to consider are provided in Table I-1A.
  - Evidence of debris such as glass, plastic, and metal. Remove the debris or consider not harvesting green onions in close proximity to the debris if the safety of the onions is compromised by their presence.
  - Evidence of open and / or unsecured chemicals.
  - Any other factor that might increase the risk of microbial contamination.
- Before beginning harvesting operations, workers should be trained in hygienic practices as outlined in section 6.0, 7.0, 8.0, and 9.0 of these guidelines as well as specific requirements in company SOPs, SSOPs, and training programs. Company employee training programs should stress the importance of good employee hygiene since epidemiological evidence of outbreaks in green onions has often associated humans as the contamination source. Additional resources for developing employee training programs are cited in section 13.0 Detailed Background Guidance Information.
  - During harvesting operations, trained personnel should monitor workers for compliance with hygienic practices as prescribed in company SOPs, SSOPs, and training programs.
- If an outside harvesting company is being used, provide proper training or verify that the company trains their workers in proper hygienic practices and assessing the environmental conditions during harvesting.

- The name and contact information of the harvesting company and operator should be included on the assessment record.
- The harvesting company should have records to demonstrate that employees have been adequately trained in hygienic practices and harvest assessments.

552 **Table I-1A. Animal Activity in Field (Wild or Domestic):** When evidence of animals intrusion in a production block occurs.

Issue		
Evidence of Intrusion	**Metric** Frequency • There should be a periodic monitoring plan in place for green onion production fields. • There should be Pre-Season, Pre-Harvest, and Harvest assessments. Variables • Physical observation of animals in the field • Downed fences • Animal tracks in production block • Animal feces or urine in production block • Eaten plants in production block	**Remedial Actions** • If there is evidence of animal intrusion, the production block should 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. The extent of the assessment should be determined by the extent of animal intrusion (i.e., a lone deer track near the edge of a field would result in a less detailed assessment compared to evidence of a herd of deer that has repeatedly eaten in the field). • In developing remedial and corrective actions, it is recommended that producers consult with wildlife and / or domestic animal experts as appropriate. • If remedial actions cannot be formulated that control or eliminate the identified risk, destroy the block by disking under the green onions. • Equipment used to destroy the onions should be cleaned and sanitized upon exiting the field. • Investigate potential causes for intrusion by animals and assess the extent of intrusion and impact on the green onion crop. • 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 habitat, restrict removal of vegetation or habitat, or restrict construction of wildlife deterrent fences in riparian areas or wildlife corridors. • Evidence of animal intrusion 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** Evaluate and monitor animal activity in and proximate to green onion fields and production environments. Conduct periodic monitoring, Pre-Season, Pre-Harvest, and Harvest assessments. **Pre-Harvest Assessment** Conduct the Pre-Harvest assessment not more than 1 week prior to harvest.	

Issue	
	Fecal Material • Do not harvest any green onions that have come into direct contact with fecal material. • If evidence of fecal material is found, conduct a food safety assessment using qualified personnel. Do not harvest green onions found within a minimum 5 foot radius buffer distance from the spot of the contamination unless remedial action can be found that adequately control the risk. The food safety professional can increase this buffer distance if deemed appropriate. • Remove fecal material from the field and dispose of properly. **Intrusion** • If evidence of animal intrusion is found in a green onion field without evidence of fecal deposits, conduct a visual food safety assessment to determine whether the areas of intrusion can be adequately controlled, or whether a three foot buffer radius non-harvest area should be applied. A few isolated animal tracks in furrows or near fields should not be treated the same as a large number of tracks, feeding, or feces on the onions. **Harvest Assessment** If evidence of animal intrusion into the production block is not discovered until harvest operations: • Stop harvest operations in affected areas. • Initiate an intensified block assessment for evidence of further contamination and take appropriate actions per the aforementioned actions. • If evidence of intrusion is discovered during production block harvest operations and equipment has been potentially contaminated by contaminated green onions 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 green onions 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 intrusion event. Documentation may include photographs, sketched maps, or other means of delineating affected portions of green onion fields.
Rationale	• The basis of these metrics is qualitative assessment of the relative risk from a variety of intrusions. Some animal feces and some signs of intrusion (feces vs. tracks) are considered to be of more concern that others. 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.

553 **Table I-1B. Crop Land and Water Source Adjacent Land Use**

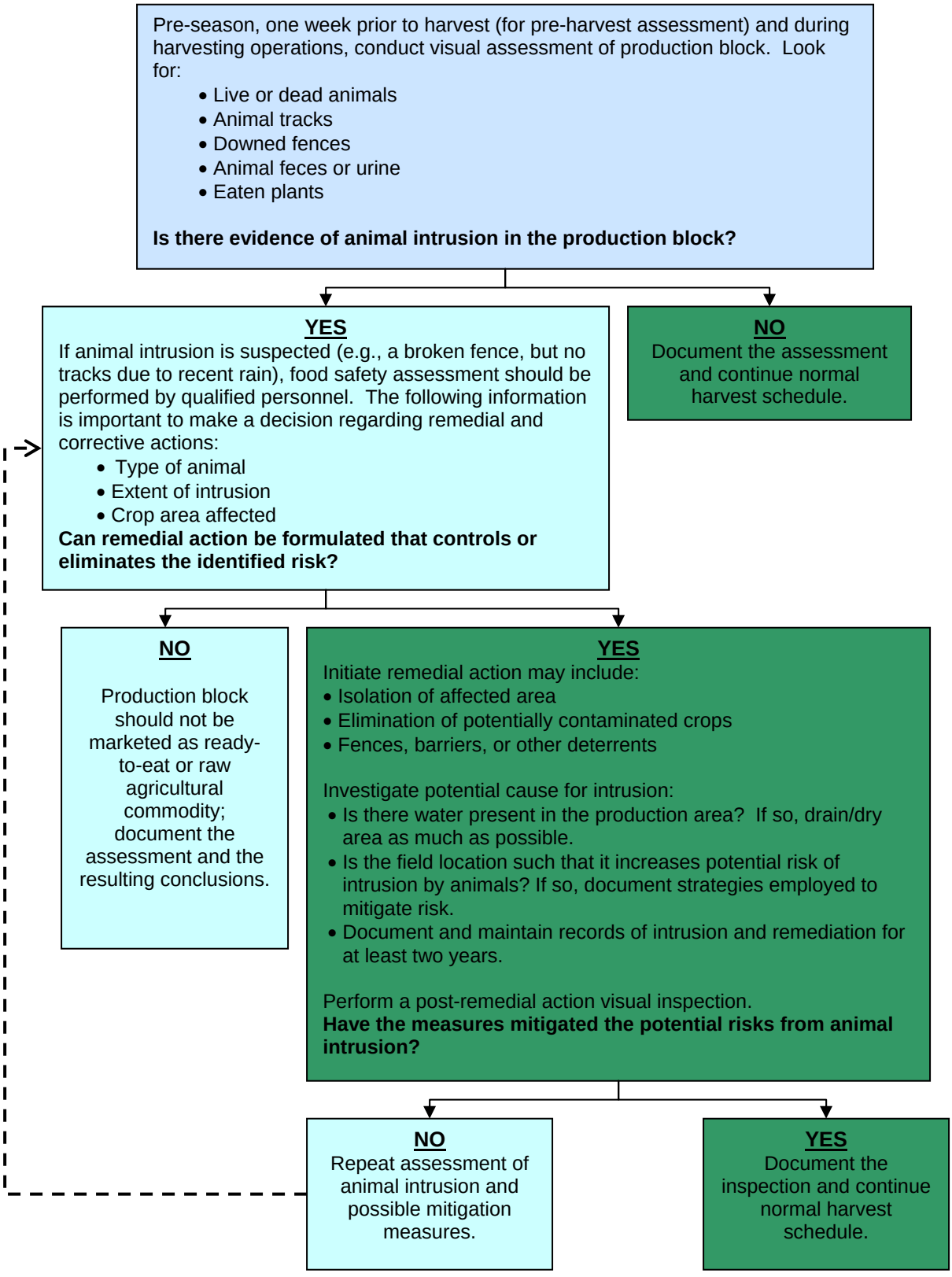
Land Use / Water Source	Metric (This distance is intended to be established by the producer and should be increased or decreased depending on the risks present and any mitigation factors employed to reduce that risk.)	Considerations for Risk Analysis*		
		Risk / Mitigation Factors	Increase Distance	Decrease 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 green onion fields	√	
		Topography: Downhill from green onion 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 factors.	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 green onion fields	√	
		Topography: Downhill from green onion 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. 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.	Access and review COA for materials in question		√
		Topography: Uphill from green onion fields	√	
		Topography: Downhill from green onion 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		√

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
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 green onion fields	√	
		Topography: Downhill from green onion 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 green onion fields	√	
		Topography: Downhill from green onion 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 run off from or through untreated manure to well head	√	
		Opportunity for soil leaching	√	
		Presence of physical barriers such as windbreaks, diversion ditches, vegetative strips		√
Surface Water Distance from 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%) is recommended.	Topography: Uphill from manure		√
		Topography: Downhill from manure	√	
		Opportunity for water runoff from or through untreated manure to surface waters.	√	

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
		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 habitat, restrict removal of vegetation or habitat, or restrict construction of wildlife deterrent fences in riparian areas or wildlife corridors. Growers may want to contact the relevant agencies (e.g., the Regional Water Quality Control Board and state and federal fish and wildlife agencies) to confirm the details of these recommendations.

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



3.0 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 green onion 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 green onions but not a proper source of water for mixing pesticides that would be applied to the aerial portion of the plant. With green onions, aerial portions of the plant are consumed along with the bulb; therefore, great care should be taken to ensure that these structures of the plant 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. Water sourced from a surface water source (e.g., a 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. 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. A trend analysis of the microbial testing data over time can provide valuable information as part of a water quality management program. 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, it is recommended that risk management strategies focus on keeping the canals clean to avoid accumulation of debris and presence of animals. These strategies should be in place and should include daily 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.

3.1 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**).

- Use irrigation water and water in harvest operations that is of appropriate microbial quality for its intended use; see Table I-2 and Figures 3A and 3B for specific numerical criteria.[18]
- Perform a Sanitary Survey (**Appendix A**) prior to use of water in agricultural operations and if water quality microbial tests are at levels that exceed the numerical values set forth in Table I-2.[19]
- Test water as close to the point-of-use as practical, and if microbial levels are above specific action levels, take appropriate remedial and corrective actions.
- Retain documentation of all test results and / or Certificates of Analysis available for inspection for a period of at least 2 years.

[18] 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, Technical Basis for Metrics.

[19] As opposed to standards for foliar and non-foliar applications that have been used for other crops, the green onion guidance only uses one numerical standard for pre-harvest water use. Both the above- and below-ground portion of the plant can be consumed, so using the more restrictive numerical standard for all irrigation water quality was determined to be appropriate.

Table I-2. Water Use

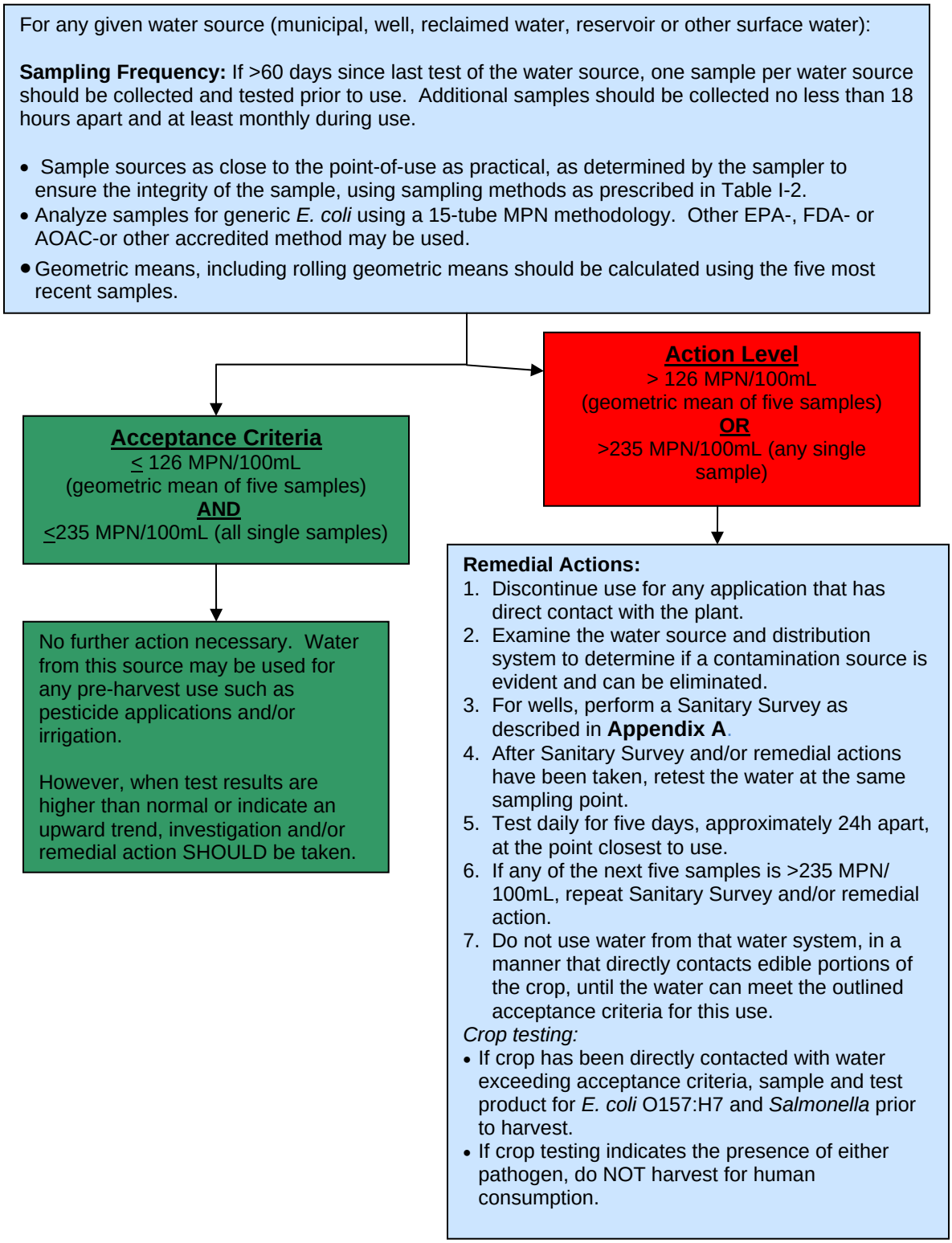
Use	Metric	Rationale / Remedial Actions
PRE-HARVEST **All Applications** (overhead sprinkler irrigation, drip irrigation, pesticides / fungicide application, etc.)	**Target Organism:** generic *E. coli*. **Sampling Procedure:** 100 mL sample collected aseptically at the point of use; e.g., one sprinkler 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, the sampling frequency may be decreased to once every six months and the recommendations for 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, to ensure the integrity of the sample, using sampling methods as prescribed in this table) where the water contacts green onions, 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. Only one sample per month per distribution system is recommended 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 remedial action SHOULD be taken when test results are higher than normal, or indicate an upward trend. Investigation and remedial action SHOULD be taken when acceptance criteria are exceeded. **Remedial Actions:** If the rolling geometric mean (n=5) or any one sample exceeds the acceptance criteria, then the water should not be used whereby the green onions are contacted by water until remedial actions have been completed and generic *E. coli* levels are within acceptance criteria: • Conduct a Sanitary Survey of water source and distribution system to determine if a contamination source is evident and can be eliminated. Eliminate identified contamination source(s). • For wells, perform a Sanitary Survey and / or treat as described in Sanitary Survey in **Appendix A**. • Retest the water after conducting the Sanitary Survey and / or taking remedial actions to determine if it meets the outlined microbial acceptance criteria for this use. This sample should represent the conditions of the original water system. If feasible, this test should be as close as practical to the original sampling point. A more aggressive sampling program (i.e., sampling once per week instead of once per month) should be instituted if an explanation for the exceedence is not readily apparent.

	Test Method: 15 tube MPN (FDA BAM) or other US EPA, AOAC, or other method accredited for quantitative monitoring of water for generic *E. coli.* Presence / absence testing with a similar limit of detection may be used as well. **Acceptance Criteria:** **≤126 MPN (or CFU*)/100 mL** (rolling geometric mean n=5) and **≤235 MPN/100 mL** for any single sample. *for the purposes of water testing, MPN and CFU should be considered equivalent.	This type of sampling program should also be instituted if an upward trend is noted in normal sampling results. **Crop Testing**: If water testing indicates that green onions have been directly contacted with water exceeding acceptance criteria, green onion plants should be sampled and tested for *E. coli* O157:H7 and *Salmonella* as described in Table I-3, prior to harvest. If crop testing indicates the presence of either pathogen, these onions should NOT be harvested for human consumption. **Records**: Information requirements: Each water sample and analysis shall record: the type of water (canal, reservoir, well, etc) date, time, and location of the sample and the method of analysis and detection limit Records of the analysis of source water may be provided by municipalities, irrigation districts or other water providers. All test results and remedial actions should be documented and available for verification from the grower / handler who is the responsible party for a period of 2 years.
POST-HARVEST Direct Product Contact or Food Contact Surfaces	**Microbial Testing** **Target Organism, Sampling Procedure, and Test Method:** as described for PRE-HARVEST, all 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 hr and at least monthly during use. **Acceptance Criteria:** Negative or below DL for all samples (≤ 2 MPN/100 mL) [20]	Water that directly contacts harvested green onions or is used on food contact surfaces, such as equipment or utensils, should meet the Maximum Contaminant Level Goal 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 vs. Multiple Pass Systems** • Single pass use – Water should have non-detectable levels (≤ 2 MPN/100 mL) of *E. coli* or breakpoint disinfectant present at point of entry. • Multi-pass use – Water should have non-detectable levels (≤ 2 MPN/100 mL) of *E. coli* and / or sufficient disinfectant to insure returned water has no detectable *E. coli* (minimally 1 ppm chlorine). **Remedial Actions**: If any one sample exceeds the acceptance criteria, then the water should not be used for this purpose unless appropriate disinfectants have been added or until remedial actions have been completed and generic *E. coli* levels are within acceptance criteria:

[20] 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

	<u>Physical / Chemical Testing</u> **Target Variable:** Water disinfectant (e.g., chlorine or other disinfectant compound) **Multi Pass Water Acceptance Criteria:** • **Chlorine** ≥1 ppm free chlorine after application and pH 6.5 – 7.5 • ORP ≥ 650 mV, and pH 6.5 – 7.5 • **Other approved treatments** per product US EPA label for human pathogen reduction in water. **Testing Procedure:** • Chemical reaction based colorimetric test, or • Ion specific probe, or • ORP, or • Other as recommended by disinfectant supplier. **Testing Frequency:** Continuous monitoring (preferred) with periodic verification by titration OR routine monitoring if the system can be shown to have a low degree of variation.	• 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 remedial actions to determine if it meets the outlined microbial acceptance criteria for this use. For example, if a water sample for water used to clean food contact surfaces has detectable *E. coli*, STOP using that water system, examine the distribution line; source the inlet as described in the Sanitary Survey (**Appendix A**), and retest from the same point of use. Continue testing daily for 5 days at the point closest to use, and do not use the water system until it consistently delivers water that is safe, sanitary, and of appropriate microbial quality (i.e., negative result) for the intended use. If any of the five samples taken during the intensive sampling period after corrective actions have been taken, have detectable *E. coli*, repeat remedial actions and DO NOT use that system until the source of contamination can be corrected. **Records**: All test results and remedial 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)



620 **Figure 3B. Post-Harvest Water Use Direct Product Contact (e.g., re-hydration,**
621 **cooling)**

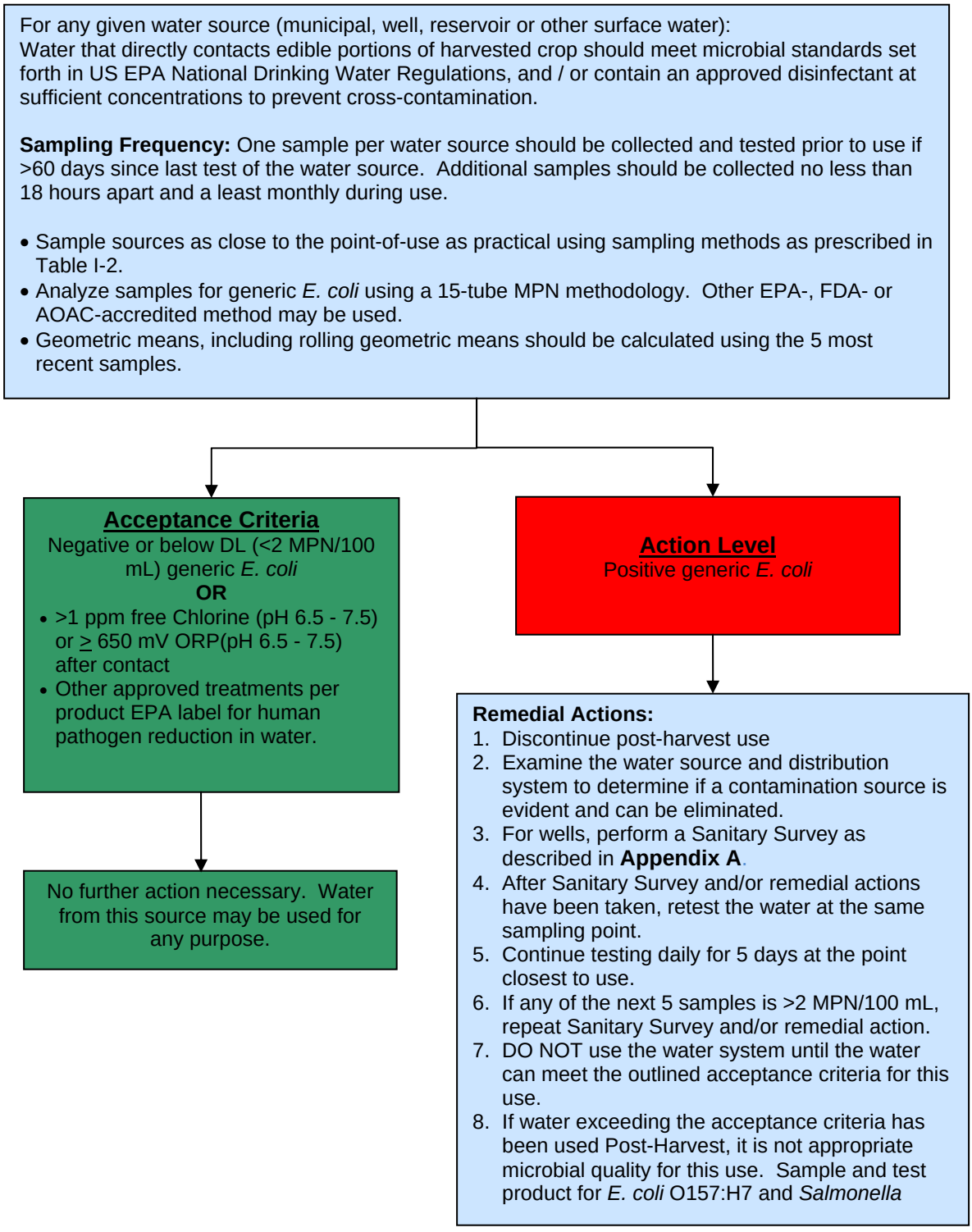


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Table I-3. Product Testing Protocol

This table is supplied as guidance for product testing in the event that irrigation water that exceeds the limits outlined in Table I-2 is applied to green onions. The protocol outlined below is provided as an example.[21] 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 laboratory-specific testing methods. It is important to confirm with your laboratory that they follow test methods acceptable to the FDA.

Protocol	Measurement Criteria	Remedial Actions	Timeline
• A composite sample of green onion plants still in the ground will be collected. Collect 8 oz samples using a pattern that covers the affected 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 affected field. Individual samples are combined into a composite sample of at least 5 lbs (pull bunch, shake off all soil, remove dead and damaged leaves). Sampling should occur 10 days or less before harvest, and should be tested for *E. coli* O157:H7 and *Salmonella*. Care should be taken not to step on plants while traversing the field. • Aseptic sample collection techniques will be utilized. • Results should be available for review before harvest of the field.	• Negative or < DL (<1/30 grams) for *E. coli* O157:H7 or *Salmonella*.	• Green onions from blocks which do not pass the above criteria will be destroyed before harvest. • All equipment utilized to destroy the green onion crop must be cleaned and sanitized upon exiting the field. • The field will not be re-planted for food crop production for the remainder of the season in which pathogens are detected. • This action will 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 green onions, product from the block must test negative for the presence of *E. coli* O157:H7 and *Salmonella*.

[21] The protocol is based on the "Immediate Technical Action Plan for the Spinach Industry of Monterey, San Benito and Santa Clara Counties" developed by Primus Labs. The addition of *Salmonella* testing to the protocol (as opposed to only testing for *E.coli* 0157:H7) is a substantial change in the plan as proposed by Primus Labs.

3.2 Other Considerations for Water

- Evaluate irrigation methods (e.g., drip irrigation, overhead sprinkler, furrow) for their potential to introduce, support, or promote the growth of human pathogens on green onions. 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 I-2.
- For surface water sources, consider the impact of storm events on irrigation practices. Bacterial loads in surface water are generally much higher after a storm than normal, and caution 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 shall 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 I-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.

4.0 ISSUE: SOIL AMENDMENTS

Soil Amendments (SAs) are commonly (but not always) incorporated prior to planting into agricultural soils used for green onion 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; Gagliardi and Karns 2000). Proper composting of animal manures via thermal treatment will reduce the risk of potential human pathogen survival. However, the persistence of many human pathogens in agricultural soils depends on many factors (e.g., soil type, soil moisture, relative humidity, UV index) and the effects of these factors is still under extensive investigation (Jiang et al. 2003; Islam et al. 2004a).

Because the edible bulb portion of the green onion plant is beneath the soil, SAs are particularly critical in this context. Field soil contaminated with human pathogens may provide a means of green onion 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. Readily detectable survival is typically less than 8 weeks following incorporation, but has been documented to exceed 12 weeks (Jiang et al. 2002; Nicholson et al. 2004). Recoverable pathogen populations, using highly sensitive techniques, have been reported to persist beyond this period under some test conditions

(Jiang et al. 2002; Ingham et al. 2004). Human pathogens do not persist for long periods of time in high UV index and low relative humidity conditions, but may persist for longer periods of time within aged manure or inadequately composted SAs (US EPA 2003). Therefore, establishing suitably conservative pre-plant intervals, appropriate for specific regional and field conditions, is an effective step towards minimizing risk (Islam et al. 2004b; Suslow et al. 2003).

4.1 The Best Practices Are:

- DO NOT USE raw manure or apply SAs that contain un-composted, incompletely composted, or non-thermally treated animal manure to fields which will be used for green onion production.
- See Table I-4 and Decision Trees (Figures 4A and 4B) for numerical criteria and guidance for compost and SAs used in green onion 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 harvest begins and it 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.
- Verify that the time and temperature process used during the composting process reduces, controls, or eliminates the potential for human pathogens being carried in the composted materials, as applicable to regulatory requirements.
- Follow the recommended time interval between SA application and time to harvest as provided in Table I-4.
- Implement practices that control, reduce or eliminate likely contamination of green onion fields in close proximity to on-farm stacking of manure.
- 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.
- Minimize the proximity of wind-dispersed or aerosolized sources of contamination (e.g., water and manure piles) that may potentially contact growing green onions or adjacent crops. Segregate equipment used for SA applications or use effective means of equipment sanitation 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 green onion 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 CCR as well as smaller operations that do not fall under Title 14 (Cal Recycle. Title 14, Natural Resources—Division 7. http://www.ciwmb.ca.gov/regulations/Title14/default.htm).
- Perform microbiological testing of SAs prior to application (Table I-4).
- Do not use biosolids as a SA for production of green onions.
- 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.

727 **Table I-4. Soil Amendments (SAs)**

Amendment	Metric / Rationale
Raw Manure or Not Fully Composted Animal Manure Containing SAs (see composted manure process definition below)	**DO NOT USE OR APPLY** SAs that contain un-composted, incompletely composted, or non-thermally treated (e.g., heated) animal manure to fields which will be used for green onion production. If these materials have been applied to a field, wait 1 year prior to producing green onions.
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^{o}F for 3 days **Windrow composting:** Active compost shall maintain aerobic conditions for a minimum of 131^{o}F for 15 days, with a minimum of five turnings. **Aerated static pile composting:** Active compost shall be covered with at least 12 inches of insulating materials and maintain a minimum of 131^{o}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)

Amendment	Metric / Rationale
	Recommended 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. **Sampling Plan:** • 12 point sampling plan composite sample (divide each lot / pile into a 3 x 4 grid and extract 12 equal volume samples). • 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 green onion 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 for compost are based on allowable levels from California state regulations (CCR Title 14 - Chapter 3.1 - Article 7 2007), with the addition of testing for *E. coli* O157:H7 as microbe of particular concern. The 45-day application interval was deemed appropriate due to the specified multiple hurdle risk reduction approach outlined. Raw manure should be composted with an approved process and pass testing requirements before an application.

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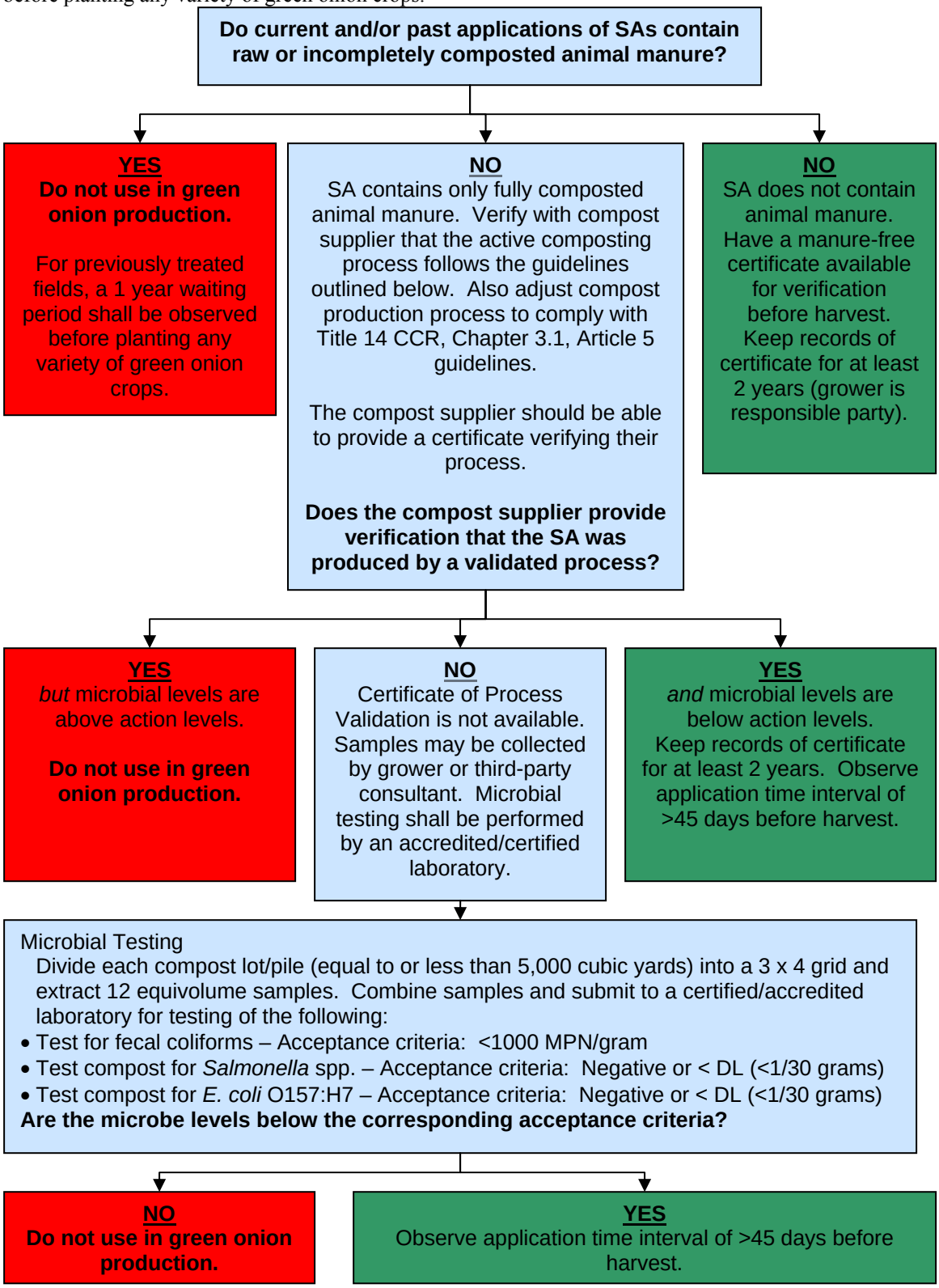
Amendment	Metric / Rationale
SAs Containing Animal Manure that has Been Physically Heat Treated or Processed by Other Equivalent Methods	• Any soil amendment containing animal manure should be validated to assure that the process is capable of reducing pathogens of human health significance to acceptable 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) **Recommended Test Methods:** • Fecal coliforms: 9 tube MPN • *Salmonella* spp: US EPA Method 1682 • *E. coli* O157:H7: Any laboratory validated method for testing SAs. • US EPA, FDA, AOAC-or other accredited methods may be used as appropriate. **Sampling Plan:** • 12 point sampling plan composite sample (divide each lot / pile into a 3 x 4 grid and extract 12 equal volume samples). • 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 green onion fields. • In lieu of the above sampling plan recommendation, 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".

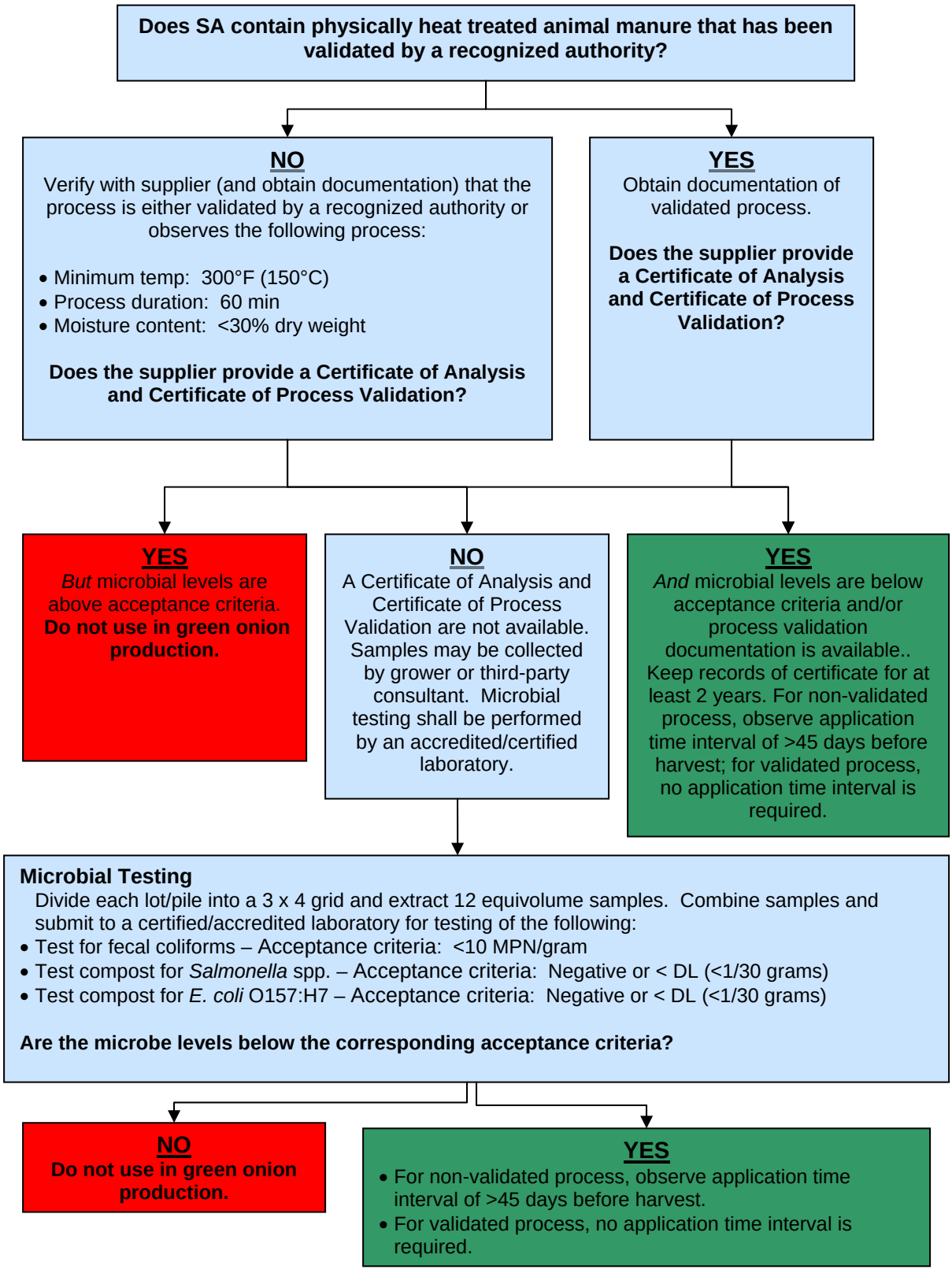
Amendment	Metric / Rationale
	Application Interval: • If the physical heat treatment process used to inactivate human pathogens of significant public health concern is validated and meets the microbial acceptance criteria outlined below, then no time interval is needed between application and harvest. • 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 recommended, and there is no application interval necessary • Any test results and / or documentation should be available for verification from the grower who is the responsible party for a period of 2 years. The suppliers operation should be validated by a process authority and a record maintained by the grower for a period of 2 years. **Rationale:** • The microbial metrics and validated processes for compost are based on allowable levels from California state regulations (CCR Title 14 - Chapter 3.1 - Article 7 2007), with the addition of testing for *E. coli* O157:H7 as the microbe of particular concern. A more stringent level of fecal coliform was also included to address the much more controlled nature of 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	• 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 recommended, and there is no application interval necessary • Any test results and / or documentation 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 1 year waiting period should be observed before planting any variety of green onion crops.



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



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5.0 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 input that contains animal manure, an animal product, and / or an animal by-product that is reasonably likely to contain human pathogens. Due to the potential for human pathogen contamination, these treatments should only be used under conditions that minimize the risk of green onion contamination.

5.1 The Best Practices Are:

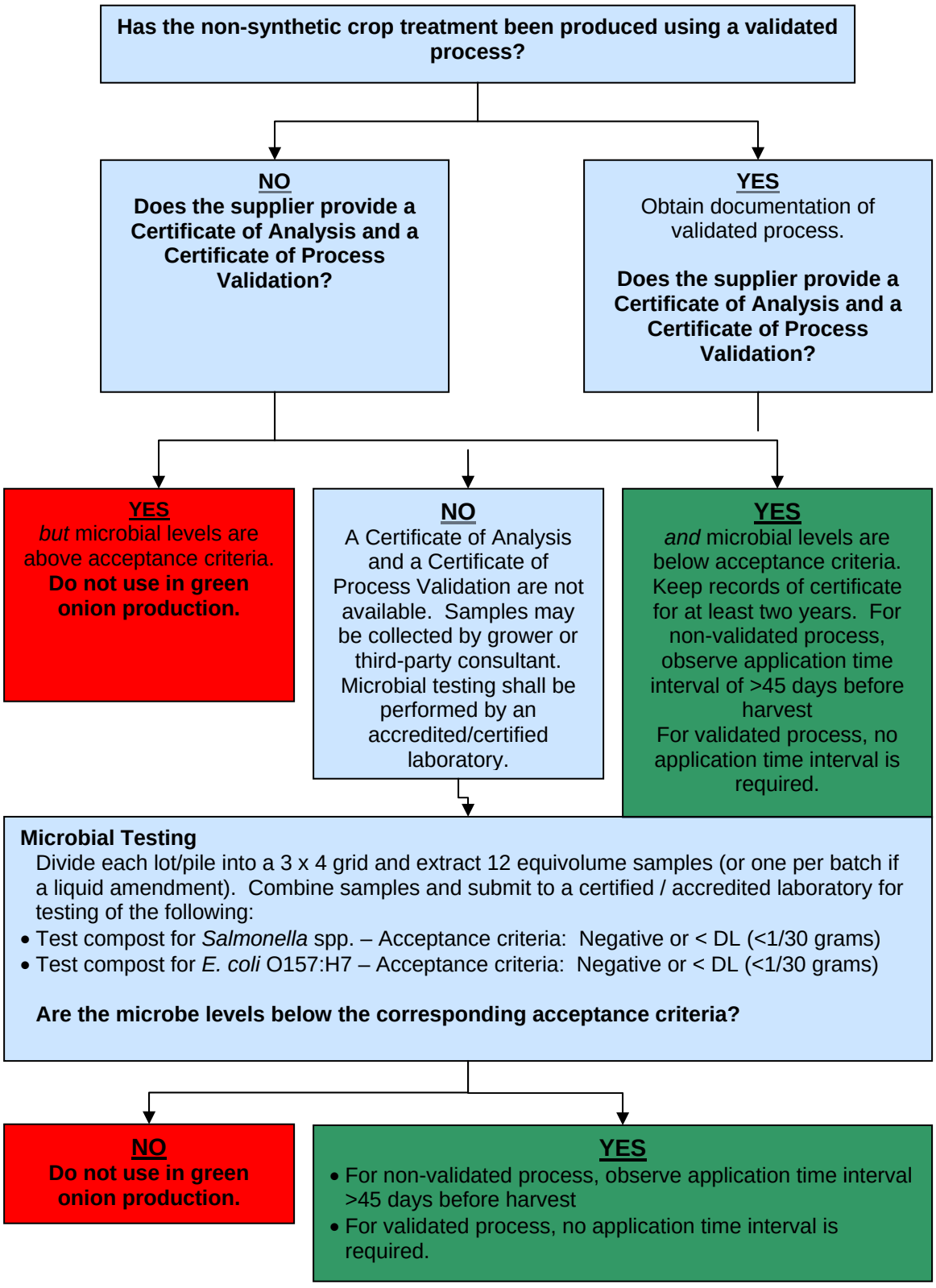
- DO NOT USE crop treatments that contain raw manure for green onion production.
- Retain documentation of all test results available for inspection for a period of at least 2 years.
- Implement management plans (e.g., timing of applications, storage location, source and quality, transport) that assure 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 recommended time interval between the crop treatment application and time to harvest as provided in Table I-5.
- Implement practices that control, reduce, or eliminate likely contamination of green onion fields that may be in close proximity to on-farm storage of crop treatments.
- 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 I-5 and Decision Tree (Figure 5) for numerical criteria and guidance for nonsynthetic crop treatments used in green onion production fields.

Table I-5. Nonsynthetic Crop Treatments

Treatment	Metric / Rationale
Any crop input that contains animal manure, an animal product, and / or an animal by-product that is reasonably likely to contain human pathogens. Examples include (but 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 green onions.** **Please see Figure 5: Decision Tree for Use of Nonsynthetic Crop Treatments.** **Process Validation** • The physical, chemical, and / or biological treatment process(es) used to render the crop input safe for application to crops should be validated. **Target Organism:** • *Salmonella* spp • *E. coli* O157:H7 **Acceptance Criteria (at point of use):** • *Salmonella* spp: Negative or < DL (<1/30 grams) • *E. coli* O157:H7: Negative or < DL (<1/30 grams) • Other pathogens appropriate for the source material. **Recommended 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:** • 12 point sampling plan composite sample (if solid) or one sample per batch if liquid • 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 green onion fields.

Treatment	Metric / Rationale
	Application Interval: • If the physical, chemical, and / or biological treatment process used to render the crop input safe for application to green onions 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 input safe for application to green onions is not validated yet meets the microbial acceptance criteria outlined above, a 45 day time interval between application and harvest is recommended. **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 metrics and validated processes for compost are based on allowable levels from California state regulations (CCR Title 14 - Chapter 3.1 - Article 7 2007), with the addition of testing for *E. coli* O157:H7 as the microbe of particular concern. The above suggested application interval was deemed appropriate due to the specified multiple hurdle risk reduction approach outlined. Any nonsynthetic crop treatment that contains animal manure shall use only fully composted manure in addition to a validated process and pass testing requirements before a application to soils or directly to green onions. The **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 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).

6.0 ISSUE: HARVEST EQUIPMENT

This section addresses harvest and harvest aid equipment used for green onions. Green onions may be harvested by hand or machine. Typically, after an initial undercut by a tractor with a chain drag or blade, almost all other harvest activities are done by hand. Hand harvest includes the use of many types of equipment including trimming boxes, trimming shears, and field containers. 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 introduction of contamination following this process step.

6.1 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 SSOPs for harvest equipment addressing the following:
  - The frequency of equipment cleaning and sanitation by developing a sanitation schedule for harvest operations.

- The need for periodic microbial swabs or other equivalent indicator for sanitation verification.
- The location of equipment cleaning and sanitizing operations to an area that will not contaminate green onions or other equipment.
- Proper cleaning, sanitation, and storage of all harvest equipment in a manner that will not contaminate green onions or other equipment.
    - Harvest tools should be sanitized at the beginning and end of each day.
    - Additionally, knives, shearers, machetes, scissors, and clippers 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).
    - 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 sheet for all sanitizers used should be kept on file.
- Appropriate cleaning and sanitizing procedures of all surfaces that come in contact with green onions including such items as tarps used for transporting and conveyor belts to reduce and control the potential for microbial cross-contamination.

- Prepare an SOP for the handling and storage of field containers that addresses the following:
    - Over night storage—field containers should be maintained and inventoried separately from post-harvest containers and finished product containers.
    - Field containers that come in contact with the ground.
    - Proper field container assembly procedures.
    - What to do with damaged field containers.
    - Use of field containers only as intended.
        - Field containers should not be used for anything other than holding green onions.
        - Field containers should not be used in the packinghouse or for finished green onion products.

- Washing / cleaning and sanitizing of field containers (preferably between uses).

- All hand-held harvesting tools should be collected at the end of each day. Employees should not take hand-held harvesting 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.
- Field containers should be constructed of materials other than wood that are easy to clean and sanitize.
- Knives, scissors, clippers, and trimming boxes should be constructed of stainless steel with either plastic or stainless steel handles so that they can be cleaned and sanitized easily. 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.
- Design equipment by using materials and construction 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 of animal intrusion or adjacent land that may pose a risk. For additional information on this issue, see Section 9.0 Equipment Facilitated Cross-Contamination.
- When a field is to be harvested more than once, develop practices and procedures to protect against the introduction of pathogens during and after the first cutting. (For example, "topped" green onions may become a conduit for contaminants due to their hollow nature; ensure that overhead watering, applications of SAs or crop protection products are not introduced into the commodity.)

7.0 ISSUE: DIRECT CONTACT WITH SOIL DURING HARVEST

Harvested green onions with intact roots are often stacked and sometimes covered with soil to control dehydration before outer layers are removed and any trimming or washing occurs. After harvest placing or stacking green onions on soil before they are placed into a container may expose the product to human pathogens if the soil is contaminated. Green onions that have been trimmed (e.g., rootless green onions) should not be placed on the soil or covered with soil.

7.1 The Best Practices Are:

- Furrow irrigation should be scheduled to avoid exposing the onions to excessive mud and soil that may be difficult to clean, especially close to harvest.
- 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 green onions on the soil, container cleaning and sanitation, single use container lining, etc.).
- Same day harvesting; harvest an entire green onion production block in 1 day to avoid product dehydration.
- Containers that come into direct contact with soil should be washed and sanitized between uses. Operators should evaluate the efficacy of this practice with intermittent testing.

8.0 ISSUE: FIELD AND HARVEST PERSONNEL TRANSFER OF HUMAN PATHOGENS BY WORKERS

Green onions may undergo significant handling by harvest crews during harvest in that each green onion plant is touched / handled as part of the harvest process. This handling can introduce contamination if effective practices and procedures are not employed. It is possible that persons working with green onions in the field may transfer microorganisms of significant public health concern. Workers may be asymptomatic. Growers / handlers should use appropriate preventive measures outlined in these guidelines such as training in appropriate and effective hand washing, mandatory glove use and replacement for certain field and harvest activities, and mandatory use of sanitary field latrines to reduce and control potential contamination. Several of the major outbreaks in green onions have involved the hepatitis A virus, which is of human origin. This may partially be a result of the labor-intensive nature of green onion production. Thus, worker hygiene practices may be even more crucial to observe during the harvest of this crop than other commodities.

8.1 The Best Practices Are:

- Prior to harvest, an individual should be designated as responsible for harvesting food safety. This person should be present when green onions are being harvested.
- Mandatory food safety training for every crew member at the beginning of each harvest season regarding proper sanitation and hygiene practices and the potential of cross-contamination of raw materials during harvesting.
    - This training should be augmented with follow-up sessions throughout the season.
    - Document all training sessions by having the workers sign a roster stating that they understand the training.

- The document should have a general description of the subject matter for the training, the trainer name, and the date training was conducted.

- Establish a written worker practices program (e.g., an SOP) that can be used to verify employee compliance with company food safety policy. This program should establish the following practices for field and harvest employees as well as for visitors.
  - Workers should 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.
  - Workers trimming or loading green onions should wear disposable gloves provided by their employer.
  - Gloves should be changed as necessary during the harvest day and after any event that may cause gloves to become contaminated (i.e., using the latrine, eating, or handling unsafe or non-food grade materials). A procedure for glove use should be established, followed, and documented.
  - If green onions are handled with bare hands, hand washing procedures should be documented.
  - Workers should wear disposable head and facial hair caps and coverings.
  - Workers should wear appropriate, clean protective garments such as disposable or cleanable aprons. Heavily soiled and / or damaged aprons should be replaced.
  - Employees should not leave hand-held harvesting tools and protective garments on top of harvesting equipment or on the ground.
  - Employees should not take knives, aprons, or any tools or protective garments inside the toilet facilities.
  - The storage of personal items away from areas where they may come in contact with green onions or onion-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 trash receptacles that are covered.
  - Prohibitions on spitting, urinating, or defecating in the field.
  - Employees should receive training on the use, storage, recordkeeping, and proper labeling of chemicals.
  - Children should not have access to green onion fields as they are often asymptomatic carriers of foodborne diseases such as hepatitis A.

- An area should be designated for storage of all hand-held harvesting tools and aprons, 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.

- A written physical hazard prevention program should be developed for green onion production and harvest activities. The program should address the following:
  - Employee clothing and jewelry (head and hair restraints, aprons, gloves, visible jewelry, etc.).
  - Removal of all objects from upper pockets.
  - Foreign objects in the field; employees should not bring glass, hard plastics, or metal containers, or other objects into the field or areas bordering the field.
- Establish a worker health practices program (i.e., an SOP) that addresses the following issues:
  - Workers with diarrhea disease or symptoms of other infectious disease are prohibited from handling green onions or being within the vicinity of the harvest fields or crews prior to or during harvesting.
  - Workers with open cuts or lesions are prohibited from handling green onions without specific measures to prevent cross-contamination of product.
  - Actions for employees to take in the event of injury or illness.
  - A policy describing procedures for handling / disposing of green onions or food contact surfaces that have come into contact with blood or other bodily fluids.
  - Recommend that workers receive vaccinations for hepatitis A.
- A field sanitary facility program (i.e., an SOP) should be implemented to address the following issues: the number, condition, and placement of field sanitation units, the accessibility of the units to the work area, facility maintenance, facility supplies (hand soap, water, paper towels, toilet paper, etc.), facility signage, facility cleaning and servicing, and a response plan for major leaks or spills.
  - Sanitary facilities should be placed such that the location minimizes the impact from potential leaks and / or spills while allowing access for cleaning and service. Under OSHA regulations, they are required to be within a ¼ mile walk of each laborer's position in the field.[22]
  - The location and sanitary design of toilets and hand wash facilities should be optimized to facilitate the control, reduction and elimination of human pathogens from employee hands. Evaluate the location of worker hygiene facilities to maximize accessibility and use, while minimizing the potential

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

for the facility to serve as a source of contamination. Under OSHA regulations, at least one toilet facility and one hand washing facility must be provided for each 20 employees or fraction thereof.

- Hand washing facilities should be supplied with potable water (e.g., meets local, state, or US EPA microbial standards for drinking water).
- 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.
- Trash receptacles should be removed from the harvest area at the end of the work shift and instructions should be provided on where to empty them and how to clean them.
- Maintain documentation of maintenance and sanitation schedules and any remedial practices for a period of 2 years.

- During harvest operations, perform an environmental assessment of the green onion production field and surrounding area. See section 2.0 Environmental Assessments for more information.

9.0 ISSUE: EQUIPMENT FACILITATED CROSS-CONTAMINATION

When farm equipment has had direct contact with raw untreated manure, untreated compost, waters of unknown quality, animals, or other potential human pathogen reservoirs it may be a source of cross-contamination. Such equipment should not be used in proximity to or in areas where it may contact green onions until it has been sanitized.

9.1 The Best Practices Are:

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

10.0 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 is reasonably likely to cause adulteration of green onions in that field. Pooled water (e.g., rainfall) that is not reasonably likely to contain microorganisms of significant public health concern and is not reasonably likely to cause adulteration of green onions should not be considered flooding.

If flood waters contain microorganisms of significant public health concern, green onions, which are in close proximity to soil, may be contaminated if there is direct contact between flood water or contaminated soil and the green onion plants (Casteel et al. 2006; Wachtel et al. 2002a; 2002b). Areas that have been flooded can be separated into three groups: 1) green onions that have come into contact with flood water, 2) green onions 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 green onions were planted. The considerations for each situation are described below and presented in Table I-6.

10.1 The Best Practices for Green Onions in Proximity to a Flooded Area Contacted By Flood Water Are:

- See Table I-6 for numerical criteria for green onion 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.
- FDA considers any crop that has come into contact with floodwater to be an "adulterated" commodity that cannot be sold for human consumption.[23, 24]
- To reduce the potential for cross-contamination do not drive harvest equipment through flooded areas reasonably likely to contain microorganisms of public health significance. See section 9.0 Equipment Facilitated Cross-Contamination.

[23] 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

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

1083 **Table I-6. Flooding**

1084 When evidence of flooding in a green onion 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 green onions 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 green onions within 30 ft of the flooding. • Recommended 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.
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 green onion fields.
Time Interval Before Planting Can Commence Following the Receding of Floodwaters	• 60 days prior to planting provided that the soil has sufficient time to dry out. • Appropriate soil testing can be used to shorten this period to 30 days prior to planting. This testing should be performed in a manner that accurately represents the production field and indicates soil levels of microorganisms lower than the recommended standards for processed compost. Suitable representative samples should be collected for the entire area suspected to have been exposed to flooding. For additional guidance on appropriate soil sampling techniques, use the "Soil Screening Guidance: Technical Background Document" (US EPA 1996). Specifically, Part 4 provides guidance for site investigations. Reputable third-party environmental consultants or laboratories provide sampling services consistent with this guidance. • Appropriate mitigation and mitigation strategies are included in the text portion of the document.
Rationale	• The basis for the 30 foot distance is the turn-around distance for production equipment to prevent cross-contamination of non-flooded ground or green onions in the fields.

10.2 The Best Practices for Green Onions in Proximity to a Flooded Area But Not Contacted By Flood Water Are:

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

10.3 The Best Practices For Formerly Flooded Production Ground Are:

- Soils from formerly flooded production ground should be allowed to dry sufficiently and reworked prior to planting green onions.
- Do not plant green onions in formerly flooded production ground for at least 60 days following the receding of floodwaters. This period or longer and active tillage of the soil provide additional protection against the survival of pathogenic organisms.
- If flooding has occurred in the past on the property, soil clearance testing may be conducted prior to planting green onions. Soil testing may be used to shorten the clearance period to 30 days. If performed, testing should indicate soil levels of *E. coli* O157:H7 and *Salmonella* lower than the standards for processed compost (see Table I-4. Soil Amendments). Representative samples should be collected for the entire area suspected to have been exposed to flooding.
- Sample previously flooded soil for the presence of microorganisms of significant public health concern or appropriate indicator microorganisms. Microbial soil sampling can provide valuable information regarding relative risks; however, sampling by itself does not guarantee that green onions grown within the formerly flooded production area will be free of the presence of human pathogens.
- 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. 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 field history and crop selection on formerly flooded production ground.

- Assess the time interval between the flooding event, crop planting, and crop harvest. Comparative soil samples may be utilized to assess relative risk if significant reductions in indicator microorganisms have occurred within this time interval.
- Evaluate the source of flood waters (drainage canal, river, irrigation canal, etc.) for potential significant upstream contributors of human pathogens at levels that pose a significant threat to human health.
- Prevent cross-contamination by cleaning or sanitizing any equipment that may have contacted previously flooded soil (also see section 9.0 Equipment Facilitated Cross-Contamination.).

11.0 ISSUE: WATER USAGE TO PREVENT GREEN ONION DEHYDRATION

Green onions 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 contaminate green onions if there is direct contact of water containing human pathogens with green onions.

11.1 The Best Practices Are:

- Due to the timing of application of water that directly contacts green onions, assure the water is of appropriate microbial quality (i.e., meets US EPA microbial standards for drinking water).
- Test the water source periodically to demonstrate if it's of appropriate microbial quality for its intended purpose (i.e., meets US EPA or WHO microbial standards for drinking water if directly contacts plant surfaces) or assure that it has appropriate disinfection potential as described in the Post-Harvest section in Table I-2.
- Establish and implement cleaning and sanitation schedules for containers and equipment that will be used in hydration.
- Maintain logs documenting cleaning and sanitation, and retain these records for at least 2 years.
- Establish policies for the storage and control of water tanks and equipment used for hydration operations when not in use.

12.0 ISSUE: DOCUMENTATION AND RECORDS [25]

As a general practice, it is important that firms that produce and harvest green onions maintain documentation and records related to operations and practices as well as information useful for tracing the product. Existing FDA regulations in 21 CFR part 1, subpart J, "Establishment, Maintenance, and Availability of Records," impose certain

[25] The basis for the green onion documentation and records best practices are the best practices outlined by the FDA in their draft commodity specific guidance for tomatoes, melons and leafy greens; obtained at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/default.htm . It is possible that these may change based on public comment.

recordkeeping requirements on persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the U.S. However, farms (as defined in the regulation) are excluded from the recordkeeping requirements of part 1, subpart J. The records specified in the regulations, must identify the immediate previous sources and immediate subsequent recipients of food, including its packaging. The recommendations below complement, but do not supersede, existing recordkeeping requirements in part 1, subpart J.

***Operational Records*:** Keeping operational records about green onion production and practices can be helpful to firms. First, such records help ensure consistency of production 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 green onions implicated in an outbreak are traced to a particular farm or facility.

***Product Tracing*:** Product tracing refers to the ability to follow the movement of a food through specified stage(s) of production, packing, processing, and distribution. Tracing information for green onions facilitates tracking the physical movement of the onions between their original source, through intermediate sources to their final recipient and tracking them from the final recipient back to their original source. Effective product tracing systems can serve as an important complement to food safety programs such as these guidelines intended to prevent microbial contamination.

12.1 The Best Practices Are:

- Develop and maintain a written food safety plan, SOPs, and SSOPs for activities such as handling and storage practices, field, facility, and vehicle cleaning and sanitation, and employee training programs.
- Maintain records for significant activities performed, such as monitoring of water sources and use; water quality testing; treatment of water; animal intrusion; cleaning and sanitation of equipment, containers and vehicles, employee training; and corrective actions taken. These records should be maintained for a period of at least 2 years.
- Record information such as the date and time, name of person(s) who completed the record, the location of the field and location in the field, if applicable, and the activity being monitored in the documentation.
- Utilize information outlined in the FDA's "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" and "Guide To Traceback of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations" in developing a product tracing system applicable to the green onions supply chain (see section 13.0 Detailed Background Documents).
- Develop and maintain standardized, clear records that can be used to enhance the ability to follow the movement of green onions through the supply chain. Examples of such records include labels with product identifying information, invoices, inventory records, bills-of-lading, and shipping / receiving records.

13.0 DETAILED BACKGROUND GUIDANCE INFORMATION

1. "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)

2. "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/)

3. "Food Security Guidelines and Questionnaire for Fresh Fruits and Vegetables," United Fresh Produce Association, 2001. (http://www2.unitedfresh.org/forms/store/ProductFormPublic/)

4. "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)

5. "Guide To Traceback Of Fresh Fruits and Vegetables Implicated in Epidemiological Investigations," U.S. Food and Drug Administration, 2006. (http://www.fda.gov/downloads/ICECI/Inspections/InspectionGuides/ucm109502.doc)

14.0 REFERENCES

Beuchat LR. 1996. Pathogenic microorganisms associated with fresh produce. *Journal of Food Protection*. 59(2):204-216.

Casteel M, Sobsey M, and Mueller J. 2006. Fecal contamination of agricultural soils before and after hurricane-associated flooding in North Carolina. *Journal of Environmental Science and Health. Part A, Toxic/Hazardous Substance and Environmental Engineering.* 41(2):173-184.

CDC. 2008. Centers for Disease Control and Prevention's Outbreak Surveillance Data (http://www.cdc.gov/foodborneoutbreaks/outbreak_data.htm).

CCR Title 14 - Chapter 3.1 - Article 5. 2007. *Article 5. Composting Operation and Facility Siting and Design Standards*. Accessed February 15, 2007. (http://www.ciwmb.ca.gov/regulations/Title14/ch31a5.htm#article5)

Dentinger C, Bower W, Nainan O, Cotter S, Myers G, Dubusky L, Fowler S, Salehi E, and Bell B. 2001. An outbreak of hepatitis A associated with green onions. *Journal of Infectious Diseases*. 183:1273-1276.

Fenlon, DR. 1985. Wild birds and silage as reservoirs of *Listeria* in the agricultural environment. *Journal of Applied Bacteriology*. 59:537-543.

Fukushima H, Hoshina K, and Gomyoda M. 1999. Long-term survival of shiga toxin-producing *Escherichia coli* O26, O111, and O157 in bovine feces. *Applied and Environmental Microbiology.* 65(11):5177-81.

Gagliardi JV and Karns JS. 2000. Leaching of *Escherichia coli* O157:H7 in diverse soils under various agricultural management practices. *Applied and Environmental Microbiology.* 66(3):877-83.

Ingham SC, Losinski JA, Andrews MP, Breuer JE, Breuer JR, Wood TM, and Wright TH. 2004. *Escherichia coli* contamination of vegetables grown in soils fertilized with noncomposted bovine manure: Garden-scale studies. *Applied and Environmental Microbiology*. 70(11):6420-6427.

Islam M, Doyle MP, Phatak SC, Millner P, and Jiang X. 2004a. Persistence of enterohemorrhagic *Escherichia coli* O157:H7 in soil and on leaf lettuce and parsley grown in fields treated with contaminated manure composts or irrigation water. *Journal of Food Protection.* 67(7):1365-70.

Islam M, Morgan J, Doyle M, and Jiang X. 2004b. Fate of *Escherichia coli* O157:H7 in manure compost-amended soil and on carrots and onions grown in an envrironmentally controlled growth chamber. *Journal of Food Protection*. 67(3):574-578.

Jiang X, Morgan J, and Doyle M. 2003. Fate of *Escherichia coli* O157:H7 during composting of bovine manure in a laboratory-scale bioreactor. *Journal of Food Protection.* 66(1):25-30.

Jiang X, Morgan J and Doyle M. 2002. Fate of *Escherichia coli* O157:H7 in manure-amended soil. *Applied and Environmental Microbiology*. 68(5):2605-2609.

Keene WE, Sazie E, Kok J, Rice DH, Hancock DD, Balan VK, Zhao T, and Doyle MP. 1997. An outbreak of *Escherichia coli* O157:H7 infections traced to jerky made from deer meat. *Journal of the American Medical Association*. 277(15):1229-31.

Monterey County Health Department Consolidated Environmental Laboratory. 2007. Testing irrigation water for generic *E. coli*: Multiple tube fermentation (SM 9221B, E, F) and quantitray (SM 9223B), Salinas.

Nicholson FA, Groves SJ, and Chambers BJ. 2004. Pathogen survival during livestock manure storage and following land application. *Bioresource Technology*. 96:135-143.

Suslow, T.V., M.P. Oria, L.R. Beuchat, E.H. Garrett, M.E. Parish, L.J. Harris, J.N. Farber, F.F. Busta. 2003. Production practices as risk factors in microbial food safety of fresh and fresh-cut produce. *Comprehensive Reviews in Food Science and Food Safety*. 2S:38-77.

Takeuchi K and Frank JF. 2000. Penetration of *Escherichia coli* O157:H7 into lettuce tissues as affected by inoculum size and temperature and the effect of chlorine treatment on cell viability. *Journal of Food Protection.* 63(4):434-40.

Takeuchi K, Matute CM, Hassan AN, and Frank JF. 2000. Comparison of the attachment of *Escherichia coli* O157:H7, *Listeria monocytogenes*, *Salmonella typhimurium*, and *Pseudomonas fluorescens* to lettuce leaves. *Journal of Food Protection.* 63(10):1433-7.

US EPA. 1996. *Soil Screening Guidance: Technical Background Document*. EPA/540/R95/128: Office of Solid Waste and Emergency Response, United States Environmental Protection Agency. (http://rais.ornl.gov/homepage/SSG_nonrad_technical.pdf)

US EPA. 2003. Center for Environmental Research Information, "Chapter 5: Class B pathogen requirements and requirements for domestic septage applied to agricultural land, a forest, or a reclamation site," Environmental Regulations and Technology: Control of Pathogens and Vector Attraction in Sewage Sludge, EPA/625/R-92/-13, U.S. Environmental Protection Agency, Cincinnati.

US FDA. 2001. Analysis and Evaluation of Preventive Control Measures for the Control and Reduction/Elimination of Microbial Hazards on Fresh and Fresh-Cut Produce. Accessed January 2010. (http://www.fda.gov/Food/ScienceResearch/ResearchAreas/SafePracticesforFoodProcesses/ucm090977.htm)

US FDA. 2004. Federal Food, Drug, and Cosmetic Act. (http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm)

Wachtel MR, Whitehand LC, and Mandrell RE. 2002a. Association of *Escherichia coli* O157:H7 with preharvest leaf lettuce upon exposure to contaminated irrigation water. *Journal of Food Protection.* 65(1):18-25.

Wachtel MR, Whitehand LC, and Mandrell RE. 2002b. Prevalence of *Escherichia coli* associated with a cabbage crop inadvertently irrigated with partially treated sewage wastewater. *Journal of Food Protection.* 65(3):471-5.

Wheeler C, Vogt T, Armstrong G, Vaughan G, Weltman A, Nainan O, Dato V, Xia G, Waller K, Amon J, Lee T, Highbaugh-Battle A, Hembree C, Evenson S, Ruta M, Williams I, Fiore A, and Bell B. 2005. An outbreak of hepatitis A associated with green onions. *New England Journal of Medicine*. 353:890-897.

SECTION II: POST-HARVEST UNIT OPERATIONS

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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." If raw green onions are packed in ice at a packinghouse, they are called iced green onions. This section covers iced green onions, 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 green onions as a raw agricultural commodity are not subject to cGMPs, operations that alter the form of green onions by cutting or chopping are considered processors or manufacturers and are subject to follow cGMPs. However 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 green onions 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.

Green onion food safety programs should focus on preventing adulteration by microbial contamination because in the U.S. these onions are typically eaten raw and without thermal treatment to reduce human pathogen levels. For that reason, it is recommended as a general practice that these products are 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 recommendations is primarily based on cGMPs put forward in 21 CFR 110 and the FDA's "Fresh-cut Guide."[26]

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. Green onions may be transported to the packinghouse / cooling facilities by numerous modes of transportation. Transportation of green onions 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

[26] 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

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 green onions 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 green onions.
- 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 green onions to the packinghouse or cooling facility.
  - Procedures that address washing and sanitizing product covers and tarps as well as keeping them in good condition.
  - Maintain truck beds (an indirect food contact surface) in clean condition.
- Follow the Best Practices under the SSOP for field containers outlined in this document to avoid cross contamination during transportation activities.

3.0 ISSUE: RECEIVING

When green onions 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, consider minimizing the time from harvest to cooling. Keep track of the product (traceability) as it is received, during inspections, and documentation. During receiving it is critical that all essential field information is appropriately maintained and transferred to packinghouse operations.

3.1 The Best Practices Are:

- For Best Practices related to field containers, please see Section I. Production and Harvest Unit Operations – section 6.0: Harvest Equipment.
- Obtain green onions from suppliers that follow GAPs and the recommendations in this guidance.
- Establish a procedure for inspecting and accepting or rejecting incoming loads of green onions.
- Establish procedures to ensure green onions are held and stored in designated areas and handled under proper conditions.

- Whenever possible, follow first-in, first-out (FIFO) practices. If this is not possible, document the inventory control practice that is used and the rationale behind its acceptability.
- Ensure that incoming documentation provides sufficient information to facilitate product traceability and establish a system to maintain that documentation.

4.0 ISSUE: WATER USED IN PACKINGHOUSE AND COOLING OPERATIONS

Washing green onions with water, if done correctly, can reduce microbial loads on the outside surface of product (Luo 2007). The use of water to reduce microbes on the surfaces is dependent on the disinfectant concentration, the type of wash system utilized, and the contact time. When used appropriately with water of adequate quality, disinfectants help minimize the further 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.[27]

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.

Ice and / or ice slurries may also be used to cool green onions by either placing on top of the product or injecting into cartons, thus providing another possible contamination source if contaminated water is used to make the ice. Ice used on green onions should be included in routine water quality testing.

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 may include using antimicrobial chemicals in the wash water or using spray type wash treatments instead of submerging produce. Alternatively, produce may be cooled by means other than hydrocooling.

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. Consider all uses of water in washing or cooling operations (including ice) where it directly contacts green onions. Water used in Post-Harvest operations may contaminate green onions if there is direct contact of water containing microorganisms of significant public health concern with green onions. To insure better microbial quality, it is

[27]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

recommended that water used in washing and cooling operations 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 green onions is a hollow leaf tube, special care should be taken if dump tanks or immersion washes are used to minimize microbial contamination.

- Water used in cooling and packing house operations that directly contacts green onions should be of drinking water quality or have sufficient levels of disinfectant so as not to contaminate the product (i.e., meets US EPA or WHO microbial standards for drinking water). See Table II-1 for guidance on post-harvest water use.[28]
- The water source should be tested (as specified in Table II-1) for its intended use. 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 generic *E. coli.*
- Consider development of 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 water disinfectants are used, levels should be monitored and maintained throughout the process by testing the water disinfectant concentration and pH or oxidation reduction potential (ORP). Active disinfectant levels should be measured and documented (i.e., measure free chlorine and not chlorine concentration). If feasible, 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.

[28] 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, Technical Basis for Metrics.

- All monitoring equipment should be adequately maintained and periodically calibrated. Maintain a log of maintenance and calibration events.
- Water reservoir tanks should be kept clean and sanitary. Tanks should be cleaned and sanitized before each season or at least once a year. Visual inspections and / or other testing (e.g., ATP, microbiological, chemical) should be performed at appropriate frequencies to verify sanitary conditions. All 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: Recycled Water

Water in packinghouse or cooling operations may be recycled or recirculated. Water quality is especially important at the end of the process when sequential washing is used. If recycled water contacts green onions, water should meet drinking water quality standards and recommended disinfectant levels should be used throughout all processes (see Tables II-1). All monitoring activities should be documented.

- When washing or cooling green onions in recirculated water, disinfectant should be present at sufficient levels and the levels monitored to reduce the potential risk of cross contamination (see Table II-1).
- When washing or cooling green onions in recirculated water, procedures should be established to determine when and how often water should be refreshed or completely changed out.
- Water disinfectants levels should be monitored and maintained throughout the process by testing the water disinfectant concentration and pH or ORP as follows:
    - Any disinfectants used should be used according to the manufacturer's specifications.
    - When disinfectants are used in a recirculation system, active disinfectant levels should be measured and documented (i.e., measure free chlorine and not chlorine concentration).
    - If feasible, 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 should be monitored to verify correct concentration. These checks should be documented.
    - 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.
- Appropriate measures should be taken for waste water disposal.
- Any water additive used to wash green onions should be food-grade and compliant with federal, state or local regulations for the intended use (i.e., compliant with 21 CFR 173.315—Chemicals used in washing or to assist in the peeling of fruits and vegetables). Copies of MSDS sheets for water additives should be maintained on file.
- Single-pass or one-use cooling water of sufficient quality for this intended purpose may also be used to cool product.

4.3 The Best Practices Are: Ice and Ice Slurry

Green onions are often "iced" or slurry iced to cool product or as a means of keeping the product cold during distribution.

- Water used to make ice that directly contacts product and is used in cooling and packinghouse operations should be drinking water quality (i.e., meets US EPA or WHO 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 II-1 on Post-Harvest Water Use).
- All equipment that holds or transports ice should be cleaned and sanitized daily.
- Ice storage should not be in proximity to raw product or chemical storage.
- Assure that ice whether manufactured on-site or purchased from outside vendors is handled, stored, and transported in a sanitary manner.
- Consider use of ice that contains an approved water disinfectant at sufficient concentration to reduce the potential for cross contamination.
- If ice is used, consider use of plastic pallet shrouds to protect product from potential cross contamination by pallets of iced product placed in storage racks above pallets of other product.

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Use	Metric	Rationale / Remedial Actions
POST-HARVEST Direct Product Contact or Food Contact Surfaces	**Microbial Testing** **Target Organism:** generic *E. coli*. **Sampling Procedure:** 100 mL 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 generic *E. coli* levels are below detection limits for five consecutive samples, the sampling frequency may be decreased to once every six months and the recommendations for 60 and 30 day sampling are waived. This exemption is void if there is a significant source or distribution system change. **Test Method:** 15 tube MPN (FDA BAM) or other US US EPA, AOAC, or other method accredited for quantitative monitoring of water for generic *E. coli.* Presence / absence testing with a similar limit of detection may be used as well.	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, to ensure the integrity of the sample, using sampling methods as prescribed in this table) where the water contacts green onions, so as to test both the water source and the water distribution system. Only one sample per month per distribution system is recommended 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 green onions or is used on food contact surfaces such as equipment or utensils, should meet the Maximum Contaminant Level Goal 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 vs. Multiple Pass Systems** • Single pass use – Water should have non-detectable levels of generic *E. coli* or breakpoint disinfectant present at point of entry. • Multi-pass use – Water should have non-detectable levels of generic *E. coli* and / or sufficient disinfectant to insure returned water has no detectable *E. coli* (minimally 1 ppm chlorine). **Remedial Actions**: If any one sample exceeds the acceptance criteria, then the water should not be used for this purpose unless appropriate disinfectants have been added or until remedial 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 remedial actions to determine if it meets the outlined microbial acceptance criteria for this use. For example, if a water sample for water used to clean food contact surfaces has detectable generic *E. coli*, STOP using that water system, examine the distribution line, source the inlet as described in the

	Acceptance Criteria: **Negative or below DL for all samples**	Sanitary Survey (**Appendix A**), and retest from the same point of use. Continue testing daily for 5 days at the point closest to use, and do not use the water system until it consistently delivers water that is safe, sanitary, and of appropriate microbial quality (i.e., negative result) for the intended use. If any of the five samples taken during the intensive sampling period after corrective actions have been taken, have detectable generic *E. coli*, repeat remedial actions and DO NOT use that system until the source of contamination can be corrected. **Records**: All test results and remedial actions should be documented and available for verification from the user of the water for a period of 2 years.
	<u>Physical / Chemical Testing</u> **Target Variable:** Water disinfectant (e.g., chlorine or other disinfectant compound) **Multi Pass Water Acceptance Criteria:** • **Chlorine** ≥1 ppm free chlorine after application and pH 6.5 – 7.5 • ORP ≥ 650 mV, and pH 6.5 – 7.5 • **Other approved treatments** per product US EPA label for human pathogen reduction in water. **Testing Procedure:** • Chemical reaction based colorimetric test, or • Ion specific probe, or • ORP, or • Other as recommended by disinfectant supplier. **Testing Frequency:** Continuous monitoring (preferred) with periodic verification by titration OR routine monitoring if the system can be shown to have a low degree of variation.	

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5.0 ISSUE: POST-HARVEST CONTAINERS, FINISHED PRODUCT CONTAINERS, AND PACKAGING MATERIALS

Green onions are generally harvested into field containers and transported to a packinghouse for further trimming, washing, sorting, and packing. These green onions are then either packaged into a waxed fiberboard carton with ice or ice slurry, or are packaged into a poly bag and then into a fiberboard carton or a returnable plastic container (RPC). Post-Harvest containers, finished product containers and packing materials may be a source of microbial contamination if they are not handled and stored in a sanitary manner. In addition, the use of RPC's that may have previously 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.

5.1 The Best Practices Are: Post-Harvest Containers

- Post-Harvest 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 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 Post-Harvest containers. Topics addressed should include (but are not limited to):
  - Cleaning frequency, sanitizer type, concentration, and specific cleaning steps.
  - Documentation should include the concentration of sanitizer used, the method of measurement, time of measurement, date, and the initials of the employee who performed the measurement.

5.2 The Best Practices Are: Finished Product Containers (RPCs / Fiberboard Cartons) and Packing Materials

- A procedure should be in place to inspect all incoming finished product 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.
- Finished product containers should be stored in a controlled area and protected against potential contamination from birds, rodents, insects, and other sources at all times. The containers should be stored on clean pallets and covered to protect them from potential contamination.
- Finished product containers should be covered adequately with plastic to prevent the intrusion of foreign material, including wind-blown dust and debris.

- The finished product containers storage area should be identified and maintained with a perimeter to facilitate inspection, cleaning, and pest control devices. If the storage area is outside of the building, it should be in a designated area with proper coverings of the materials, routinely monitored for any potential contamination sources, and have a well-documented pest control program.
- Any finished product containers that are identified as potentially contaminated and not suitable for use in storing food products should be discarded.
- Cleaning, sanitation and / or verification procedures should be in place to ensure RPCs are in sanitary condition suitable for use and are not a potential source of cross contamination.
- Packing materials (e.g., poly bags, labels, pallet film, tape) used for green onions that have been washed, sorted, and / or trimmed must be handled and stored in a sanitary manner.
- A formal inspection and repair program should be implemented for pallets. Pallets used with finished product containers should be in good condition, (i.e., free from loose pieces such as nails or staples). Damaged wood pallets should not be used.
- Pallets used during production and harvesting operations should not be used to hold Post-Harvest containers containing green onions that have been washed.
- Pallets used during production and harvesting operations should not be used to hold finished product containers.

6.0 ISSUE: PACKINGHOUSE AND COOLING FACILITIES

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 green onions 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, it is the recommendation of these guidelines that facilities which pack and cool green onions follow the requirements for buildings and grounds, packing and holding of foods, equipment and utensils, sanitary facilities and controls, and sanitary operations as provided for under 21 CFR Part 110, as appropriate to the facility. 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 green onions. Facilities and staging areas should be designed to facilitate maintenance and good sanitation practices so that contamination may be controlled throughout receiving, cooling, packing, and storage operations.

6.1 The Best Practices Are: General Considerations

- Consider validating your packinghouse and / or cooling facility procedures to assure that green onions are not contaminated during these unit operations.
- Consider limiting access to the packinghouse, cooling facility, and surrounding areas to authorized personnel only.

6.2 The Best Practices Are: Grounds

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

- Properly store equipment, remove litter and waste, and cut weeds or grass within the immediate vicinity of 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, foot-borne filth, or providing 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.

6.3 The Best Practices Are: General Maintenance and Design

Packinghouse and cooling facilities and equipment should be designed, constructed and maintained to facilitate easy 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.

- 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.
- Consider using under-floor drains in areas where green onions are trimmed, peeled, packaged, or otherwise processed.
- 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.

- If two food contact surfaces meet, consider using a cover over the juncture to prevent food debris from collecting in the crevice and creating an area that is difficult to clean.
- Avoid use of hollow structures such as table legs, conveyer rollers, and racks because they may collect water and debris, and thus, harbor pathogens.
- The building structure should be such that pests can be excluded from gaining entrance to the facility.
- Ensure that all exterior doors have an adequate seal.
- All lights should be designed to prevent the potential for broken glass contamination of the product. Lights should be of tube-in-tube construction or have similar protective applications to prevent broken fixture material from contaminating the products.
- Pipelines should be designed to avoid pipe and wall condensation to avoid becoming a contamination source.
- Water pipes into the facility and waste water piping exiting the facility 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 for employees to store personal items that is not in a food handling area.

6.4 The Best Practices Are: Sanitary Facility (Toilets and Hand-Washing Stations) Construction and Design

Operations with poorly designed and constructed sanitary facilities may provide direct or indirect contamination of green onions and water sources used on the onions.

- Sanitary facility design and construction including number and location should be in compliance with applicable local, state, and federal regulations.[29]
- Consider the number and location of toilet and hand-washing sanitary facilities needed for number of employees present. A recommended ratio of sanitary facilities per employee is 1 per 20 employees, per gender.
- Evaluate the location of worker hygiene facilities to maximize accessibility and use, while minimizing the potential for the facility to serve as a source of contamination.
- Toilet facilities should not open directly into areas where product is located.
- Hand-washing units should be located in close proximity to toilet facilities.

[29] OSHA. Sanitation. 1910-141.
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9790

- Hand-washing units should provide 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 should be provided.
- Single-use paper towels should be provided for worker use.
- Each individual toilet facility should have toilet paper in a proper holder.
- Trash containers with covers should be provided for disposal of single-use towels.
- Hand-washing units and toilet facilities should be constructed with properly designed drainage systems.
- The door to the toilet facility and doors for each individual toilet should be self-closing and lockable from the inside.
- Sanitary facility should be constructed of materials that can be easily cleaned and sanitized using cleaners and / or oxidizing agents.
- Sanitary facilities should have proper screens to exclude vermin.
- Signs should be posted indicating that *the water is only for hand-washing purposes* (in appropriate languages).
- Ideally, "on / off" switches for water should be "hands-free" (i.e., workable without using potentially soiled hands with devices such as elbow / knee faucet controls or foot pedals).
- Catch basins for waste water should be sealed and plumbing should be free of leaks.

6.5 The Best Practices Are: Packinghouse and Cooling Facility Sanitary Operation

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 green onions arriving from the field never cross paths with, or are commingled with, finished product.

- Each facility should have a flow diagram of the packinghouse and / or cooling operation and should consider performing 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.
- 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.

- It is often useful to develop a pre-operative check list that can be used to conduct the inspection and provide documentation that the inspection was completed. It is equally useful to have a corrective actions section that identifies food safety infractions and assigns responsibility to correct the infraction.
- Operators should be aware of and operate in accordance with all relevant laws and regulations that describe facility sanitation practices.
- Operators should be aware of and operate in accordance with all relevant laws and regulations with regard to handling processing and sanitation chemicals including the posting of MSDS sheets.
- There should be clear separation of raw and finished products storage to reduce the potential for cross-contamination.
- Green onions should not come into contact with the floor or any other non-food contact surface. Onions that fall on the floor should be discarded.
- There should be proper drainage of floors in packing or storage areas to avoid water build-up and reduce the potential for cross-contamination.
- Appropriate measures should be taken for waste water disposal.
- Garbage should be placed in appropriate receptacles and removed from the facility on a regularly scheduled basis.
- Garbage receptacles should have serviceable lids.
- 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 contact and those that are used for general cleaning and may contact non-food contact surfaces.
- Old, unused equipment should be removed from the packinghouse and cooling facilities.
- Appropriate signage should be displayed throughout packinghouse and cooling facility to remind employees to adhere to company food safety policies.

7.0 ISSUE: PACKINGHOUSE AND COOLING FACILITY SANITATION

Sanitation programs are critical to ensuring that green onions 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.

When green onions 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 green onions, sanitary 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 green onions, onion-contact surfaces, or packaging materials.

7.1 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. Consider use of a master sanitation schedule for these areas that clearly identifies cleaning frequency, sanitizers to be used, precautions, etc.
- 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 packaging or raw or finished products.
- 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.
- Toxic 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.
- An MSDS sheet should be kept on file for each cleaning and sanitizing chemical.
- Consider performing environmental testing (e.g., microbiological or bioluminescense testing) on a regular basis to confirm the efficacy of the facility cleaning and sanitation. Testing data should be maintained on file.

7.2 The Best Practices Are: Cooling Facility Sanitation

- Operators should be aware of and operate in accordance with all relevant laws and regulations that describe cooling facility sanitation practices.
- The cooling facility should have a written sanitation program (SSOP) 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 for *Listeria* spp. (e.g., hydrovac and icing rooms).[30]
- Condensation from ice delivery systems may drip onto product potentially serving as a source of cross-contamination. These systems should be kept clean and sanitary.
- Bins and shovels used to contain and / or move ice should be kept clean and sanitary.
- Floors should drain properly to prevent standing water.
- Workers should be trained about the potential for cross-contamination when using water to clean the floors.

7.3 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.

- Open windows, vents, fans, and similar features should be adequately screened to prevent pest entry.
- Rodent traps should be deployed around the inside and outside perimeter of the facility. Detailed maps demonstrating the location of each trap should be available for review. Traps should be inspected routinely as part of the pre-operative inspection and any corrective actions (e.g., cleaning out traps, replacing damaged traps) documented.
- All pesticides, traps, bait, and chemicals used in pest control must be acceptable for use around food in accordance with local, state, and federal regulations.
- 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.
- Exterior doors should have adequate weather stripping.

[30] 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

- 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 a third party is used for pest control, a copy of their license, any chemicals used, MSDS sheets, and a schedule of their activities and actions should be maintained and available for review.
- If pest control is performed internally, a copy of the applicators license, any chemicals used, MSDS sheets, and a schedule of their activities and actions should be maintained and available for review.

7.4 The Best Practices Are: Sanitary Facility (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 green onions and water sources used on green onions.

- Establish the frequency of toilet and hand-washing facility maintenance and sanitation such as a daily cleaning and supply-check schedule.
- Maintain written documentation of service and maintenance of sanitary facilities that demonstrates compliance with applicable worker health and safety regulations.

7.5 The Best Practices Are: Sanitary Facility (Toilets and Hand-Washing Stations) Waste Disposal

Operations with poor management of human and other wastes in the packinghouse or cooling facility can significantly increase the risk of contaminating green onions.

- 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 packinghouse / cooling facility.
- 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. Toilet or waste baskets must be used and managed so as not to allow the waste paper to spill onto the floor.

7.6 The Best Practices Are: Equipment Sanitation

All sorting, grading, and packing equipment that makes contact with green onions 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.

- 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). Ideally, the operator should have written procedures (SSOPs) for each piece of packinghouse and cooling facility equipment.
- All food-contact surfaces should be cleaned and sanitized daily.
- If any equipment includes filters, these should be routinely inspected and changed according to the manufacturers instructions.
- 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.
- Avoid cleaning and sanitizing equipment during processing operations
- Consider performing routine environmental testing (e.g., microbial or bioluminescense testing) to verify the efficacy of cleaning and sanitation. Testing data should be kept on file.
- All equipment inspection, maintenance, cleaning, and sanitizing activities should be documented.
- 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 packaging of raw or finished products.
- An MSDS sheet should be kept on file for each sanitizing chemical.

8.0 ISSUE: EMPLOYEE HYGIENE

Green onions greens are often extensively handled by employees at the packinghouse and possibly by persons working with produce 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 produce and people are in proximity. The importance of workers and supervisors understanding and practicing proper hygiene cannot be overemphasized.

Workers can contaminate fresh produce, water supplies, and other workers, and transmit human pathogens 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 employee roles and responsibilities in producing a safe product, sanitation principles, and sanitary practices including appropriate and effective hand-washing, glove use and replacement, and mandatory use of sanitary facilities. Training should be designed to help employees understand what is expected of them and why these practices are important.

8.1 The Best Practices Are:

- Employees should receive training in company policies about personal hygiene and food safety practices before they begin employment and at regular intervals during their employment with the minimum being once a year.
- Document worker hygiene training frequency and issues covered during training sessions.
- Employees should be trained on how, when, and why they must properly wash their hands and exposed portions of their arms. Employees should wash their hands:
  - Before beginning work.
  - Before putting on a new pair of gloves.
  - After touching human body parts or anything other than green onions or food contact surfaces.
  - After using the toilet.
  - After coughing, sneezing, or using a handkerchief or tissue.
  - After using tobacco, eating, or drinking.
  - After engaging in any activity that may contaminate hands, such as handling garbage, cleaning chemicals, or incoming produce before it has been washed.
  - After caring for or touching animals.
  - Before returning to a workstation.
- Instruct workers to inform the supervisor of any issues with the hand-washing or toilet units.
- Workers handling green onions should wear disposable gloves provided by their employer.
- Gloves should be changed as necessary during the work day and after any event that may cause gloves to become contaminated (e.g., using the latrine, eating, handling unsafe or non-food grade materials). A procedure for glove use should be established, followed, and documented.
- Workers should wear disposable head and facial hair coverings.
- Workers should wear appropriate, clean protective garments such as disposable or cleanable aprons. Heavily soiled and / or damaged reusable aprons should be replaced.
- Establish policies that prohibit employees from directly or indirectly contacting produce while they are ill and requires them to report illnesses to supervisors before beginning work.

- Train supervisors to know the typical signs and symptoms of infectious disease; these symptoms are vomiting, nausea, diarrhea, and abdominal cramps.
- Cuts and wounds should be covered with a suitable waterproof dressing when workers with injuries are permitted to continue working.
- Workers with wounds or cuts that cannot be covered to prevent contact with the product should not perform tasks that require contact with green onions, processing equipment, or tools until the wound has healed.
- Eating, drinking, or smoking outside of designated areas should be prohibited to reduce the potential for product contamination.
- In areas where green onions are present, workers should refrain from activities such as chewing gum or spitting.
- Establish storage and control procedures for employee equipment and supplies when not in use.

9.0 ISSUE: COLD STORAGE AND WAREHOUSING

Cold storage and warehouse facilities are often the last area that house green onions 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.

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 green onions 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.
- Ideally green onions should be stored as close to 32°F as possible (between 32-36°F) to preserve product quality.[31, 32] Ideally, the facility should have a cold storage area with refrigeration that meets this need.
- 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.
- Measures should be taken to prevent condensate and defrost water from evaporator-type cooling systems from dripping onto finished product.

[31] Adamicki. No Date. Onion. http://www.ba.ars.usda.gov/hb66/099onion.pdf
[32] The Ohio State University Extension. Recommended Storage Temperature and Relative Humidity Compatibility Groups. http://ohioline.osu.edu/fresh/Storage.pdf

- Use an appropriate inventory system to ensure FIFO shipment of finished product.
- The storage area should be included in daily cleaning and sanitation operations. Special care should be given to not splash water up onto finished products when cleaning floors or drains.
- 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 and sanitized on a regular basis.
- Sanitation activities should be documented.

10.0 ISSUE: TRANSPORTATION FROM PACKINGHOUSE OR COOLING FACILITY

Green onion 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 green onion products should be managed to reduce, control or eliminate the risk of contamination.

10.1 The Best Practices Are:

- Vehicles used to transport green onions 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 equipment do not potentially contaminate green onion 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) used for cleaning the vehicles and schedule / log of cleaning activity.
- Ensure that equipment in refrigerated vehicles is designed to circulate cold air uniformly throughout the vehicle while taking the load layout into consideration.
- The operator should maintain an appropriate temperature throughout transportation as close to 32°F as possible (i.e., approximately 32-36°F) and maintain records that document the temperature. Shelf life will decrease at temperatures above 40°F.
- Place green onions in transportation vehicles in a manner that allows for proper air circulation.
- Load and unload in a manner that minimizes damage and contamination.
- Ship green onions on a FIFO basis to minimize storage time.

11.0 ISSUE: DOCUMENTATION AND RECORDKEEPING[33]

As a general practice, it is important that firms involved in Post-Harvest operations relating to green onions maintain documentation and records related to operational information about the 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 impose 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 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 identifying information regarding the food. The regulation requires, among other things, that records maintained by nontransporters include an "adequate description" of the food, including brand name and specific variety.

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.

11.1 The Best Practices Are:

- Developing and maintaining written food safety plans and SOPs for areas such as handling and storage practices, facility and vehicle cleaning and sanitation, and employee training programs.
- Maintaining 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.
- Recording information such as the date and time, name of person(s) who completed the record, and the activity being monitored in the documentation.

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 green onions facilitates tracking the physical movement of green onion 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

[33] The basis for the green onion documentation and records best practices are the best practices outlined by the FDA in their draft commodity specific guidance for tomatoes, melons and leafy greens; obtained at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/default.htm . It is possible that these may change based on public comment.

tracing systems can serve as an important complement to food safety programs intended to prevent microbial contamination.

11.2 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 green onion 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 green onion 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.
- Make sure required documentation is provided when green onions 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 insure 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
  - Harvest time
  - Harvest date
  - Crew ID
  - Lot ID
- Lot coding of green onion 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, green onions ranches / farms may undergo multiple harvests over multiple days or weeks from one contiguous plot of land. Make sure that a lot is coded in a way that allows identification of the sources.
- Any tags used in packinghouses and cooling facilities should be secured to Post-Harvest containers in a manner that does not create a potential for damaged packaging materials or foreign object inclusion.

12.0 DETAILED BACKGROUND GUIDANCE INFORMATION:

"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)

Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Human Food, Code of Federal Regulations, Title 21, Part 110. (http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=110)

"Food Safety Guidelines for the Fresh-Cut Produce Industry," United Fresh Produce Association, 2001. (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 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/)

"Food Security Guidelines and Questionnaire for Fresh Fruits and Vegetables," United Fresh Produce Association, 2001. (http://www2.unitedfresh.org/forms/store/ProductFormPublic/)

Bioterrorism Act of 2002. (http://www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm)

SECTION III: VALUE-ADDED UNIT OPERATIONS

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1.0 ISSUE: IMPORTANT CONSIDERATIONS ABOUT VALUE-ADDED GREEN ONIONS

Green onions are primarily sold as raw and value-added product. Value-added iceless green onions are different from raw green onions that are packed in ice at a packinghouse primarily because they are packed in a processing facility where they are cleaned, trimmed, sometimes cut and packed in some form of plastic, protective packing. In addition, valued-added green onions are not considered ready-to-eat (RTE) because they require washing and further preparation prior to consumption. In some processing facilities green onions are chopped mainly for use in foodservice and are therefore considered an RTE product. For purposes of this section we are only addressing value-added operations and not operations that produce value-added, RTE green onions.

Green onion food safety programs should focus on preventing adulteration by microbial contamination because in the U.S. these onions are typically eaten raw and without thermal treatment to reduce human pathogen levels. For that reason, even though value-added green onions are not considered RTE, it is recommended as a general practice that these products are handled according to the FDA's "Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables" ("Fresh-cut Guide")[34] and processing facilities operate under cGMPs. This set of recommendations are primarily based on cGMPs from the Code of Federal Regulations Title 21, Part 110 (21 CFR 110) and the FDA "Fresh-cut Guide."

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. As such, the cGMPs are centrally important in reducing the risk of product adulteration and food safety risk to consumers. FDA's 2008 "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 recommendations here 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.

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. The food safety program for a value-added processing facility is generally built upon a number of foundation programs such as: cGMPs, SSOPs, SOPs, traceback and recall processes, maintenance procedures, employee training and pest control.

[34] 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

2.0 ISSUE: PROCESSING 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:

2.1 The Best Practices Are:

- 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, foot-borne filth, or providing 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.

3.0 ISSUE: HACCP PLAN DEVELOPMENT AND OPERATION

Hazard Analysis and Critical Control Point (HACCP) is a systematic preventative approach to food safety designed to prevent, reduce to acceptable levels, or eliminate the microbial, chemical, and physical hazards associated with food production. As one component of a comprehensive food safety program, HACCP is a proactive approach 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 preventive controls determined by a firm to be appropriate to its individual operations will enhance the safety of green onions.[35]

3.1 The Best Practices Are:

- Develop a flow diagram of the processing operation.
- Perform a hazard analysis for the operation.
- Establish critical control points (CCPs) for all identified significant hazards.
- Establish parameters or critical limits around the CCPs.
- Establish procedures for monitoring CCPs.

[35] 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

- Establish corrective actions to mediate any breach or violation of established parameters / critical limits.
- The analysis or HACCP plan should be documented and available for review.
- If the process is changed (e.g., updated equipment), then the HACCP plan should be updated and revised.
- Prepare and review documentation for all CCPs daily, including corrective actions when warranted, in accordance with the HACCP plan.

4.0 ISSUE: 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 green onions arriving at the facility will never cross paths or commingle with finished product.

4.1 The Best Practices Are:

- Consider validating your processing procedures to ensure that green onions are not experiencing microbial contamination or build up during these unit operations.
- A pre-operative inspection of the processing plant 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.
- Develop a pre-operative check list that can be used to conduct the inspection and provide documentation that the inspection was completed. It is also recommended to have a corrective action section that identifies food safety infractions and assigns responsibility to correct the infraction.
- Operators should be aware of and operate in accordance with all relevant laws and regulations that describe facility sanitation practices.[36, 37]
- Operators should be aware of and operate in accordance with all relevant laws and regulations with regard to handling processing and sanitation chemicals including the posting of MSDS sheets.
- Documenting procedures to inspect incoming raw product for potential food safety hazards.
- Remove as much dirt as possible from incoming product.
- Raw and finished product storage should be clearly separated to reduce the potential for cross-contamination.

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

[37] FDA. 2009. Code of Federal Regulations, Title 21, Part 110 – Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food.
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=110

- Green onions should not come into contact with the floor or any other non-food contact surface. Green onions that fall on the floor should be disposed of immediately.
- Inspect green onions 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 green onions, extraneous matter, and onions that appear to be contaminated (e.g., by animal feces, fuel, machine grease, or oil).
- Appropriate measures should be taken for waste water disposal.
- Garbage should be placed in appropriate receptacles and removed from the facility on a regularly scheduled basis.
- Garbage receptacles should have serviceable lids.
- 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 facility.
- Appropriate signage should be displayed throughout the processing facility to remind employees to adhere to company food safety policies.

5.0 ISSUE: GENERAL MAINTENANCE AND FACILITY DESIGN

Well designed and maintained processing facilities can reduce the potential for contamination by using appropriate location and / or flow of humans, product, equipment, and air. Buildings, fixtures, and equipment should be maintained in a sanitary condition and should be kept in repair sufficient to prevent food from becoming adulterated.

5.1 The Best Practices Are:

- Facility design and construction should be in compliance with applicable local, state, and federal regulations.
- The following practices regarding the flow of personnel, product, equipment, or air are recommended 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).
- Air intake for the facility should be located to minimize contamination of the intake air by:
    - Keeping the number of entrances and exits to the processing areas to a minimum.
    - Restricting the movement of lift trucks, bins, totes, maintenance tools, cleaning implements, clothing, and people from receiving and storage zones to processing and packaging areas.
- Consider color coding 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.

- 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.
- Locate hand dip and foot bath stations at each employee entrance so that employees must pass through them to enter the processing / packing area. The hand dip and foot bath stations should contain an appropriate sanitizer to prevent tracking of microbes from outside into the packing area.
- Locate the door to the outside in an area other than into a processing area.
- 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 washed and sanitized with chemical cleaners.
- Construct floors so that water drains well. Floor drains in processing or storage areas should be properly designed to avoid water build up and to reduce the potential for cross-contamination.
- Floor drains should be designed to be accessible for cleaning and capable of preventing pest entry.
- Consider using under-floor drains in processing areas.
- Waste water collection areas should be designed to prevent product and equipment contamination.
- Water pipes into the facility and waste water piping exiting the facility should be equipped with back-flow prevention devices to prevent potential contamination of the water supply.

- Pipelines should be designed to avoid pipe and wall condensation to avoid becoming a contamination source.
- 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.
- If two food contact surfaces meet, consider using a cover over the juncture to prevent food debris from collecting in the crevice and creating an area that is difficult to clean.
- 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.
- Have a microbiology lab that opens into an area other than into a processing area.
- All lights should be designed to prevent the potential for broken glass contamination of the product. Lights should be of tube-in-tube construction or have similar protective applications to prevent broken fixture material from contaminating the products.
- Provide a designated area separate from food handling areas for employees to store personal items.

6.0 ISSUE: 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.

6.1 The Best Practices Are:

- Permit the use of insecticides or rodenticides only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials. It is recommended that these materials 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.
- Open windows, vents, fans, and similar features should be adequately screened to prevent pest entry.

- Rodent traps should be deployed around the inside and outside perimeter of the facility. Detailed maps demonstrating the location of each trap should be available for review. Traps should be inspected routinely and any corrective actions (e.g., cleaning out traps, replacing damaged traps) documented.
- All pesticides, traps, bait, and chemicals used in pest control must be acceptable for use in a food processing facility in accordance with local, state, and federal regulations.
- 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.
- Exterior doors should have adequate weather stripping.
- 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 a third party is used for pest control, a copy of their license, any chemicals used, MSDS sheets, and a schedule of their activities and actions should be maintained and available for review.
- If pest control is performed internally, a copy of the applicators license, any chemicals used, MSDS sheets, and a schedule of their activities and actions should be maintained and available for review.

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, for example appropriate number of toilet facilities, proper hand-washing facilities, maximum worker to restroom distances, sewage disposal, etc. 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 sheets. Cleaning and sanitizing of utensils and equipment shall 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. Toxic 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.

7.1 The Best Practices Are: Process and Packing Equipment

- Processing facility equipment should be maintained clean and free from debris.
- Processing facility equipment 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, 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., rinse with potable water, sanitize with chlorine based sanitizer and rinse with fresh, potable water).
- All food-contact surfaces should be cleaned and sanitized daily.
- If any equipment includes filters, these should be routinely inspected and changed according to the manufacturers instructions.
- 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.
- Monitor the effectiveness of cleaning by visual inspection and environmental testing for microbial growth. Special attention should be given to grooves and niches in equipment. Testing data should be kept on file.
- Develop a log detailing or verifying that each piece of equipment was cleaned and sanitized.
- Only personnel trained in the use of the sanitizing chemicals should work with those chemicals. Training records should be kept at the facility for inspection.
- 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 packaging or raw or finished products.
- An MSDS sheet should be kept on file for each sanitizing chemical.
- Ideally, an eye wash station should be available in the sanitation storage / chemical mixing area.

7.2 The Best Practices Are: Process 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. The operator should have a master sanitation schedule for these areas that clearly identifies cleaning frequency, sanitizers to be used, precautions, etc.
- 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 packaging or raw or finished products.

- 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.
- An MSDS sheet should be kept on file for each cleaning and sanitizing chemical.
- Consider performing environmental testing (e.g., microbiological or bioluminescense testing) on a regular basis to confirm the efficacy of the facility cleaning and sanitation. Testing data should be maintained on file.

8.0 ISSUE: PROCESS WASH WATER QUALITY

Washing green onions with water, if done correctly can reduce microbial loads on the outside surface of product (Luo 2007). The use of water to reduce microbes on the surfaces is dependent on the disinfectant concentration, the type of wash system utilized, and the contact time. When used appropriately with adequate quality water, disinfectants help minimize the further 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.[38]

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 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 may include using antimicrobial chemicals in the wash water or using spray type wash treatments instead of submerging produce. Alternatively, produce may be cooled by means other than hydrocooling.

8.1 The Best Practices Are:

- Wash water used in processing operations should be of drinking water quality or have sufficient levels of disinfectant so as not to contaminate the product

[38] 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

(i.e., meets US EPA or WHO microbial standards for drinking water). See Table III-1 Water Use in Processing Operations.[39]

- Disinfectant levels should be tested periodically to ensure they are adequate and being maintained.
- The wash water source should be tested, as specified in Table III-1, for its intended use.
- 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 generic *E. coli.*
- Consider development of 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.
- Any water additive used to wash green onions should be food-grade and compliant with federal, state or local regulations for the intended use (i.e., compliant with 21 CFR 173.315 - Chemicals used in washing or to assist in the peeling of fruits and vegetables). Copies of MSDS sheets should be maintained on file.
- Wash water disinfectant levels should be monitored and maintained throughout processing operations. Monitor wash water disinfectant levels by testing the water disinfectant concentration and pH or ORP. If feasible, continuous monitoring of disinfectant levels is preferred.
    - *Active* disinfectant levels should be measured and documented (i.e., measure free chlorine and not chlorine concentration).
    - 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 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 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.

[39] 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, Technical Basis for Metrics.

- Calibrating all measuring devices (e.g., ORP or pH monitoring equipment) daily.
- To ensure efficient operation, routinely inspect and maintain equipment designed to assist in maintaining water quality such as chlorine injectors, filtration systems, and backflow devices.
- Reservoir tanks that hold wash water should be kept clean and sanitary. Tanks should be cleaned and sanitized before each season or at least once a year. Visual inspections and / or other testing (e.g., ATP, microbiological, chemical) should be performed at appropriate frequencies to verify sanitary conditions. All verification activities should be documented. For more on the care of finished water storage tanks see the Sanitary Survey in **Appendix A**.

8.2 The Best Practices Are: Recycled Water

Water in processing operations may be continuously reused or recycled. Water quality is especially important at the end of the process when sequential washing is used. If recycled water contacts green onions, water should meet drinking water quality standards and recommended disinfectant levels should be used (see Table III-1) throughout all processes.

- If water is reused in a series of processes, water flow should be arranged to be counter to the movement of green onions through different operations so that as the onions are further processed, they are exposed to the cleanest water.
- When washing or cooling green onions 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).
- When washing or cooling green onions in recirculated water, procedures should be established to determine when and how often water should be refreshed or completely changed out.
- Water disinfectants levels should be monitored and maintained throughout the process by testing the water disinfectant concentration and pH or ORP as follows:
    - Any disinfectants used should be used according to the manufacturer's specifications, monitoring activities should be documented
    - If disinfectants are used in a recirculation system, active disinfectant levels should be measured and documented (i.e., measure free chlorine and not chlorine concentration).
    - If feasible, 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 should be monitored to verify correct concentration. These checks should be documented.
- 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.
- Appropriate measures should be taken for waste water disposal.
- Any water additive used to wash green onions should be food-grade and compliant with federal, state or local regulations for the intended use (i.e., compliant with 21 CFR 173.315 - Chemicals used in washing or to assist in the peeling of fruits and vegetables). Copies of MSDS sheets should be maintained on file.
- Single-pass or one-use cooling water of sufficient quality for this intended purpose may also be used to cool product.

2602 **Table III-1. Water Use in Processing Operations**

Use	Metric	Rationale / Remedial Actions
Direct Product Contact or Food Contact Surfaces	**<u>Microbial Testing</u>** **Target Organism:** generic *E. coli*. **Sampling Procedure:** 100 mL 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 generic *E. coli* levels are below detection limits for five consecutive samples, the sampling frequency may be decreased to once every six months and the recommendations for 60 and 30 day sampling are waived. This exemption is void if there is a significant source or distribution system change. **Test Method:** 15 tube MPN (FDA BAM) or other US EPA, AOAC, or other method accredited for quantitative monitoring of water for generic *E. coli.* Presence / absence testing with a similar limit of detection may be used as well.	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, to ensure the integrity of the sample, using sampling methods as prescribed in this table) where the water contacts green onions, so as to test both the water source and the water distribution system. Only one sample per month per distribution system is recommended 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 green onions or is used on food contact surfaces, such as equipment or utensils, should meet the Maximum Contaminant Level Goal 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 vs. Multiple Pass Systems** • Single pass use – Water should have non-detectable levels of generic *E. coli* or breakpoint disinfectant present at point of entry. • Multi-pass use – Water should have non-detectable levels of generic *E. coli* and / or sufficient disinfectant to insure returned water has no detectable *E. coli* (minimally 1 ppm chlorine). **Remedial Actions**: If any one sample exceeds the acceptance criteria, then the water should not be used for this purpose unless appropriate disinfectants have been added or until remedial 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 remedial actions to determine if it meets the outlined microbial acceptance criteria for this use.

	Acceptance Criteria: **Negative or Below DL for All Samples**	For example, if a water sample for water used to clean food contact surfaces has detectable generic *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 5 days at the point closest to use, and do not use the water system until it consistently delivers water that is safe, sanitary, and of appropriate microbial quality (i.e., negative result) for the intended use. If any of the five samples taken during the intensive sampling period after corrective actions have been taken, have detectable generic *E. coli*, repeat remedial actions and DO NOT use that system until the source of contamination can be corrected. **Records**: All test results and remedial actions should be documented and available for verification from the user of the water for a period of 2 years.
	<u>Physical / Chemical Testing</u> **Target Variable:** Water disinfectant (e.g., chlorine or other disinfectant compound) **Multi Pass Water Acceptance Criteria:** • **Chlorine** ≥1 ppm free chlorine after application and pH 6.5 – 7.5 • ORP ≥ 650 mV, and pH 6.5 – 7.5 • **Other Approved Treatments** per product US EPA label for human pathogen reduction in water. **Testing Procedure:** • Chemical reaction based colorimetric test, or • Ion specific probe, or • ORP, or • Other as recommended by disinfectant supplier. **Testing Frequency:** Continuous monitoring (preferred) with periodic verification by titration OR routine monitoring if the system can be shown to have a low degree of variation.	

9.0 ISSUE: TOILET / SANITARY FACILITIES

The processing facility should be equipped with adequate sanitary facilities (toilets and hand-washing facilities) 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.

9.1 The Best Practices Are: Sanitary Facility (Toilets and Hand-Washing Stations) Construction and Design

Operations with poorly designed and constructed sanitary facilities may provide direct or indirect contamination of the green onions and water sources used on green onions.

- Sanitary facility design and construction, including number and location, should be in compliance with applicable local, state, and federal regulations.[40]
- Consider the number and location of toilet and hand-washing sanitary facilities needed for number of employees present. A recommended ratio of sanitary facilities per employee is 1 per 20 employees, per gender.
- Evaluate the location of worker hygiene facilities to maximize accessibility and use, while minimizing the potential for the facility to serve as a source of contamination.
- Toilet facilities should not open directly into areas where product is located.
- Hand-washing units should be located in close proximity to toilet facilities.
- Hand-washing units should provide 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 should be provided.
- Single-use paper towels should be provided for worker use.
- Each individual toilet facility should have toilet paper in a proper holder.
- Trash containers with covers should be provided for disposal of single-use towels.
- Hand-washing units and toilet facilities should be constructed with properly designed drainage systems.
- The door to the toilet facility and doors for each individual toilet should be self-closing and lockable from the inside.
- Sanitary facility should be constructed of materials that can be easily cleaned and sanitized using cleaners and / or oxidizing agents.
- Sanitary facilities should have proper screens to exclude vermin.

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

- Signs should be posted indicating that *the water is only for hand-washing purposes* (in appropriate languages).
- Provide cGMP signage that reminds employees to wash their hands after use of the facilities.
- Ideally, "on / off" switches for water should be "hands-free," (e.g., workable without using potentially soiled hands with devices such as elbow / knee faucet controls or foot pedals).
- Ideally the toilet units should operate in a "hands-free" mode.
- Catch basins for waste water should be sealed and plumbing should be free of leaks.
- Sanitary facility maintenance should be documented and archived.

9.2 The Best Practices Are: Sanitary Facility (Toilets and Hand-Washing Stations) Sanitation

Inadequately supplied or improperly maintained restrooms and hand-washing facilities may provide direct or indirect contamination of the green onions and water sources used on green onions.

- Individual toilet and hand-washing units should be properly maintained in a clean and sanitary condition for the worker's health, safety, and comfort.
- Establish the frequency of toilet and hand-washing facility maintenance / sanitation.
- Maintain written documentation of service and maintenance of sanitary facilities that demonstrates compliance with applicable worker health and safety regulations.
- Consider use of a daily cleaning and supply-check schedule.

9.3 The Best Practices Are: Sanitary Facility (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 green onions.

- Maintain a written waste collection service schedule.
- All trash containers should be removed daily and emptied, washed and returned to the sanitary facilities.
- All waste from sanitation facilities should be disposed of according to applicable laws and regulations and not contaminate the environment of the processing facility.
- Disposal of used hand-washing water should not cause unsanitary conditions or contamination of the processing facility.

10.0 ISSUE: EMPLOYEE PRACTICES / CGMPS

Green onions 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 workers and supervisors understanding and practicing proper hygiene cannot be overemphasized. Workers can contaminate fresh produce, water supplies, and other workers, and transmit human pathogens 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, and mandatory use of sanitary facilities. 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.

10.1 The Best Practices Are:

- Employees should receive training in company policies about personal hygiene and food safety practices before they begin employment and at regular intervals during their employment with the minimum being once a year.
- Document worker hygiene training frequency and issues covered during training sessions.
- A supervisor or quality assurance personnel should conduct a daily inspection to insure 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).
- Employees should be trained 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.
- Employees should be trained on how, when, and why they must properly wash their hands and exposed portions of their arms. Employees should wash their hands:
    - Before beginning work.
    - Before putting on a new pair of gloves.
    - After touching human body parts or anything other than green onions or food contact surfaces.

- After using the toilet.
- After coughing, sneezing, or using a handkerchief or tissue.
- After using tobacco, eating, or drinking.
- After engaging in any activity that may contaminate hands, such as handling garbage, cleaning chemicals, or incoming produce before it has been washed.
- After caring for or touching animals.
- Before returning to a workstation.

- Instruct workers to inform the supervisor of any issues with the hand-washing or toilet units.
- Workers handling green onions should wear disposable gloves provided by their employer.
- Gloves should be changed as necessary during the work day and after any event that may cause gloves to become contaminated (e.g., using the latrine, eating, handling unsafe or non-food grade materials). A procedure for glove use should be established, followed, and documented.
- Gloves should not be worn in the restroom or break areas.
- Workers should wear disposable head and facial hair coverings.
- Smocks and aprons should not be worn outside designated areas and should not be brought into the sanitary / toilet facilities or employee break area.
- Establish policies that prohibit employees from directly or indirectly contacting produce while they are ill and requires them to report illnesses to supervisors before beginning work.
- Train supervisors to know the typical signs and symptoms of infectious disease; these symptoms are vomiting, nausea, diarrhea, and abdominal cramps.
- Cuts and wounds should be covered with a suitable waterproof dressing when workers with injuries are permitted to continue working.
- Workers with wounds or cuts that cannot be covered to prevent contact with the product should not perform tasks that require contact with green onions, processing equipment, or tools until the wound has healed.
- Eating, drinking, or smoking outside of designated areas should be prohibited to reduce the potential for product contamination. Any designated employee break area should be physically separate from the processing area. The break area should be equipped with trash receptacles that are emptied and cleaned daily. The break areas should be included on the master sanitation schedule.

- In areas where green onions are present, workers should refrain from activities such as chewing gum or spitting.
- Establish storage and control procedures for employee equipment and supplies when not in use. Designate an area for hanging smocks, aprons, and gloves when leaving the processing area.
- All personal items should be stored outside the processing area in the area designated for personal items.
- Jewelry should not be worn in the processing area.
- Tools, pens, and pencils should not be stored in top shirt pockets.
- Glass should not be permitted in the processing area.

11.0 ISSUE: COLD STORAGE AND WAREHOUSING

Cold storage and warehouse facilities are often the last area that house green onions 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.

11.1 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 green onions 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.
- Ideally, green onions should be stored as close to 32°F as possible (between 32-36°F) to preserve product quality. Ideally, the facility should have a cold storage area that is equipped with refrigeration that meets this need.
- 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.
- Use an appropriate inventory system to ensure FIFO shipment of finished product.

- The storage area should be included in daily cleaning and sanitation operations. Special care should be given to not splash water up onto finished products when cleaning floors or drains.
- 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 and sanitized on a regular basis. Sanitation should be verified through documentation.

12.0 ISSUE: FINISHED PRODUCT CONTAINERS AND PACKAGING MATERIALS

Any material including packaging material that comes into contact with green onions 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.

12.1 The Best Practices Are:

- A procedure should be in place to inspect all incoming finished product 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.
- Finished product containers should be stored in a controlled area and protected against potential contamination from birds, rodents, insects, and other sources at all times. The containers should be stored on clean pallets and covered to protect them from potential contamination.
- Finished product containers should be covered adequately with plastic to prevent the intrusion of foreign material, including wind-blown dust and debris.
- The finished product containers storage area should be identified and maintained with a perimeter to facilitate inspection, cleaning, and pest control devices. If the storage area is outside of the building, it should be in a designated area with proper coverings of the materials, a well-documented pest control program, and be routinely monitored for any potential contamination sources.
- Any finished product containers that are identified as potentially contaminated and not suitable for use in storing food products should be discarded.
- Cleaning, sanitation and / or verification procedures should be in place to ensure RPCs are not a source of cross contamination and are in sanitary condition and suitable for use.
- Packaging materials (e.g., poly bags, labels, pallet film, tape) used for green onions that have been washed, sorted, and / or trimmed must be handled and stored in a sanitary manner.

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

13.0 ISSUE: METAL DETECTION

While there is no regulatory requirement for metal detection, green onion 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.

13.1 The Best Practices Are:

- All finished product bags should pass through metal detection. The metal detector should operate within the parameters established in the company food safety program.
- The metal detector should be calibrated daily using ferrous, non-ferrous and stainless steel standards. Calibration should be documented.
- Check metal detector operation at least hourly by placing a standard in a sample bag of product and running it through the detector. Proper operation would result in the bag being rejected. Operational tests should be documented.
- Use a metal detector that is designed so that "contaminated" product is removed from the production line.
- Quality control personnel should evaluate any rejected product to determine the cause.

14.0 ISSUE: LABELING OF RAW AGRICULTURAL COMMODITY (RAC) VERSUS READY-TO-EAT (RTE) PRODUCTS

End-users, including consumers, may have difficulty in quickly and easily differentiating a RAC, which should be washed before consumption, from an RTE food product, which need not be washed again before consumption.

14.1 The Best Practices Are:

- Clearly label products to avoid end-user confusion regarding whether or not a product needs to be washed before consumption. For example, label value-added, ready-to-eat products as "washed, " "triple washed" or "ready-to-eat" on the package, to indicate that there is no need to wash the product again.

15.0 ISSUE: DOCUMENTATION AND RECORDKEEPING[41]

As a general practice, it is important that firms involved in Post-Harvest operations relating to green onions maintain documentation and records related to operational information about the 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 impose 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 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 identifying information regarding the food. The regulation requires, among other things, that records maintained by non-transporters include an "adequate description" of the food, including brand name and specific variety.

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.

15.1 The Best Practices Are:

- Developing and maintaining written food safety plans and SOPs for areas such as handling and storage practices, facility and vehicle cleaning and sanitation, and employee training programs.
- Maintaining records for significant activities performed. Record information such as the date and time, name of person(s) who completed the record, and the activity being monitored in the documentation. Documentation can include but not be limited to:
  - Daily pre-operation inspections.
  - Daily cGMP inspections.
  - Employee training verification records.
  - Logs for raw or finished products that are placed on "hold" due to non-conformance for food safety specifications.

[41] The basis for the green onion documentation and records best practices are the best practices outlined by the FDA in their draft commodity specific guidance for tomatoes, melons and leafy greens; obtained at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/default.htm . It is possible that these may change based on public comment.

- Logs to detail unusual events or activities, activities that fall outside accepted practices, and the corrective actions undertaken to return the process to specifications.
- Pest control monitoring logs.
- Daily sanitation log verifying sanitation was completed satisfactorily.
- Microbial and / or ATP bioluminescence data verifying sanitation.
- Chlorine, free chlorine or ORP data verifying wash water treatments; pH data should also be included.
- Microbial water testing results for facility water.
- Environmental testing data.
- Temperature data for the cold storage area.
- Cleaning records for toilet / sanitary facility areas.
- Metal detector operational testing logs.
- Metal detector calibration logs.
- Raw product receiving records identifying the source of all raw products received (e.g., lot numbers, amount received, time received).
- Daily production codes.
- Mock recall files.
- Calibration logs for all monitoring equipment (e.g., ORP and / or pH measuring equipment).

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 green onions facilitates tracking the physical movement of green onion 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 complement to food safety programs intended to prevent microbial contamination.

15.2 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 green onion 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 green onion 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.
- Make sure required documentation is provided when green onions 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 insure 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
    - Harvest time
    - Harvest date
    - Crew ID
    - Lot ID
    - Production date
    - Production code
    - Expiration date
- Any tags used in the 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.

16.0 DETAILED BACKGROUND GUIDANCE INFORMATION:

"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)

Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding Human Food, Code of Federal Regulations, Title 21, Part 110. (http://www.accessdata.fda.gov/SCRIPTs/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=110)

"Food Safety Guidelines for the Fresh-Cut Produce Industry," United Fresh Produce Association, 2001. (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 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/)

"Food Security Guidelines and Questionnaire for Fresh Fruits and Vegetables," United Fresh Produce Association, 2001. (http://www2.unitedfresh.org/forms/store/ProductFormPublic/)

Bioterrorism Act of 2002. (http://www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm)

17.0 REFERENCES

Casteel M, Sobsey M, and Mueller J. Fecal contamination of agricultural soils before and after hurricane-associated flooding in North Carolina. *Journal of Environmental Science and Health. Part A, Toxic/Hazardous Substance and Environmental Engineering.* 41(2):173-184.

CCR Title 14 - Chapter 3.1 - Article 5. 2007. *Article 5. Composting Operation and Facility Siting and Design Standards*. Accessed February 15, 2007. (http://www.ciwmb.ca.gov/regulations/Title14/ch31a5.htm#article5)

CDC. 2008. Centers for Disease Control and Prevention's Outbreak Surveillance Data (http://www.cdc.gov/foodborneoutbreaks/outbreak_data.htm).

Committee on the Review of the Use of Scientific Criteria and Performance Standards for Safe Food, Scientific Criteria to ensure Safe Food. 2003. Institute of Medicine, National Research Council, National Academies Press, Washington, D.C.

Dentinger C, Bower W, Nainan O, Cotter S, Myers G, Dubusky L, Fowler S, Salehi E, and Bell B. 2001. An outbreak of Hepatitis A associated with green onions. *Journal of Infectious Diseases*. 183:1273-1276.

Fukushima H, Hoshina K, and Gomyoda M. 1999. Long-term survival of shiga toxin-producing *Escherichia coli* O26, O111, and O157 in bovine feces. *Applied and Environmental Microbiology* 65 (11):5177-81.

Gagliardi JV and Karns JS. 2000. Leaching of *Escherichia coli* O157:H7 in diverse soils under various agricultural management practices. *Applied and Environmental Microbiology.* 66(3):877-83.

Ingham SC, Losinski JA, Andrews MP, Breuer JE, Breuer JR, Wood TM, and Wright TH. 2004. *Escherichia coli* contamination of vegetables grown in soils fertilized with noncomposted bovine manure: Garden-scale studies. *Applied and Environmental Microbiology*. 70(11):6420-6427.

Islam M, Doyle MP, Phatak SC, Millner P, and Jiang X. 2004a. Persistence of enterohemorrhagic *Escherichia coli* O157:H7 in soil and on leaf lettuce and parsley grown in fields treated with contaminated manure composts or irrigation water. *Journal of Food Protection.* 67(7):1365-70. (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&dopt=Citation&list_uids=15270487)

Islam M, Morgan J, Doyle M, and Jiang X. 2004b. Fate of *Escherichia coli* O157:H7 in manure compost-amended soil and on carrots and onions grown in an envrironmentally controlled growth chamber. *Journal of Food Protection*. 67(3):574-578.

Jiang X, Morgan J, and Doyle M. 2003. Fate of *Escherichia coli* O157:H7 during composting of bovine manure in a laboratory-scale bioreactor. *Journal of Food Protection.* 66(1):25-30.

Jiang X, Morgan J and Doyle M. 2002. Fate of *Escherichia coli* O157:H7 in manure-amended soil. *Applied and Environmental Microbiology*. 68(5):2605-2609.

Lui Y. 2007. Fresh-cut produce water reuse affects water quality and packaged product quality and microbial growth in romaine lettuce. *HortScience*. 42(6):1413-1419.

Monterey County Health Department Consolidated Environmental Laboratory. 2007. Testing irrigation water for generic *E. coli*: Multiple tube fermentation (SM 9221B, E, F) and quantitray (SM 9223B), Salinas.

Nicholson FA, Groves SJ, and Chambers BJ. 2004. Pathogen survival during livestock manure storage and following land application. *Bioresource Technology*. 96:135-143.

Suslow, T.V., M.P. Oria, L.R. Beuchat, E.H. Garrett, M.E. Parish, L.J. Harris, J.N. Farber, F.F. Busta. 2003. Production practices as risk factors in microbial food safety of fresh and fresh-cut produce. *Comprehensive Reviews in Food Science and Food Safety.* 2S:38-77.

Takeuchi K and Frank JF. 2000. Penetration of *Escherichia coli* O157:H7 into lettuce tissues as affected by inoculum size and temperature and the effect of chlorine treatment on cell viability. *Journal of Food Protection.* 63(4):434-40.

Takeuchi K, Matute CM, Hassan AN, and Frank JF. 2000. Comparison of the attachment of *Escherichia coli* O157:H7, *Listeria monocytogenes*, *Salmonella typhimurium*, and *Pseudomonas fluorescens* to lettuce leaves. *Journal of Food Protection.* 63(10):1433-7.

US EPA. 1996. *Soil Screening Guidance: Technical Background Document*. EPA/540/R95/128: Office of Solid Waste and Emergency Response, United States Environmental Protection Agency. (http://rais.ornl.gov/homepage/SSG_nonrad_technical.pdf)

US EPA. 2002. *Implementation Guidance for Ambient Water Quality Criteria for Bacteria: May 2002 Draft*. EPA-823-B-02-003: United States Environmental Protection Agency. (http://www.epa.gov/waterscience/standards/bacteria/bacteria.pdf)

U.S. EPA. 2003. Center for Environmental Research Information, "Chapter 5: Class B Pathogen Requirements and Requirements for Domesdtic Septage Applied to Agricultural land, a Forest, or a Reclamation Site," Environmental Regulations and Technology: Control of Pathogens and Vector Attraction in Sewage Sludge, EPA/625/R-92/-13, U.S. Environmental Protection Agency, Cincinnati.

US FDA. 2001. Chapter II: Production Practices as Risk Factors in Microbial Food Safety of Fresh and Fresh-Cut Produce. In *Analysis and Evaluation of Preventive Control Measures for the Control and Reduction/Elimination of Microbial Hazards on Fresh and Fresh-Cut Produce*. (http://www.cfsan.fda.gov/~comm/ift3-2a.html)

US FDA. 2004. Federal Food, Drug, and Cosmetic Act. http://www.cfsan.fda.gov/~lrd/cfr110.html

Wachtel MR, Whitehand LC, and Mandrell RE. 2002a. Association of *Escherichia coli* O157:H7 with preharvest leaf lettuce upon exposure to contaminated irrigation water. *Journal of Food Protection.* 65(1):18-25.

Wachtel MR, Whitehand LC, and Mandrell RE. 2002b. Prevalence of *Escherichia coli* associated with a cabbage crop inadvertently irrigated with partially treated sewage wastewater. *Journal of Food Protection.* 65(3):471-5.

Wheeler C, Vogt T, Armstrong G, Vaughan G, Weltman A, Nainan O, Dato V, Xia G, Waller K, Amon J, Lee T, Highbaugh-Battle A, Hembree C, Evenson S, Ruta M,

3076 Williams I, Fiore A, and Bell B. 2005. An outbreak of hepatitis A associated
3077 with green onions. *New England Journal of Medicine*. 353:890-897.

APPENDIX A: SANITARY SURVEY

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 microbial contamination. Whenever possible the Sanitary Survey should begin at the water system source as this is the first opportunity for controlling microbial contaminants.

- Wells: Sanitary Surveys 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 prior to use of water in agricultural operations and if water quality microbial tests are at levels that exceed the numerical values set forth in Table I-2, Table II-1, or Table III-1.
  - Check the surrounding area for cleanliness and remove any debris.
  - To avoid water collection near the wellhead, the gradient of the surrounding area should slope away from the wellhead.
  - The wellhead should be located away from potential sources of contamination. Several of these potential sources are listed below along with guidelines for the minimum horizontal distance from a wellhead: [42]
    - Portable toilets – 50 ft.
    - Sewers – 50 ft.
    - Watertight septic tank or subsurface sewage leaching field – 100 ft.
    - Cesspool or seepage pit – 150 ft.
    - Animal enclosure – 100 ft.
  - Keep records of the date of inspection, observations / issues, and remedial actions taken.
- Surface Water in Canals, Laterals, Ditches, and Well Reservoirs: A visual assessment of these waterways should focus on the integrity of surrounding bank systems and potential point source (e.g., animal feces) and non-point source confluences (e.g., drainage into these systems).
  - Inspections should occur prior to use of water in agricultural operations and if water quality microbial tests are at levels that exceed the numerical values set forth in Table I-2. Items to be on alert for during an inspection include:

[42] California Department of Water Resources, Southern District, California Well Standards - Chapter II, Part II Well Construction, Section 8. "Well Location with Respect to Pollutants and Contaminants, and Structures." http://www.dpla.water.ca.gov/sd/groundwater/california_well_standards/wws/wws_combined_sec8.html. For more information, please see Appendix A, Technical Basis Document.

        - Evidence of animal intrusion.
        - Contaminating waters that may be draining into the surface water system.
        - Encroachment of overhanging tree branches.
        - Debris and trash accumulation.
    - Keep records of the date of inspection, observations / issues, and remedial actions taken.

- Irrigation Systems: Sanitary surveys should focus on the mechanical components and water lines. Irrigation system components should be properly stored and maintained as to avoid contamination.
    - Inspections should occur prior to use of water in agricultural operations and if water quality microbial tests are at levels that exceed the numerical values set forth in Table I-2. Items to be on alert for during an inspection include:
        - Check primary and secondary filtration equipment for cleanliness and proper function.
        - Check for leaks on seals, gaskets, and fittings.
        - Check water lines for visual evidence of microbial growth such as white stringy slime or red filamentous sludge.
    - Based on the Sanitary Survey and a risk assessment of the water source, evaluate the need for use of a disinfectant such as chlorine to minimize the potential for contamination.
        - Because bacteria can grow in filters, inject disinfectant upstream from filter units. To verify that there is enough disinfectant available to disinfect the system, measure residual disinfectant levels downstream from the filter units.
        - Disinfectants may be injected continuously or as a shock treatment (See Table B-1 for appropriate concentrations).
        - Disinfectants are only recommended for use when necessary to assure proper water quality.
    - Keep records of the date of inspection, observations / issues, and remedial actions taken.

Table A-1. Recommended Disinfectant Treatments [43]

Disinfectant	Residual concentration for continuous injection[44,45]	Concentration for shock treatment
Chlorine	1-2 ppm	10-30 ppm
Chlorine dioxide	0.25-0.5 ppm	NA
Ozone	0.25-0.5 ppm	NA

- Water Distribution System: A Sanitary Survey should focus on the integrity of the distribution system.
  - When surveying your water distribution system for possible vulnerabilities, consider all distribution system components whether above or below ground, including source, distribution, and flow. Utilize the system description developed in Section 3.1 Best Practices for Water to ensure evaluation of key system components.
  - Inspect the distribution system prior to use of water in agricultural operations and if water quality microbial tests are at levels that exceed the numerical values set forth in Table I-2, Table II-1, and Table III-1. Items to be on alert for during an inspection include:
    - Signs of damaged underground components such as unexplained erosion or patches of lush green grass
    - Cross connections: The US 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. The physical connection could allow water of questionable quality to backflow into the water system. Cross connections occur in places where proper air gaps between water surfaces and water sources are not maintained and therefore allow flow reversals. An example of a 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.
    - Back-flow protection: Back-flow prevention devices should be installed on every outdoor faucet and checked seasonally or at least annually to ensure they are intact and working properly.

[43] Environzone Technograph Pvt. Ltd. Useful Information Help You To Understand Ozone. http://www.scribd.com/doc/15943764/Envirozone-Ozone-Presentation
Newman. 2008. Disinfecting Irrigation Water for Disease Management.http://ghadvisor.blogspot.com/2008/10/disinfecting-irrigation-water-for.html
Gurol. 2005. Facts and Myths About Irrigation Water. http://www.fischerecoworks.com/Gurol-FactsandMyths.doc

[44] These concentrations refer to concentrations in water post-treatment; the pretreatment concentration depends heavily on the quality of the source water; if the source water has high levels of organic matter substantially more disinfectant may need to be added to obtain the residual levels than in clean source water.

[45] In addition to measuring residual concentrations, it may be appropriate to measure the oxidization-reduction potential (ORP). For all of these disinfectants an ORP of greater than 650 mV should be maintained.

        - Dead-end or unused water lines connected to the plumbing system: remove or regularly flush unused lines.
        - Abandoned or inactive wells: Should be destroyed (e.g., filled with cement) so they do not function as a vertical conduit for contaminants.
    - Keep records of the date of inspection, observations / issues, and remedial actions taken.
- Finished Water Storage Tanks: Sanitary Survey should focus on the integrity of the storage tank and the surrounding area (or the surrounding equipment if the tank is mounted on a truck or other harvest equipment).
    - Inspect water storage tanks and surrounding area on a regular basis. Items to be on alert for during an inspection include:
        - Tank is structurally sound (e.g., free of rust or significant physical damage).
        - Access hatch lids are properly fitted with a gasket and secured.
        - Location of the tank should be away from livestock and septic systems.
        - Storage tank site should be graded for proper drainage and free of debris and weeds.
        - Any vents are adequately screened with corrosion-resistant material.
        - Overflow and drain pipes are screened and have proper air gaps.
    - Tanks should be cleaned before each season or at least once a year. Verify that tanks are sanitary prior to use (e.g., indirect microbiological tests such as ATP detection, chemical tests such as surface swabs for protein, fat or starches).
    - Use of backflow or check valves at any tapping or access points (e.g., spigots, water bibs).
    - Keep records of the date of inspection, observations / issues, and remedial actions taken.

APPENDIX B: TECHNICAL BASIS FOR METRICS

This document serves as a supplementary source of information to the "Commodity Specific Food Safety Guidelines for the Production and Harvest of Green Onions." 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.

This document discusses the technical basis for the proposed metrics. In general, a three-tier approach was used to identify appropriate metrics:

- A comprehensive literature review was conducted to establish whether a scientifically valid basis for establishing a metric has been published.
- 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.
- 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 following sections provide a detailed explanation of the processes and rationale for derivation of the metrics. In some cases, metrics for green onions are based on similar metrics for lettuce and leafy greens. In those cases, text from the Technical Basis Document for "Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain" ("Leafy Green Guide") is provided for context.

WATER SOURCES AND USES

Metrics for water sources and uses 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, the presence of fecal contamination may not be detected even if significant contamination is present (Ashbolt et al. 2001; WHO 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 (WHO 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 contaminated 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 were created for two uses determined to be most critical to green onion food safety:

- Pre-Harvest applications. Prior to removal of green onions from the ground.
- 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," US 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 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 values by the state of Arizona as irrigation water quality standards. These values are also used in the "Leafy Green Guide" as Pre-Harvest (direct contact) irrigation water quality metrics.

For Post-Harvest direct contact applications, 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. Hence, the metric for this standard has been set at <2 MPN/100 mL, which is essentially the limit of detection. Guidelines for continuous monitoring of disinfectant in Post-Harvest systems are also provided in the "Commodity Specific Food Safety Guidelines for the Production and Harvest of Green Onions" to facilitate meeting this strict standard. This value is also used in the "Leafy Green Guide" for Post-Harvest water quality metrics.

SOIL AMENDMENTS (SAS)

Considerably more guidance exists for establishing metrics for SAs than water sources. Many regulatory bodies have set guidelines for production of SAs as well as acceptable levels of microbial organisms in finished products.

Manure

The application of manure to green onion 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 Green Guide," and was discussed in the Technical Basis document for that crop 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 green onions industry group and expert reviewers decided that similar metrics are appropriate for green onions.

COMPOSTED SAS

Due to the existence of California state regulations regarding the production of compost (CCR Title 14 - Chapter 3.1 - Article 5 2007), these guidelines were essentially adopted "as is" for the "Commodity Specific Food Safety Guidelines for the Production and Harvest of Green Onions," with the addition of *E. coli* O157:H7 testing as an additional safeguard. 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 green onions. The first hurdle requires use of a validated process for compost production; the second requires microbial testing, and the third requires applying an application interval to minimize risk from remaining pathogenic microorganisms.

A 45-day application interval was deemed appropriate due to the three hurdle metric design. Raw manure must be composted with an approved process and pass testing requirements before an application interval is observed. The use of the National Organic Program's 120-day waiting period for use of raw manure was suggested. However, because the 120-day period is specific to raw (uncomposted) manure, it was judged reasonable to shorten this period to 45-days.

PHYSICALLY HEAT TREATED SAS

Due to limited information related to the process and expected microbial populations found in physically heat treated SAs, metrics were primarily based on the composting metrics described above. Some processes are discussed in the literature and this information was used to set some metrics for temperature and contact times (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 SAs.

Due to the stricter testing requirements and more tightly controlled process used with heat treated SAs, 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 due to the three hurdle metric design.

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.).

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 due to the three hurdle metric design.

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 Green Onions." 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. An option to reduce this time period to 30 days is provided if growers can demonstrate, through a valid sampling program that soil microbial levels are lower than those required for composted soil amendments. The development of the soil sampling plan and the sampling itself must be undertaken by a reputable third-party environmental consultant or laboratory.

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.

Environmental Assessments

In order to maintain vigilance over the conditions associated with the production of green onions, 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.

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 green onions, the "Commodity Specific Food Safety Guidelines for the Production and Harvest of Green Onions" 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 green onion 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 green onions 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 acceptable.

- 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 animal intrusion 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 green onions, how much buffer distance should be assigned for various intrusions, and whether remedial options might reduce or eliminate risk from intrusions. The only established metric for this area is the recommendation not to harvest green onions 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.

CROP LAND & WATER SOURCE ADJACENT LAND USE

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 Green 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 green onions industry group decided that similar metrics were appropriate for green onions.

REFERENCES

Ashbolt N, Grabow W, and Snozzi M. 2001. Indicators of microbial water quality. *Water Quality: Guidelines, Standards and Health: Assessment of Risk and Risk Management for Water-related Infectious Disease,* pp. 289–315.

California Department of Health Services (CDHS) and California Department of Food and Agriculture (CDFA). 2006. Meeting with CDHS and CFDA regulators. Sacramento, California, November 27.

CCR Title 14 - Chapter 3.1 - Article 5. 2007. *Article 5. Composting Operation and Facility Siting and Design Standards*. Accessed February 15, 2007. http://www.calrecycle.ca.gov/Laws/Regulations/Title14/ch31a5.htm

CDC. 2006. Disease Listing > *Escherichia coli O157:H7*. Division of Bacterial and Mycotic Diseases, Centers for Disease Control and Prevention. Accessed February 22, 2007. http://www.cdc.gov/nczved/dfbmd/disease_listing/stec_gi.html

Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens. July 10, 2009. http://www.wga.com/DocumentLibrary/scienceandtech/LGMAAcceptedGAPs07.10.09.pdf

Entry JA, Leytem AB, and Verwey S. 2005. Influence of solid dairy manure and compost with and without alum on survival of indicator bacteria in soil and on potato. *Environmental Pollution.* 138 (2):212-8.

Jin G, Jeng HW, Bradford H, and Englande AJ. 2004. Comparison of *E. coli*, enterococci, and fecal coliform as indicators for brackish water quality assessment. *Water Environment Research.* 76(3):245-55.

US EPA. 1986. *Ambient Water Quality Criteria for Bacteria - 1986*. EPA 440/5-84-002: Office of Water Regulations and Standards Criteria and Standards Division, United States Environmental Protection Agency. http://www.epa.gov/waterscience/criteria/library/ambientwqc/bacteria1986.pdf

US EPA. 1994. *A Plain English Guide to the EPA Part 503 Biosolids Rule*. EPA/832/R-93/003: United States Environmental Protection Agency. http://www.epa.gov/owm/mtb/biosolids/503pe/index.htm

US EPA. 2003. *Bacterial Water Quality Standards for Recreational Waters (Freshwater and Marine Waters): Status Report*. EPA-823-R-03-008: United States Environmental Protection Agency. http://www.epa.gov/waterscience/beaches/local/statrept.pdf

US FDA. 2006. Conference call with multiple FDA participants. November 28.

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

World Health Organization. 2008. Guidelines for drinking-water quality, third edition, incorporating first and second addenda. Volume 1: recommendations. World

Health Organization, Geneva, Switzerland.
http://www.who.int/water_sanitation_health/dwq/gdwq3rev/en/