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

MAY 24, 2007

Authors Note: This document supersedes all previously published versions of the Commodity Specific Food Safety Guidelines for the Production and Harvest of Leafy Greens including those dated March 23, 2007 and April 18, 2007.

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Aerosolized	The dispersion or discharge of a substance under pressure 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.
animals of significant risk	Animals that have been determined by the Centers for Disease Control to have a higher risk of carrying E. coli O157:H7. These animals are cattle, sheep, goats, wild pigs, and deer.
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.
Biofertilizers	Organisms such as bacteria, fungi, and cyanobacteria that enrich the nutrient quality of soil.
Biosolids	Solid, semisolid, or liquid residues generated during primary, secondary, or advanced treatment of domestic sanitary sewage through one or more controlled processes.
colony forming units (CFU)	Viable micro-organisms (bacteria, yeasts & 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 and crops, vegetation forage growth, or post-harvest residues are not sustained in the normal growing season over any portion of the lot or facility. In addition, there must be more than 1,000 'animal units' (as defined in 40 CFR 122.23) confined at the facility; or more than 300 animal units confined at the facility if either one of the following conditions are met: pollutants are discharged into navigable waters through a man-made ditch, flushing system or other similar man-made device; or pollutants are discharged directly into waters of the United States which originate outside of and pass over, across, or through the facility or otherwise come into direct contact with the animals confined in the operation.

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coliforms	Gram-negative, non-sporeforming, rod-shaped bacteria that ferment lactose to gas. They are frequently used as indicators of process control, but exist broadly in nature.
cross contamination	The transfer of microorganisms, such as bacteria and viruses, from one place to another.
E. coli	*Escherichia coli* is a common bacteria that lives in the lower intestines of animals (including humans) and is generally not harmful. It is frequently used as an indicator of fecal contamination, but can be found in nature from non-fecal sources.
fecal coliforms	Coliform bacteria that grow at elevated temperatures and may or may not be of fecal origin. Useful to monitor effectiveness of composting processes. Also called "thermotolerant coliforms."
Flooding	The flowing or overflowing of a field with water outside a grower's control that is reasonably likely to contain microorganisms of significant public health concern and is reasonably likely to cause adulteration of edible portions of fresh produce in that field.
food contact surface	A surface of equipment or a utensil with which food normally comes into contact, or from which food may drain, drip or splash into a food or onto a surface normally in contact with food.
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 formal training in scientific principles and a solid understanding of the principles of food safety as applied to agricultural production.
geometric mean	Mathematical def.: the n-th root of the product of n numbers, or: Geometric Mean = n-th root of $(X_1)(X_2)...(X_n)$, where X_1, X_2, etc. represent the individual data points, and n is the total number of data points used in the calculation. Practical def.: the average of the logarithmic values of a data set, converted back to a base 10 number.

Hydroponic	The growing of plants in nutrient solutions with or without an inert medium (as soil) to provide mechanical support.
Indicator microorganisms	An organism that when present suggests the possibility of contamination or under processing.
leafy greens	Iceberg lettuce, romaine lettuce, green leaf lettuce, red leaf lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole, endive, spring mix, spinach, kale, arugula and chard.
most probable number (MPN)	Estimated values that are statistical in nature; a method for enumeration of microbes in a sample when present in small numbers.
nonsynthetic crop treatments	Any crop input that contains animal manure, an animal product, and/or an animal by-product that is reasonably likely to contain human pathogens.
oxidation reduction potential (ORP)	An intrinsic property that indicates the tendency of a chemical species to acquire elections and so be reduced; the more positive the ORP, the greater the species' affinity for electrons.
parts per million (ppm)	Usually describes the concentration of something in water or soil; one particle of a given substance for every 999,999 other particles.
Pathogen	A disease causing agent such as a virus, parasite, or bacteria.
pooled water	An accumulation of standing water; not free-flowing.
process authority	A regulatory body, person, or organization that has specific responsibility and knowledge regarding a particular process or method; these authorities publish standards, metrics, or guidance for these processes and/or methods.
risk mitigation	actions to reduce the severity/impact of a risk
ultraviolet index (UV index)	A measure of the solar ultraviolet intensity at the Earth's surface; indicates the day's exposure to ultraviolet rays. The UV index is measured around noon for a one-hour period and rated on a scale of 0-15.
Validated process	A process that has been demonstrated to be effective though a statistically-based study, literature, or regulatory guidance.

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ACRONYMS AND ABBREVIATIONS

AFOs: Animal feeding operations
AOAC: the Association of Official Agricultural Chemists
BAM: Bacteriological Analytical Manual
CAFOs: Concentrated animal feeding operations
CSG2: *Commodity Specific Guidance for Leafy Greens and Lettuce, 2nd Edition*
CFU: colony forming units
cGMP: current good manufacturing practices
COA: Certificate of Analysis
DL: Detection Limit
FDA: Food and Drug Administration
GAPS: good agricultural practices
GLPs: good laboratory practices
HACCP: hazard analysis critical control point
MPN: most probable number
NGO: nongovernmental organization
NRCS: Natural Resources Conservation Service
ORP: Oxidation reduction potential
PPM: parts per million
RTE: ready-to-eat
SSOPs: Sanitation Standard Operating Procedures
USEPA: United States Environmental Protection Agency
UV: ultraviolet
WHO: World Health Organization

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INTRODUCTION

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

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

In response to continued concerns regarding the microbial safety of fresh produce, this edition of the guidelines (which focuses solely on production and harvest practices) was prepared to provide more specific and quantitative measures of identified best practices. A key focus of this revision was to identify, where possible and practical, metrics and measures that could be used to assist the industry with compliance with the guidelines. In preparing this document, metrics were researched for three primary areas: water quality, soil amendments, and environmental assessments/conditions. A three-tier approach was used to identify these metrics in as rigorous a manner as possible:

1. A comprehensive literature review was conducted to determine if there was a scientifically valid basis for establishing a metric for the identified risk factor or best practice.
2. If the literature research did not identify scientific studies that could support an appropriate metric, standards or metrics from authoritative or regulatory bodies were used to establish a metric.
3. If neither scientific studies nor authoritative bodies had allowed for suitable metrics, consensus among industry representatives and/or other stakeholders was sought to establish metrics.

In the last 10 years, the focus of food safety efforts has been on the farm, initial cooling and distribution points, and value-added processing operations. Fruit and vegetable processing operations have developed sophisticated food safety programs largely centered on current

Good Manufacturing Practices (cGMPs) and the principles of Hazard Analysis Critical Control Point (HACCP) programs. As we develop a greater understanding of food safety issues relative to the full spectrum of supply and distribution channels for fruits and vegetables, it has become clear that the next generation of food safety guidance needs to encompass the entire supply chain.

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

SCOPE

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

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

Lettuce/leafy greens present multiple opportunities to employ food safety risk management practices to enhance the safety of lettuce/leafy greens. It should be noted that processed or value-added versions of lettuce/leafy greens packaged products are also commonly found in the marketplace in both retail and foodservice stores. These products are generally considered "ready-to-eat" (RTE) owing to the wash process used in their preparation and the protective packaging employed in their distribution and marketing. In a processing operation, the basic principles of cGMPs, HACCP, sanitation and documented operating procedures are commonly employed in order to produce the safest products possible. Lettuce/leafy greens are highly perishable and it is strongly recommended that they be distributed, stored and displayed under refrigeration.

Safe production, packing, processing, distribution and handling of lettuce/leafy greens depend upon a myriad of factors and the diligent efforts and food safety commitment of many parties throughout the distribution chain. No single resource document can anticipate

every food safety issue or provide answers to all food safety questions. These guidelines focus on minimizing only the microbial food safety hazards by providing suggested actions to reduce, control or eliminate microbial contamination of lettuce/leafy greens in the field to fork distribution supply chain.

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

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

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

Due to the close association between production blocks and environmentally sensitive areas in many locations, it is important to consult environmental regulators when any mitigation strategies that may impact these areas are employed. Growers should implement strategies that not only protect food safety but also support conservation practices, water quality, habitat protection and natural flood flow dynamics. All parties involved with implementing the practices outlined in this document should be aware that these metrics are not, in any way, meant to encourage growers to violate environmental regulations.

Users are strongly urged to maintain regular contact with and utilize information available from their trade associations, the U.S. Food and Drug Administration, the U.S. Department of Agriculture, the U.S. Environmental Protection Agency, the Centers for Disease Control and Prevention, and state agricultural, environmental, academic, and public health authorities.

The Sanitary Survey and Technical Basis Documents prepared as Appendices to these guidelines are considered to be additional resources. They are intended to provide clarification, assist with interpretation and provide additional guidance as users develop food

safety programs based on these Guidelines. They are not intended for measurement or verification purposes.

Lettuce/Leafy Greens Commodity Specific Guidance
Production & Harvest Unit Operations

1. PURPOSE

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

2. ISSUE: GENERAL REQUIREMENTS

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

2.1. The Best Practices Are:

- A written Leafy Greens Compliance Plan which specifically addresses the Best Practices of this document shall be prepared. This plan shall address at least the following areas: water, soil amendments, environmental factors, work practices, and field sanitation.
- If appropriate, an up to date growers list with contact and location information shall be prepared.
- If required under law, the handler shall comply with the requirements of The Public Health Security and Bioterrorism Preparedness and Response Act of 2002.
- A traceback process shall be implemented that allows for identification of both the previous non-transporter source and the subsequent non-transporter recipient of all product at a minimum.
- Each grower and handler shall designate an individual responsible for their operation's food safety program. Twenty-four hour contact information shall be available for this individual in case of food safety emergencies.

3. ISSUE: ENVIRONMENTAL ASSESSMENTS

This section addresses assessments that shall be completed by all growers prior to the first seasonal planting and within one week prior to harvesting. These two environmental assessments are intended to identify any issues related to the produce field, adjacent land uses, or intrusion by animal of significant risk (see Table 5) that might impact produce safety or cause microbial contamination.

3.1. The Best Practices Are:

- Prior to the first seasonal planting and within one week prior to harvest, perform an environmental assessment of the production field and surrounding area. Focus these assessments on evaluating the production field for possible animal of significant risk intrusion or other sources of microbial contamination, assessing adjacent land uses for possible sources that might contaminate the production field, and evaluating nearby water sources for the potential of past or present flooding.
    - Assessment of Produce Field
        - Evaluate all produce fields for evidence of animal of significant risk intrusion and/or feces. If any evidence is found, follow procedures identified in the "Production Locations - Encroachment by Animals and Urban Settings."
    - Assessment of Adjacent Land Use
        - Evaluate all land and waterways adjacent to all production fields for possible sources of microbial contamination. These sources include, but are not limited to, manure storage, compost storage, CAFO's, grazing/open range areas, surface water, sanitary facilities, and composting operations (see Table 6 for further detail). If any possible uses that might result in produce contamination are present, follow management practices identified in the sections below related to environmental and land use concerns.
    - Assessment of Historical Land Use
        - To the degree practical, determine and document the historical land uses for production fields and any potential issues from these uses that might impact food safety (i.e., hazardous waste sites, landfills, etc.).
    - Assessment of Flooding
        - Evaluate all produce fields for evidence of flooding. If any evidence is found, follow procedures identified in the "Flooding" section below.

4. ISSUE: WATER

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

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

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

4.1. The Best Practices Are:

- A water system description shall be prepared. This description can use maps, photographs, drawings or other means to communicate the location of permanent fixtures and the flow of the water system (including tail water).
- Use irrigation water and water in harvest operations that is of appropriate microbial quality for its intended use; see Table 1 and Decision Trees (1A, 1B and 1C) for specific numerical criteria. Appendix B provides the basis for these water quality metrics.
- Perform a sanitary survey prior to use of water in agricultural operations and if water quality microbial tests are at levels that exceed the numerical values set forth in Table 1. The sanitary survey is described in Appendix A.
- Test water as close to the point-of-use as practical, and if microbial levels are above specific action levels, take appropriate remedial and corrective actions.
- Retain documentation of all test results and/or Certificates of Analysis available for inspection for a period of at least 2 years or per regulatory requirements if longer.
- Evaluate irrigation methods (drip irrigation, overhead sprinkler, furrow, etc.) for their potential to introduce, support or promote the growth of human pathogens on lettuce and leafy greens. Consider such factors as the potential for depositing soil on the crop, presence of pooled or standing water that attracts animals, etc.
- When waters from various sources are combined, consider the potential for pathogen growth in the water.
- For surface water sources, consider the impact of storm events on irrigation practices. Bacterial loads in surface water are generally much higher after a storm than normal, and caution should be exercised when using these waters for irrigation.
- Use procedures for storing irrigation pipes and drip tape that reduce or eliminate potential pest infestations. Develop procedures to provide for microbiologically safe use of irrigation pipes and drip tape if a pest infestation does occur.
- Reclaimed water shall be subject to applicable state and federal regulations and standards. Use of this water for agricultural purposes must meet the most stringent standard as defined by the following: state and federal regulation or Table 1 of this document.

TABLE 1. WATER USE

Use	Metric	Rationale /Remedial Actions
PREHARVEST Foliar Applications Whereby Edible Portions of the Crop **ARE** Contacted by Water (*e.g.* overhead sprinkler irrigation, pesticides/fungicide application, etc.)	**Target Organism:** generic *E. coli*. **Sampling Procedure:** 100 mL sample collected aseptically at the point of use; i.e., one sprinkler head per water source for irrigation, water tap for pesticides, etc. **Sampling Frequency:** One sample per water source shall be collected and tested prior to use if >60 days since last test of the water source. Additional samples shall be collected no less than 18 hr apart and at least monthly during use from points within the distribution system. **Municipal & Well Exemption:** For wells and municipal water sources, if generic *E. coli* are below detection limits for five consecutive samples, the sampling frequency may be decreased to once every six months and the requirements 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 U.S. EPA, AOAC, or other method accredited for quantitative monitoring of water for generic *E. coli.* Presence/absence testing with a similar	For any given water source (municipal, well, reclaimed water, reservoir or other surface water), samples for microbial testing shall be taken at a point as close to the point of use as practical where the water contacts the crop, so as to test both the water source and the water distribution system. Only one sample per month per distribution system is required under these metrics. If there are multiple potential point-of-use sampling points in a distribution system, then samples shall be taken from different point-of-use locations each subsequent month (randomize or rotate sample locations). Water for preharvest, direct edible portion contact shall meet or exceed microbial standards for recreational water, based on a rolling geometric mean of the five most recent samples. If the water source has not been tested in the past 60 days, the first water sample shall be tested prior to use, to avoid using a contaminated water source. After the first sample is shown to be within acceptance criteria, subsequent samples shall be collected no less frequently than monthly at points of use within the distribution system. Ideally, preharvest water should not contain generic *E. coli*, but low levels do not necessarily indicate that the water is unsafe. Investigation and/or remedial action SHOULD be taken when test results are higher than normal, or indicate an upward trend. Investigation and remedial action SHALL be taken when acceptance criteria are exceeded. **Remedial Actions:** If the rolling geometric mean (n=5) or any one sample exceeds the acceptance criteria, then the water shall not be used whereby edible portions of the crop are contacted by water until remedial actions have been completed and generic *E. coli* levels are within acceptance criteria: • Conduct a sanitary survey of water source and distribution system to determine if a contamination source is evident and can be eliminated. Eliminate identified contamination source(s). • For wells, perform a sanitary survey and/or treat as described in Appendix A Sanitary Survey. • Retest the water at the same sampling point after conducting the sanitary survey and/or taking remedial actions to determine if it meets the outlined microbial acceptance criteria for this use. A more aggressive sampling program (i.e., sampling once per week instead of once per month) should be instituted at the sampling point that was out of compliance if an explanation for the exceedence is not readily apparent. This type of sampling program should also be instituted if an upward trend is noted in normal sampling results. For example, if one irrigation water sample has a count >235 MPN/100 mL, STOP IRRIGATION using that system, examine the distribution line and water source as described in Appendix A Sanitary Survey, and retest from the same point of use. In addition, continue testing daily for 5 days at other sprinkler

	limit of detection may be used as well. **Acceptance Criteria:** **≤126 MPN (or CFU*)/100 mL** (rolling geometric mean n=5) and **≤235 MPN/100mL** for any single sample. *for the purposes of water testing, MPN and CFU shall be considered equivalent.	heads (or points-of-use), and do not use the irrigation system until the rolling geometric mean of these five samples is ≤126 MPN (or CFU*)/100 mL. If any of the 5 samples is >235 MPN/ 100 mL, repeat the sanitary survey and/or remedial action and do not use the water system for direct foliar applications until the source of contamination can be corrected. **Crop Testing**: If water testing indicates that a crop has been directly contacted with water exceeding acceptance criteria, product shall be sampled and tested for *E. coli* O157:H7 and *Salmonella* as described in Appendix C, prior to harvest. If crop testing indicates the presence of either pathogen, the crop shall NOT be harvested for human consumption. **Records**: All test results and remedial actions shall be documented and available for verification from the grower who is the responsible party for a period of two years.
PREHARVEST Non-foliar Applications Whereby Edible Portions of the Crop are **NOT** Contacted by Water (*e.g.*, furrow or drip irrigation, dust abatement water; if water is not used in the vicinity of produce, then testing is not necessary)	**Target Organism, Sampling Procedure, Sampling Frequency and Test Method:** as described for foliar application. **Acceptance Criteria:** **≤126 MPN /100 mL** (rolling geometric mean n=5) and **≤576 MPN /100 mL** for any single sample.	Testing and remedial actions for preharvest water that does not come in direct contact with edible portions of the crop are the same as for direct contact water, but acceptance criteria are less stringent because of the reduced risk of contact of the edible portion with contamination from water. Acceptance criteria here are derived from U.S. EPA recreational water standards.
POSTHARVEST Direct Product Contact or Food Contact Surfaces (*e.g.* re-hydration, core in field, harvest equipment cleaning, bin cleaning, product	**Microbial Testing** **Target Organism, Sampling Procedure, and Test Method:** as described for foliar application. **Sampling Frequency:** One sample per water source shall be collected and tested prior to use if >60 days since last test of the water source. Additional	Water that directly contacts edible portions of harvested crop, or is used on food contact surfaces, such as equipment or utensils, shall meet the Maximum Contaminant Level Goal for *E. coli* as specified by U.S. EPA or contain an approved disinfectant at sufficient concentration to prevent cross contamination. Microbial or physical/chemical testing shall be performed, as appropriate to the specific operation, to demonstrate that acceptance criteria have been met. **Single Pass vs. Multiple Pass Systems** • Single pass use – Water must have non-detectable levels of *E. coli* or breakpoint disinfectant present at point of entry

<table>
<tr>
<td>cooling, product washing)</td>
<td>samples shall be collected at intervals of no less than 18 hr and at least monthly during use. Rolling average should include data no longer than 1 year old.

Acceptance Criteria:
Negative or below DL for all samples

<u>Physical/Chemical Testing</u>
Target Variable:
Water disinfectant (e.g. chlorine or other disinfectant compound, ORP)

Multi Pass Water Acceptance Criteria:
• <u>Chlorine</u>
≥1 ppm free chlorine after application or ORP
≥ 650 mV,
• And pH 6.5 – 7.0
• <u>Other approved treatments</u> per product EPA label for human pathogen reduction in water.
Testing Procedure:
• Chemical reaction based colorimetric test, or
• Ion specific probe, or
• ORP, or
• Other as recommended by disinfectant supplier.

Testing Frequency:
Continuous monitoring (preferred) with periodic verification by titration
OR
Routine monitoring if the system can be shown to have a low degree of variation.</td>
<td>• Multi-pass use – Water must have non-detectable levels 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 shall 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 water source and distribution system to determine if a contamination source is evident and can be eliminated. Eliminate identified contamination source(s).
• For wells, perform a sanitary survey and/or treat as described in Appendix A Sanitary Survey.
• Retest the water at the same sampling point after conducting the sanitary survey and/or taking remedial actions to determine if it meets the outlined microbial acceptance criteria for this use.

For example, if a water sample for water used to clean food contact surfaces has detectable E. coli, STOP using that water system, examine the distribution line and source inlet as described in Appendix A Sanitary Survey, and retest from the same point of use. Continue testing daily for 5 days at the point closest to use, and do not use the water system until it consistently delivers water that is safe, sanitary water and of appropriate microbial quality (i.e. Negative result) for the intended use. If any of the 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 shall be documented and available for verification from the user of the water (e.g., harvester, packing house, cooling facility, processor) for a period of two years.</td>
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Figure 1A. Decision Tree for PRE-HARVEST WATER USE – Foliar Applications whereby edible portions of the crop are contacted by water (e.g. overhead irrigation, pesticide/fungicide applications)

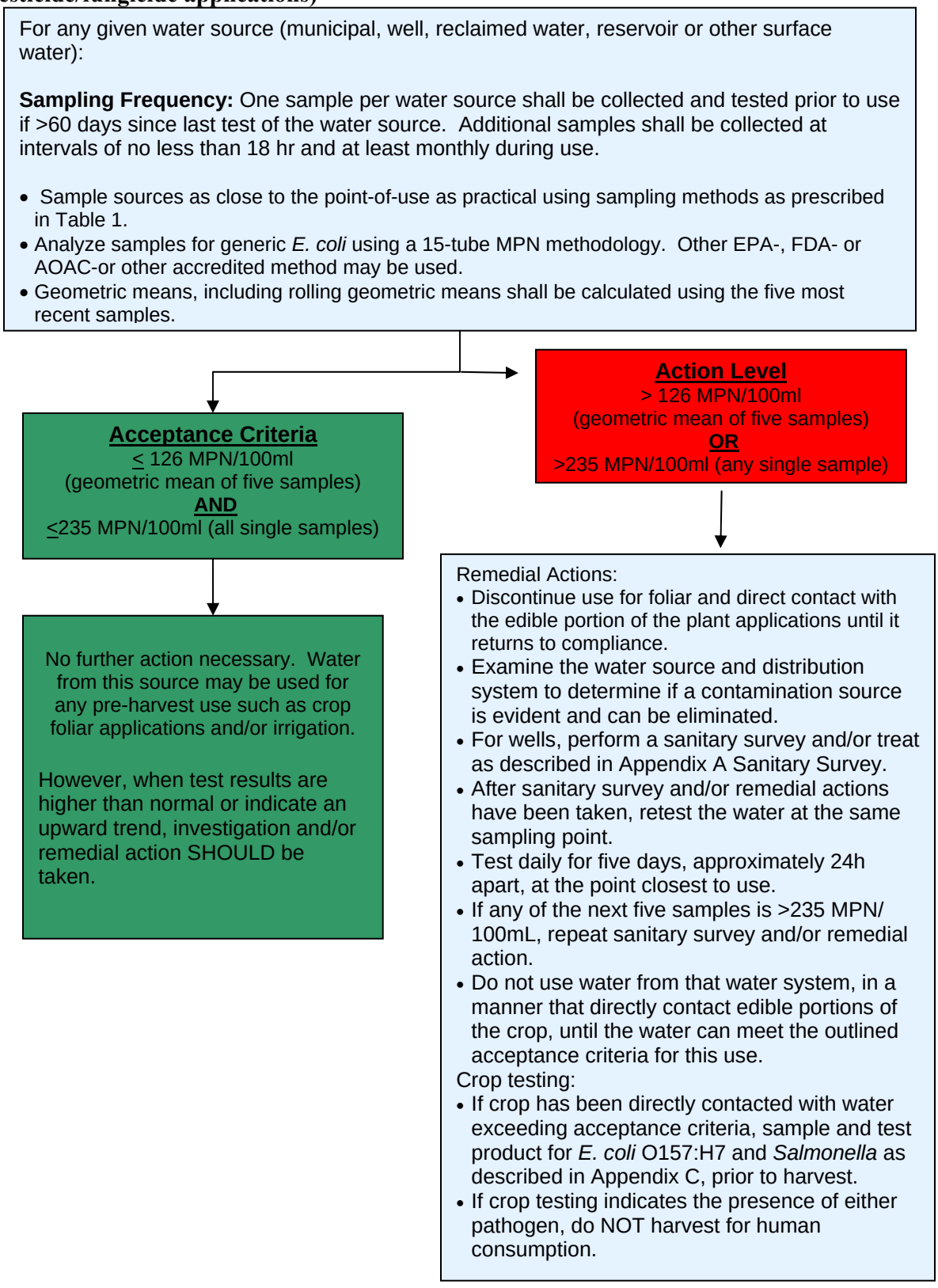


Figure 1B. Decision Tree for PRE-HARVEST WATER USE – Non-Foliar Applications whereby edible portions of the crop are NOT contacted by water (e.g. furrow or drip irrigation, dust abatement water)

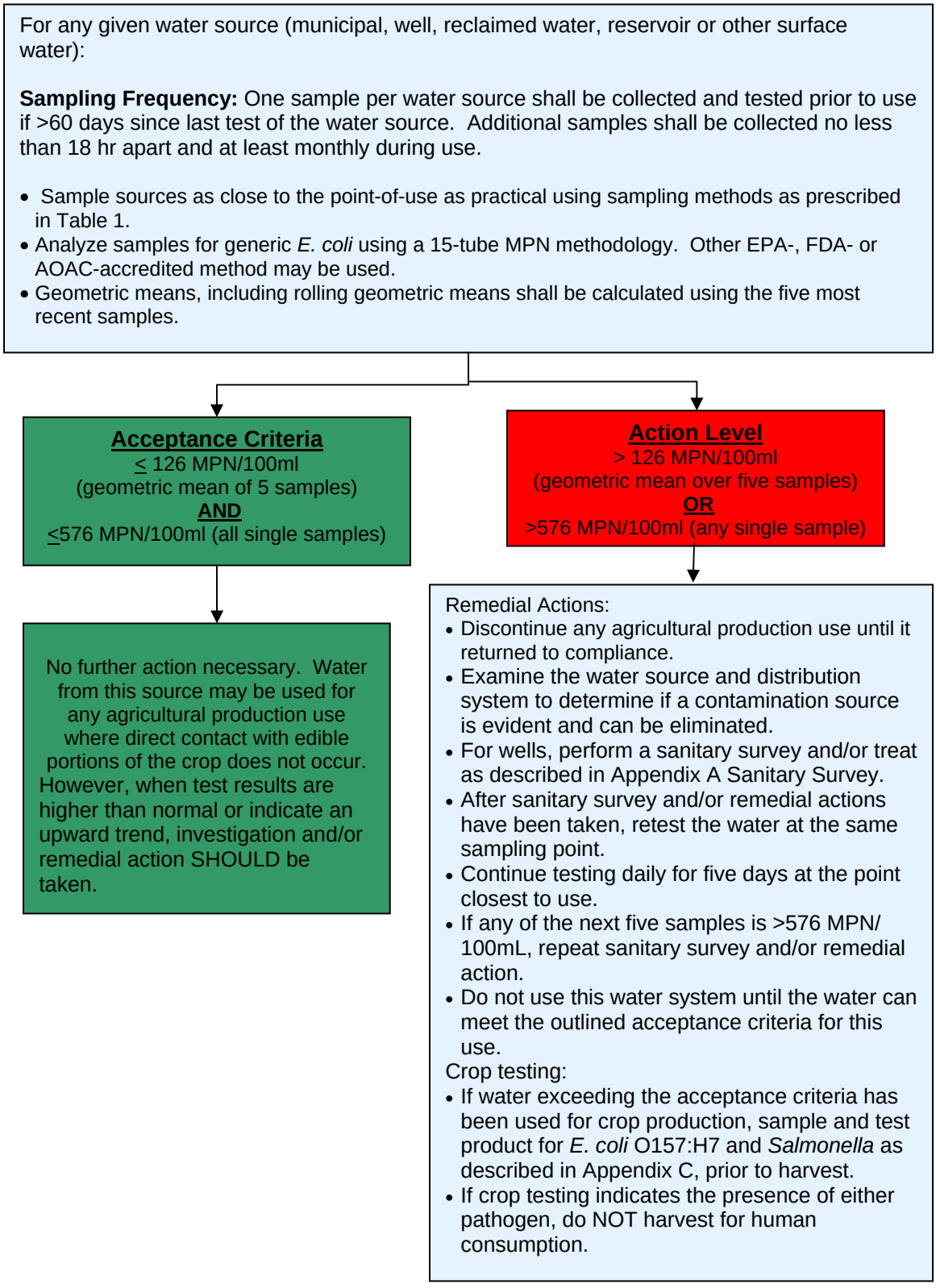
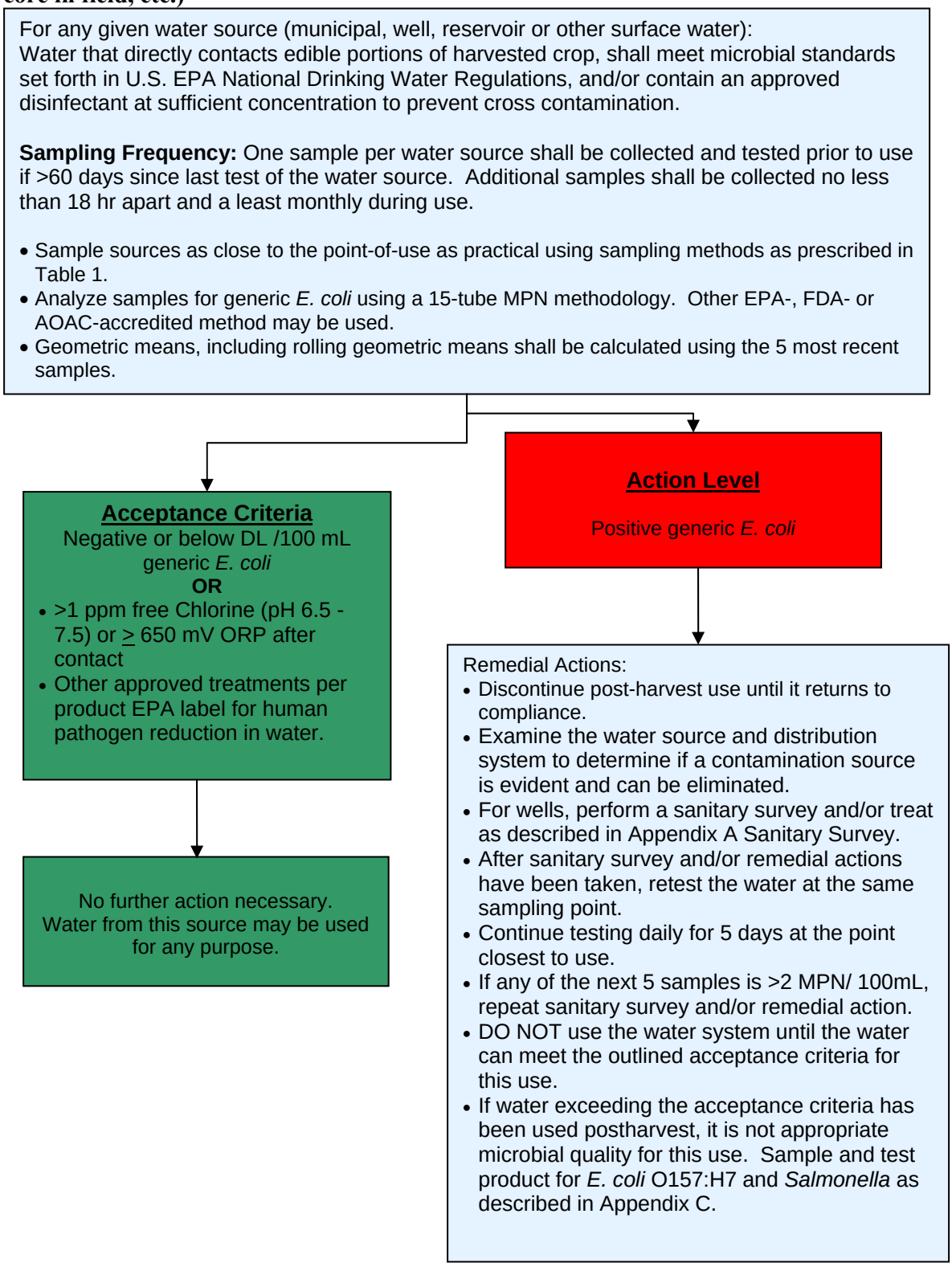


Figure 1C. POSTHARVEST WATER USE – Direct product contact (e.g. re-hydration, core in field, etc.)



5. ISSUE: SOIL AMENDMENTS

Soil amendments are commonly but not always incorporated prior to planting into agricultural soils used for lettuce/leafy greens production to add organic and inorganic nutrients to the soil as well as 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 (soil type, relative humidity, UV index, etc.) and the effects of these factors is under extensive investigation (Jiang *et al.* 2003; Islam *et al.* 2004).

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

5.1. The Best Practices Are:

- DO NOT USE raw manure or soil amendment that contain un-composted, incompletely composted or non-thermally treated animal manure to fields which will be used for lettuce and leafy green production.
- See Table 2 and Decision Trees (Figures 2A and 2B) for numerical criteria and guidance for compost and soil amendments used in lettuce and leafy greens production fields. The "Technical Basis Document" (Appendix B) describes the process used to develop these metrics.
- Any soil amendment that does not contain animal manure must have a certificate (e.g., ingredient list, statement of identity, letter of guaranty, etc.) from the producer or seller demonstrating that it is manure free. The manure free certificate must be available for verification before harvest begins and it must be saved and available for inspection for 2 years.
- Implement management plans (e.g., timing of applications, storage location, source and quality, transport, etc.) that significantly reduce the likelihood that soil amendments being used contain human pathogens.
- Verify that the time and temperature process used during the composting process reduces, controls, or eliminates the potential for human pathogens being carried in the composted materials, as applicable to regulatory requirements.

- Maximize the time interval between soil amendment application and time to harvest.
- Implement practices that control, reduce or eliminate likely contamination of lettuce/leafy green fields in close proximity to on-farm stacking of manure.
- Use soil amendment application techniques that control, reduce or eliminate likely contamination of surface water and/or edible crops being grown in adjacent fields.
- Segregate equipment used for soil amendment handling, preparation, distribution, applications or use effective means of equipment sanitation before subsequent use that effectively reduce the potential for cross contamination.
- Minimize the proximity of wind-dispersed or aerosolized sources of contamination (e.g., water and manure piles) that may potentially contact growing lettuce/leafy greens or adjacent edible crops. Segregate equipment used for soil amendment applications or use effective means of equipment sanitation before subsequent use.
- Compost suppliers shall have written Standard Operating Procedures to prevent cross-contamination of finished compost with raw materials through equipment, runoff, or wind, and growers shall obtain proof that these documents exist.
- Compost operations supplying compost to ready to eat crops shall maintain temperature monitoring and turning records for at least two years, and growers shall 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.
- Perform microbiological testing of soil amendments prior to application (Table 2).
- Do not use biosolids as a soil amendment for production of lettuce or leafy greens.
- Retain documentation of all processes and test results by lot (at the supplier) and/or Certificates of Analysis available for inspection for a period of at least two years.

TABLE 2. SOIL AMENDMENTS

Amendment	Metric/Rationale
Raw Manure or Not Fully Composted Animal Manure Containing Soil Amendments (see composted manure process definition below)	**DO NOT USE OR APPLY** soil amendments that contain un-composted, incompletely composted or non-thermally treated (e.g., heated) animal manure to fields which will be used for lettuce and leafy greens production. If these materials have been applied to a field, wait one year prior to producing leafy greens.
Composted Soil Amendments (containing animal manure or animal products) *Composted soil amendments should not be applied after emergence of plants.	**Please see Figure 2A: Decision Tree for Use of Composted Soil Amendments.** **Composting Process Validation:** Enclosed or within-vessel composting: Active compost must maintain a minimum of 131°F for 3 days, with a curing/aging period of at least 45 days before application to fields. Windrow composting: Active compost must maintain aerobic conditions for a minimum of 131°F for 15 days, with a minimum of five turnings followed by a curing/aging period of at least 45 days before application to fields. Aerated static pile composting: Active compost must be covered with at least 12 inches of insulating materials and maintain a minimum of 131°F for 3 days, with a curing/aging period of at least 45 days before application to fields. **Target Organisms:** • Fecal coliforms • *Salmonella* spp • *E. coli* O157:H7 **Acceptance Criteria:** • Fecal coliforms <1000 MPN/gram • *Salmonella*: Negative or < DL (<1/ 30 grams) • *E. coli* O157:H7: Negative or < DL (<1/ 30 grams)

Amendment	Metric/Rationale
	Recommended Test Methods: • Fecal coliforms: 9 tube MPN • *Salmonella spp:* U.S. EPA Method 1682 • *E. coli* O157:H7: Any laboratory validated method for compost sampling. • Other U.S. EPA, FDA, 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 equivolume samples.) • Sample may be taken by the supplier if trained by the testing laboratory • Laboratory must be certified/accredited for microbial testing by an appropriate process authority **Testing Frequency:** • Each lot before application to production fields. A lot is defined as a unit of production equal to or less than 5,000 cubic yards. **Application Interval:** • Must be applied >45 days before harvest **Documentation:** • All test results and/or Certificates of Analysis shall be documented and available for verification from the grower (the responsible party) for a period of two years. **Rationale:** • The microbial metrics and validated processes for compost are based on allowable levels from California state regulations (CCR Title 14 - Chapter 3.1 - Article 5 2007), with the addition of testing for *E. coli* O157:H7 as microbe of particular concern. The 45-day application interval was deemed appropriate due to the specified multiple hurdle risk reduction approach outlined. Raw manure must be composted with an approved process and pass testing requirements before an application.

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Soil amendments containing animal manure that has been physically heat treated or processed by other equivalent methods.	**Please see Figure 2B: Decision Tree for Use of Physically Heat Treated Soil Amendments.** **Physical Heat Process Validation** • The physical heat treatment processes applied to the soil amendment containing animal manure shall be done via a process validated to assure that the process is capable of reducing pathogens of human health significance to acceptable levels. **Target Organism:** • Fecal coliforms • *Salmonella* spp • *E. coli* O157:H7 **Acceptance Criteria:** • Fecal coliforms Negative or < DL per gram • *Salmonella*: Negative or < DL (<1/ 30 grams) • *E. coli* O157:H7: Negative or < DL (<1/ 30 grams) **Recommended Test Methods:** • Fecal coliforms: 9 tube MPN • *Salmonella spp:* U.S. EPA Method 1682 • *E. coli* O157:H7: Any laboratory validated method for testing soil amendments. • U.S. 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 equivolume samples) • Sample may be taken by the supplier if trained by the testing laboratory • Laboratory must be certified/accredited by annual review of laboratory protocols based on GLPs by recognized NGO. **Testing Frequency:** • Each lot before application to production fields.

	Application Interval: • If the physical heat treatment process used to inactivate human pathogens of significant public health concern that may be found in animal manure containing soil amendments, is validated and meets the microbial acceptance criteria outlined below, then no time interval is needed between application and harvest. • If the physical heat treatment process used to inactivate human pathogens of significant public health concern that may be found in animal manure containing soil amendments is not validated but will likely significantly reduce microbial populations of human pathogens (minimum temperature: 300°F (150°C) for 60 minutes resulting in a moisture content <30% dry weight) and meets that microbial acceptance criteria outlined above, then a 45 day interval between application and harvest is required. **Documentation:** • All test results and/or Certificates of Analysis shall be documented and available for verification from the grower who is the responsible party for a period of two years. The suppliers operation should be validated by a process authority and a record maintained by the grower for a period of two years. **Rationale:** • The microbial metrics and validated processes for compost are based on allowable levels from California state regulations (CCR Title 14 - Chapter 3.1 - Article 5 2007), with the addition of testing for *E. coli* O157:H7 as the microbe of particular concern. A more stringent level of fecal coliform was also included to address the much more controlled nature of soil amendments produced in this manner. The above suggested application interval was deemed appropriate due to the specified multiple hurdle risk reduction approach outlined. Raw manure must be composted with an approved process and pass testing requirements before application.
Soil Amendments Not Containing Animal Manure	• Any soil amendment that DOES NOT contain animal manure must have documentation that it is manure-free. • The documentation must be available for verification before harvest begins. • If there is documentation that the amendment does not contain manure or animal products then no additional testing is required, and there is no application interval necessary • Any test results and/or documentation shall be available for verification from the grower who is the responsible party for a period of two years.

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

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

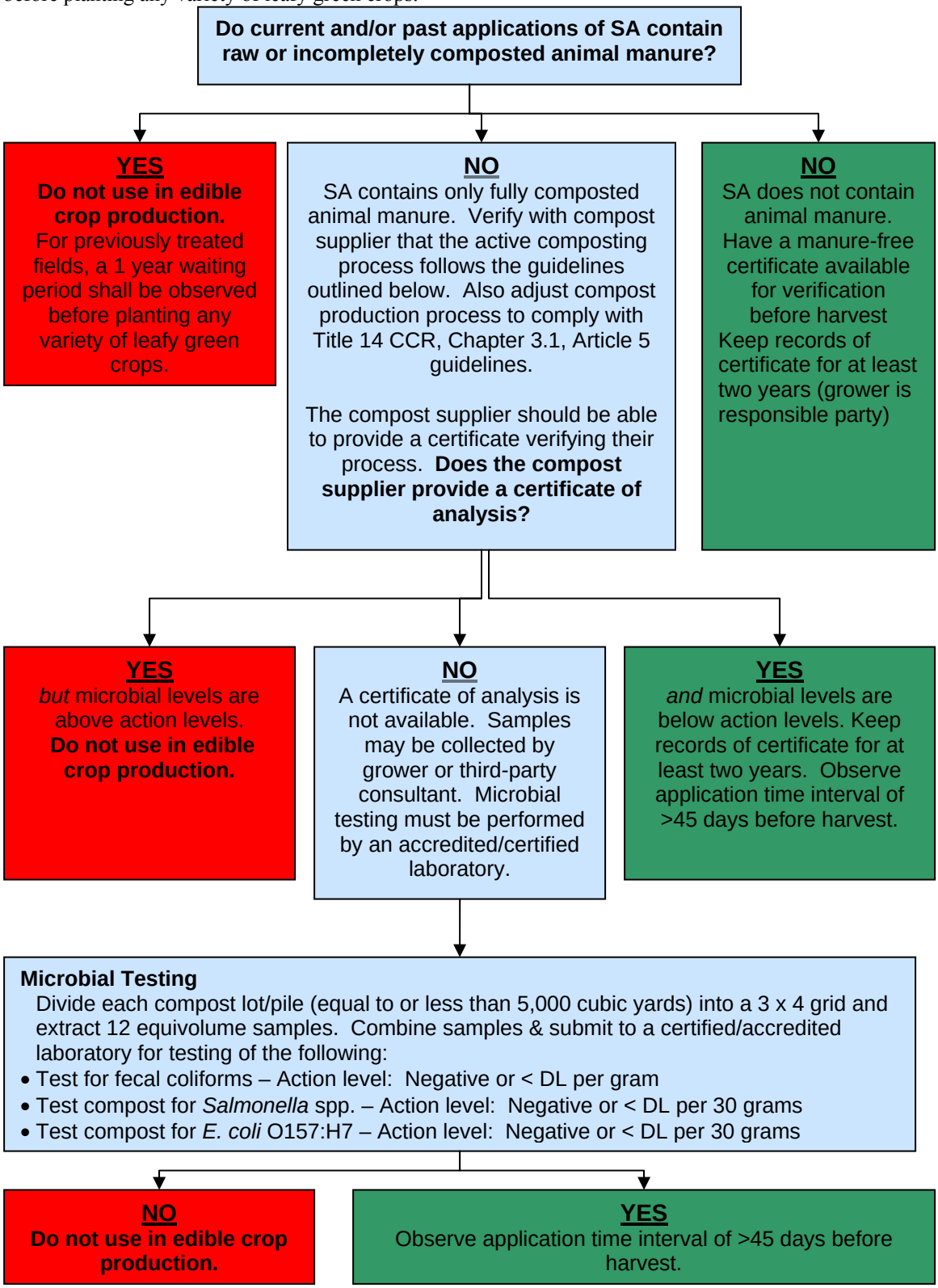
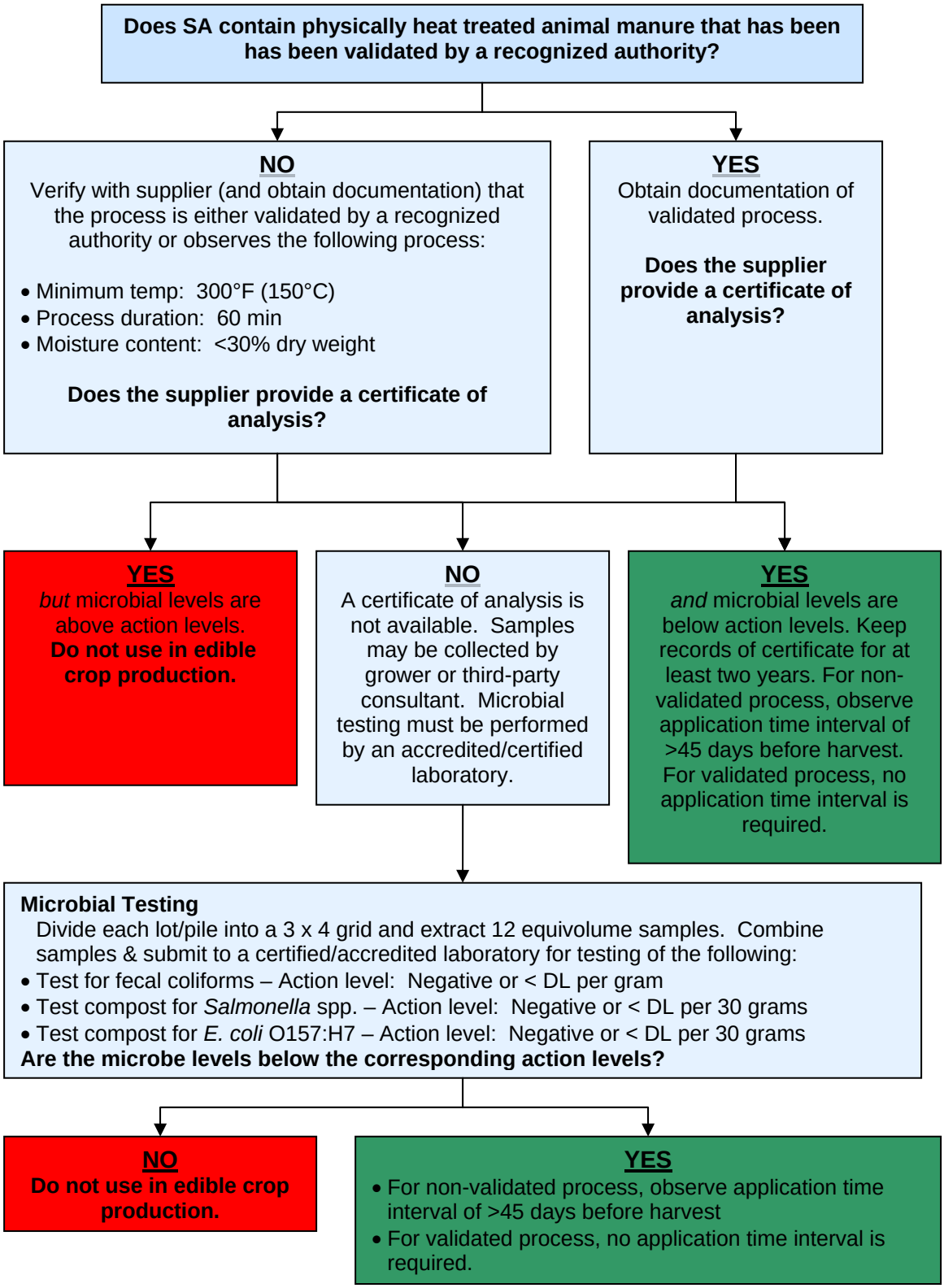


Figure 2B. Decision Tree for Physically Heat Treated Animal Manure Containing Soil Amendments (SA)



6. ISSUE: NONSYNTHETIC CROP TREATMENTS

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

6.1. The Best Practices Are:

- Do not use crop treatments that contain raw manure for lettuce or leafy green produce.
- Retain documentation of all test results available for inspection for a period of at least two years.
- Implement management plans (e.g. timing of applications, storage location, source and quality, transport, etc.) that assure to the greatest degree practicable that the use of crop treatments does not pose a significant pathogen contamination hazard.
- Verify that the time and temperature process used during crop treatment manufacture reduces, controls, or eliminates the potential for human pathogens being carried in the composted materials, as applicable to regulatory requirements.
- Maximize the time interval between the crop treatment application and time to harvest.
- Implement practices that control, reduce or eliminate likely contamination of lettuce/leafy green fields that may be in close proximity to on-farm storage of crop treatments.
- Use crop treatment application techniques that control, reduce or eliminate the likely contamination of surface water and/or edible crops being grown in adjacent fields.
- Segregate equipment used for crop treatment applications or use effective means of equipment sanitation before subsequent use.
- See Table 3 and Decision Tree (Figure 3) for numerical criteria and guidance for nonsynthetic crop treatments used in lettuce and leafy greens production fields. The "Technical Basis Document" (Appendix B) describes the process used to develop these metrics.

TABLE 3. 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 are 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 shall disclose on labels, certificates of analysis, or other companion paperwork whether the product contains any animal manure or products.	**Non synthetic crop treatments that contain animal products or animal manure that have not been physically heat treated or processed by other equivalent methods shall NOT be directly applied to the edible portions of lettuce and leafy greens.** **Please see Figure 3: Decision Tree for Use of Nonsynthetic Crop Treatments.** **Process Validation** • The physical, chemical and/or biological treatment process(es) used to render the crop input safe for application to edible crops must be validated. **Target Organism:** • *Salmonella* spp • *E. coli* O157:H7 **Acceptance Criteria (at point of use):** • *Salmonella*: 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:* U.S. EPA Method 1682 • *E. coli* O157:H7: Any laboratory validated method for the non synthetic material to be tested. • Other U.S. EPA, FDA, or AOAC-accredited methods may be used as appropriate **Sampling Plan:** • 12 point sampling plan composite sample (if solid), one sample per batch if liquid (if liquid-based, then water quality acceptance levels as described in Table 1 should be used) • Sample may be taken by the supplier if trained by the testing laboratory • Laboratory must be certified/accredited by annual review of laboratory protocols based on GLPs by recognized NGO **Testing Frequency:** • Each lot before application to production 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 edible crops 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 edible crops is not validated yet meets the microbial acceptance criteria outlined above, a 45 day time interval between application and harvest is required. **Documentation:** • All test results and/or Certificates of Analysis shall be documented and available from the grower for verification for a period of 2 years. The grower the party responsible party for maintaining the appropriate records. **Rationale:** • The microbial metrics and validated processes for compost are based on allowable levels from California state regulations (CCR Title 14 - Chapter 3.1 - Article 5 2007), with the addition of testing for *E. coli* O157:H7 as the microbe of particular concern. The above suggested application interval was deemed appropriate due to the specified multiple hurdle risk reduction approach outlined. Any non synthetic crop treatment that contains animal manure must use only fully composted manure in addition to a validated process and pass testing requirements before a application to soils or directly to edible portions of lettuce and leafy greens.

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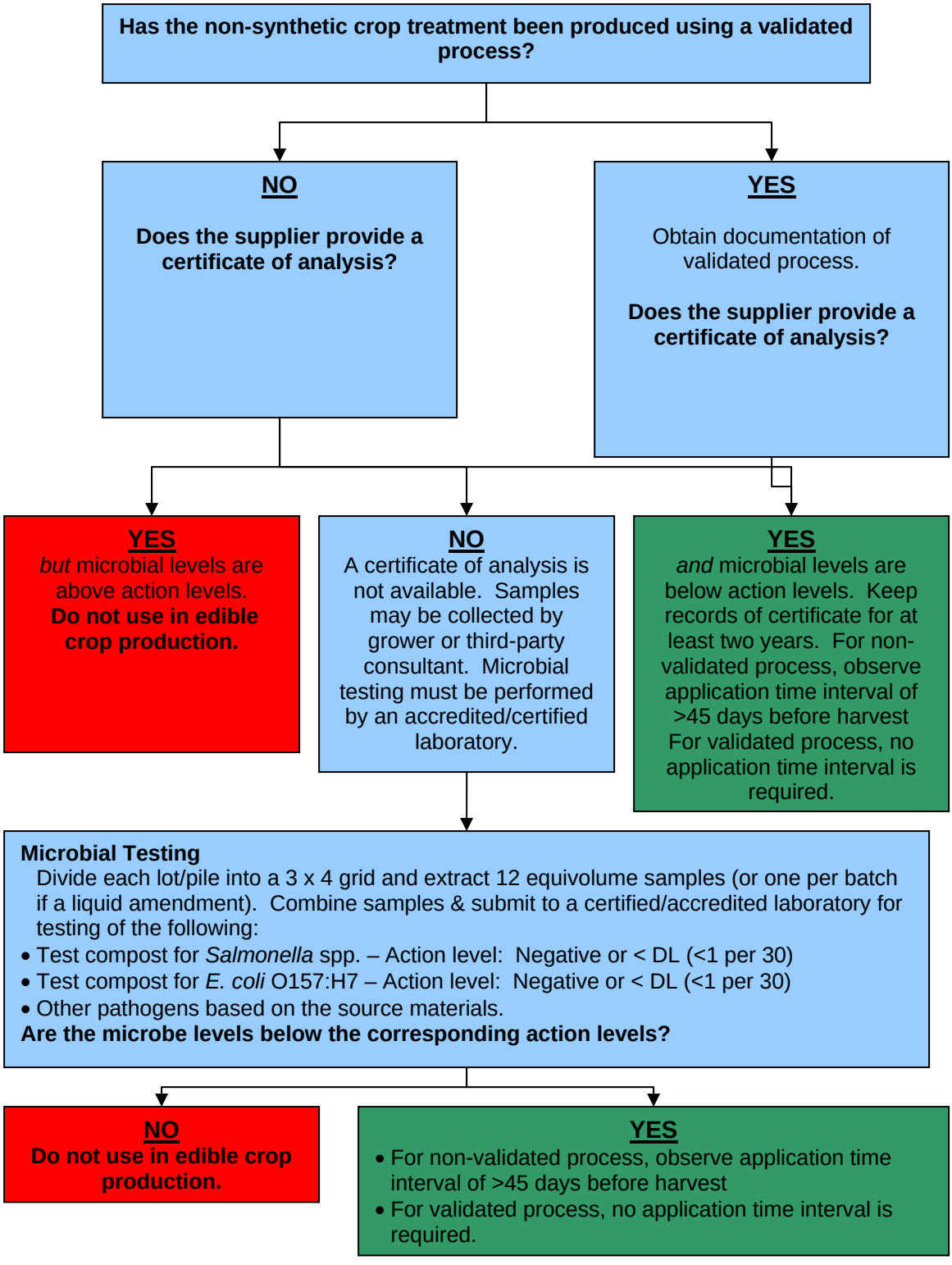
Figure 3. Decision Tree for Nonsynthetic Crop Treatments That Contain Animal Products



7. ISSUE: HARVEST EQUIPMENT

This section addresses harvest and harvest aid equipment used for lettuce/leafy greens that will be further processed into a ready-to-eat product. Mechanical or machine harvest has become increasingly prevalent and provides opportunity for increased surface contact exposure. This includes field cored lettuce operations that use various harvest equipment and aids.

7.1. The Best Practices Are:

- Prepare an SOP for harvest equipment that addresses the following:
  - Sanitation verification
  - Daily inspection
  - Periodic microbial swabs or other equivalent indicator
  - Proper cleaning, sanitation and storage of hand harvest equipment (knives, scythes, etc.)
  - Control procedures when equipment is not in use, including policy for removal of equipment from the work area or site and the use of scabbards, sheathes or other storage equipment.
- Prepare an SOP for handling and storage of product containers that addresses the following:
  - Over night storage
  - Contact with the ground
  - Container assembly (RPC, fiber bin, plastic bin, etc)
  - Damaged containers
  - Use of containers only as intended
- Prepare an SOP for sanitary operation of equipment.
- Establish appropriate measures that reduce and control the potential introduction of human pathogens at the cut surface during and after mechanical harvest operations. Due to the cut surface being more vulnerable to microbial contamination, this best practice is extremely important and all practical means should be taken to reduce the possibility of introduction of contamination at this process step.
- If re-circulated rinse or antioxidant solutions are used on the cut surface, take all practicable precautions to prevent them from becoming a source of contamination.
- Design equipment to facilitate cleaning by using materials and construction that facilitate cleaning and sanitation of equipment food contact surfaces (e.g., transportation tarps, conveyor belts, etc.).

- Establish the frequency of equipment cleaning and sanitation by developing Sanitation Standard Operating Procedures (SSOPs) and a sanitation schedule for machine harvest operations.
- Evaluate the use of cleaning verification methods for harvesting equipment (e.g., ATP test methods).
- Locate equipment cleaning and sanitizing operations away from product and other equipment to reduce the potential for cross contamination.
- Establish equipment storage and control procedures to minimize the potential for contamination when not in use. Establish policies and sanitary design options that facilitate frequent and thorough cleaning and sanitizing of food contact surfaces.
- Develop and implement appropriate cleaning, sanitizing, storage and handling procedures of all food contact surfaces to reduce and control the potential for microbial cross contamination.
- Allow adequate distance for the turning and manipulation of harvest equipment to prevent cross contamination from areas of animal of significant risk intrusion or adjacent land that may pose a risk.

8. ISSUE: HARVEST PERSONNEL - DIRECT CONTACT WITH SOIL DURING HARVEST

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

8.1. The Best Practices Are:

- Evaluate appropriate measures that reduce and control the potential introduction of human pathogens through soil contact at the cut surface after harvest (e.g. frequency of knife sanitation, no placement of cut surfaces of harvested product on the soil, container sanitation, single use container lining, etc.).
- Do not stack soiled bins on top of each other if the bottom of one bin has had direct contact with soil.

9. ISSUE: FIELD AND HARVEST PERSONNEL - TRANSFER OF HUMAN PATHOGENS BY WORKERS

Lettuce/leafy greens are handled by harvest crews during harvest in that each lettuce/leafy greens plant is touched/handled as part of the harvest process. It is possible that persons working with produce in the field may transfer microorganisms of significant public health concern. Workers may be asymptomatic.

9.1. The Best Practices Are:

- Use appropriate preventive measures outlined in GAPs such as training in appropriate and effective hand washing, glove use and replacement, and mandatory use of sanitary field latrines to reduce and control potential contamination.
- Establish a written worker practices program (i.e., 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 visitors.
    - Prior to harvest, an individual should be designated as responsible for harvesting food safety
    - Preparation of daily harvesting food safety reports
    - Use, storage, record keeping, and proper labeling of chemicals
    - Training on proper sanitation and hygiene practices
    - Requirements for workers to wash their hands before beginning or returning to work
    - Confinement of smoking, eating and drinking to designated areas separate from where product is grown
    - Personal item storage
    - Employee clothing and jewelry (head and hair restraints, aprons, gloves, visible jewelry, etc.)
    - Removal of all objects from upper pockets
    - How to handle broken glass, spills and leaks, and inoperative water sprays
- Establish a worker health practices program (i.e., an SOP) that address the following issues:
    - Workers with diarrhea disease or symptoms of other infectious disease are prohibited from handling fresh produce.
    - Workers with open cuts or lesions are prohibited from handling fresh produce.
    - Actions for employee to take in the event of injury or illness.
    - A policy describing procedures for handling/disposition of produce or food contact surfaces that have come into contact with blood or other body fluids.
- A field sanitary facility program (i.e., an SOP) shall be implemented, and it should address the following issues: the number, condition, and placement of field sanitation units, the accessibility of the units to the work area, facility maintenance, facility supplies (i.e., 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.

- 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 for the facility to serve as a source of contamination.
- Establish the frequency of toilet and hand washing facility maintenance/sanitation.
- Establish equipment and supply storage and control procedures when not in use.
- Maintain documentation of maintenance and sanitation schedules and any remedial practices for a period of two years.

Minimize the harvest of lettuce/leafy greens that have visible signs of decay due to the possible increased risk of the presence of human pathogens associated with decay or damage.

10. ISSUE: EQUIPMENT FACILITATED CROSS CONTAMINATION

When farm equipment has had direct contact with raw untreated manure, untreated compost, waters of unknown quality, animals of significant risk, or other potential human pathogen reservoirs it may be a source of cross contamination. Such equipment should not be used in proximity to or in areas where it may contact edible portions of lettuce and or leafy greens.

10.1. 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.
- Use effective means of equipment cleaning and sanitation before subsequent equipment use in lettuce/leafy greens production, if it was previously used in a high-risk operation.
- Develop appropriate means of reducing and controlling the possible transfer of human pathogens to soil and water that may directly contact edible lettuce/leafy green tissues through use of equipment.
- Maintain appropriate records related to equipment cleaning and possible cross-contamination issues for a period of two years.

11. ISSUE: FLOODING

Flooding for purposes of this document 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 the edible portions of fresh produce in that field. Pooled water (e.g., rainfall) that is not reasonably likely to contain microorganisms of significant public health concern and is not

reasonably likely to cause adulteration of the edible portion of fresh produce should not be considered flooding.

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

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

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

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

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

- See Table 4 for numerical criteria for lettuce and leafy greens production fields that have possibly come into contact with flood waters. The "Technical Basis Document" (Appendix B) describes the process used to develop these metrics.
- FDA considers any crop that has come into contact with floodwater to be an "adulterated" commodity that cannot be sold for human consumption.
- To reduce the potential for cross contamination do not drive harvest equipment through flooded areas reasonably likely to contain microorganisms of public health significance (see previous section).

TABLE 4. FLOODING

When evidence of flooding in a production block occurs.

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

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

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

11.3. The Best Practices For Formerly Flooded Production Ground Are:

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

12. ISSUE: WATER USAGE TO PREVENT PRODUCT DEHYDRATION

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

12.1. The Best Practices Are:

- Due to the timing of application of water that directly contacts edible portions of lettuce/leafy greens, assure the water is of appropriate microbial quality (e.g., meets U.S. EPA microbial standards for drinking water).
- Test the water source periodically to demonstrate it is of appropriate microbial quality for its intended purpose (e.g., meets U.S. EPA or WHO microbial standards for drinking water) or assure that it has appropriate disinfection potential as described in Table1.
- Establish and implement cleaning and sanitation schedules for containers and equipment that will be used in hydration.
- Maintain logs documenting cleaning and sanitation, and retain these records for at least two years.
- Establish policies for the storage and control of water tanks and equipment used for hydration operations when not in use.

13. ISSUE: PRODUCTION LOCATIONS - CLIMATIC CONDITIONS AND ENVIRONMENT

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

13.1. The Best Practices Are:

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

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

Lettuce/leafy greens 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). Specific wildlife species that have been shown to pose the greatest risk are the focus of this section and are listed in Table 5. In addition, extensive development in certain farming communities has also created situations with urban encroachment and unintentional access by domestic animals and livestock which may also pose varying degrees of risk depending on the animal species. Finally, it is possible that some land uses may be of greater concern than others when located near production fields. Table 6 provides a list of these uses and recommended buffer distances.

14.1. The Best Practices Are:

- See Tables 5 and 6 and Decision Tree (Figure 5) for numerical criteria and guidance applicable to animal encroachment and adjacent land uses. The "Technical Basis Document" (Appendix B) describes the process used to develop these metrics.
- During the Environmental Assessments discussed in Section 2, the location of any adjacent land uses that may be of potential risk should be documented. In addition, as specified in Table 6, any deviations from the recommended buffer distances due to mitigation factors or increased risk should be documented and explained.
- Fencing, vegetation removal, and destruction of habitat may result in adverse impacts to the environment. Potential adverse impacts include loss of habitat to beneficial insects and pollinators; wildlife loss; increased discharges of sediment and other pollutants resulting from the loss of vegetative filtering; and increased air quality impacts if bare soil is exposed to wind. It is recommended that

producers 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.

- Monitor animal of significant risk encroachment immediately prior to planting and regularly during production periods.
- Evaluate and monitor animal of significant risk activity in and proximate to lettuce/leafy greens fields and production environments. Conduct periodic monitoring, pre-season, pre-harvest, and harvest assessments. If there are animals of significant risk present, make particular efforts to reduce their access to lettuce and leafy green produce.
- Evaluate the risk to subsequent crop production on production acreage that has experienced recent postharvest grazing with or by domesticated animals that used field culls as a source of animal feed.
- Locate production blocks to minimize potential access by animals of significant risk and maximize distances to possible sources of microbial contamination. For example, consider the proximity to water (i.e., riparian areas), animal of significant risk harborage, open range lands, non-contiguous blocks, urban centers, etc. Periodically monitor these factors and assess during preseason and preharvest assessments as outlined in Tables 5 and 6. If the food safety professional deems that there is the potential for microbial contamination from adjacent areas, a risk assessment shall be performed to determine the risk level as well as to evaluate potential mitigation strategies.
- DO NOT harvest areas of fields where unusually heavy activity by animals of significant risk occurs. If animal of significant risk intrusions are common on a particular production field, consider fencing, barriers, noisemakers, and other practices that may reduce intrusions.
- Train harvest employees to recognize and report evidence (e.g., feces) of animal of significant risk activity.
- Pooled water (e.g., a seasonal lake) from rainfall may attract animals of significant risk and should be considered as part of any land use evaluation.
- Consider controlling risks associated with encroachment by urban development. Risks may include, but are not limited to, domestic animal fecal contamination of production fields and harvest equipment and septic tank leaching.
- 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 requirements. In addition, growers may wish to consult with local NRCS to evaluate the food safety risks associated with wildlife, livestock, domestic animals and other adjacent land uses and to develop and document risk mitigation strategies for discrete production blocks.

TABLE 5. ANIMAL OF SIGNIFICANT RISK ACTIVITY IN FIELD (WILD OR DOMESTIC)

When evidence of animal of significant risk intrusion in a production block occurs.

Issue	Metric	Remedial Actions
Evidence of Intrusion	Frequency • There shall be a periodic monitoring plan in place for production fields. • There shall be Pre Season, Pre Harvest, and Harvest Assessments Variables • Physical observation of animals in the field • Downed fences • Animal tracks in production block • Animal feces or urine in production block • Eaten plants in production block Animals of Significant Risk • Deer • Wild Pigs • Cattle • Goats and Sheep	• If there is evidence of intrusion by animals of significant risk, the production block must undergo a detailed food safety assessment by appropriately trained food safety personnel (see Glossary) prior to harvest, as defined in the text of this document. • In developing remedial and corrective actions, consider consulting 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 crop. • Equipment used to destroy crop must be cleaned and sanitized upon exiting the field. • Investigate potential causes for intrusion by animals of significant risk and assess the extent of intrusion and impact on crop food risk. • 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 intrusion by animals of significant risk and corrective actions shall be documented and available for verification for a period of two years.
Allowable Harvest Distance from Evidence of Intrusion	**Please see Figure 5. Decision Tree for Conducting Pre-Harvest and Harvest Assessments.** *Monitoring* Evaluate and monitor animal of significant risk activity in and proximate to lettuce/leafy greens 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 one week prior to harvest. **Fecal Material** • Do not harvest any produce that has come into direct contact with fecal material. • If evidence of fecal material is found, conduct a food safety assessment using qualified personnel. Do not harvest any crop found within a minimum 5 foot radius buffer distance from the spot of the contamination unless remedial action can be found that	

Issue	Metric	Remedial Actions
	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 of significant risk intrusion is found in a production field, conduct a food safety assessment to determine whether the areas of intrusion can be adequately controlled (e.g., solitary deer track with no evidence of feeding), or whether a three foot buffer radius non-harvest area should be applied (e.g., wide areas of wild pig rooting and tracks). *Harvest Assessment* If evidence of animal of significant risk intrusion into the production block is not discovered until harvest operations: • Stop harvest operations. • Initiate an intensified block assessment for evidence of further contamination and take appropriate actions per the aforementioned actions. • If evidence of intrusion is discovered during production block harvest operations and the harvest rig has been potentially contaminated by contaminated product or feces, clean and sanitize the equipment before resuming harvest operations. • Require all employees to wash and sanitize their hands/gloves before resuming harvest operations. • If contamination is discovered in harvest containers such as bins/totes, discard the product, and clean and sanitize the container before reuse.	
Verification	• Archive documentation for a period of two years following the intrusion event. Documentation may include photographs, sketched maps, or other means of delineating affected portions of production fields.	
Rationale	• The basis of these metrics is qualitative assessment of the relative risk from a variety of intrusions. Some animal feces and some signs of intrusion (feces vs. tracks) are considered to be of more concern 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.	

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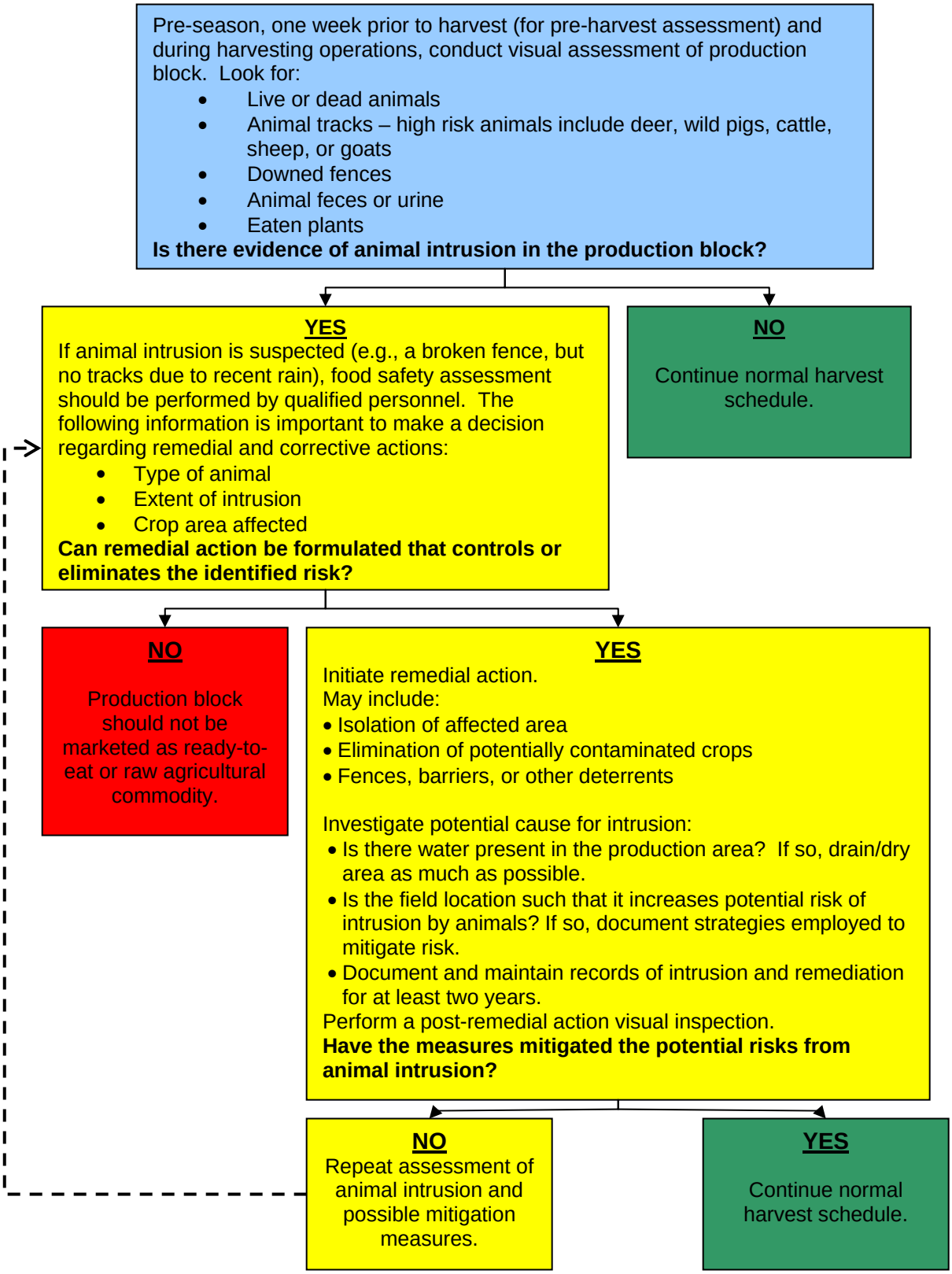
Land Use/Water Source	Metric (This distance may be either increased or decreased depending on risk and mitigation factors.)	Considerations for Risk Analysis*		
		Risk/Mitigation Factors	Increase Distance	Decrease Distance
Composting Operations (manure or animal products)	Due to the lack of science at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

Land Use/Water Source	Metric (This distance may be either increased or decreased depending on risk and mitigation factors.)	Considerations for Risk Analysis*		
		Risk/Mitigation Factors	Increase Distance	Decrease Distance
Grazing Lands/Domestic Animals (includes homes with hobby farms, and non commercial livestock)	30 ft from the edge of crop.	Fencing and other physical barriers such as berms, diversion ditches and vegetated strips can be employed to prevent intrusion of domestic animals, control runoff, etc.		√
		Topography: Uphill from crop	√	
		Topography: Downhill from crop		√
		Opportunity for water run off through or from grazing lands	√	
		Opportunity for soil leaching	√	
Homes or other building with a septic leach field.	30 ft from the edge of crop to the leach field.	Active leach field: < 10 yrs old		√
		Active leach field: > 25 yrs old	√	
		Inactive leach field		√
		Topography: Uphill from crop	√	
		Topography: Downhill from crop		√
		Physical barriers		√
Well Head Distance from Untreated Manure	200 ft separation of untreated manure from wells, although less distance may be sufficient.	Topography: Uphill from manure		√
		Topography: Downhill from manure	√	
		Opportunity for water 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 may be either increased or decreased depending on risk and mitigation factors.)	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.			

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

Figure 5. Decision Tree for Conducting Pre-harvest and Harvest Assessment of Animal Activity in Field (Wild or Domestic)



15. DETAILED BACKGROUND GUIDANCE INFORMATION

15.1. Required Reference Documents

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

15.2. References

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