PROPOSED AMENDMENTS
TO
Section 1: Production and Harvesting Unit Operations
of
COMMODITY SPECIFIC FOOD SAFETY GUIDELINES FOR THE
LETTUCE AND LEAFY GREENS SUPPLY CHAIN,
1ST EDITION, APRIL 25, 2006

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 guidelines, which were considered voluntary, was published by the industry in April 2006 as the "Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain, 1st Edition" ("Guidelines").

In response to continued concerns regarding the microbial safety of fresh produce, that document is being revised to identify and delineate further the best practices currently contemplated as well as those considered the industry standard. A key focus of this revision is to identify, where possible and practical, metrics and measures that can 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 conditions/risks. A three-tier approach was used to identify new 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 parameter of interest.
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. The development of specific metrics and practices in other sections of the "Guidelines" is ongoing.

In addition to this document, several supplemental documents are in development 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 basis for the changes made in this "best practices" document, a Sanitary Survey document that describes the processes for assessing the integrity and remediation of water systems, and a "self-audit" form for use in preproduction and preharvest assessments. All of these items will be included 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) nor should it be construed to apply to other commodities. Examples of "lettuce/leafy greens" include, but are not limited to, 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 raw agricultural commodities and fresh-cut/value added products are highly perishable and it is (strongly) recommended that they be distributed, stored and displayed under refrigeration to maintain product quality.

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 amendments 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.

It is suggested that all companies involved in the lettuce/leafy greens farm to table supply chain implement the recommendations contained within these amendments as a baseline set of best practices 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. Western Growers and all other contributors and reviewers to these amendments 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.

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.

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

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 (Solomon *et al.* 2003). Irrigation methods may have varying potential to introduce human pathogens or promote human pathogen growth on lettuce and leafy greens.

THE BEST PRACTICES ARE:

- To the greatest degree practicable, use irrigation water and water in harvest operations that is of appropriate microbial quality for its intended use; see Tables 1 and 2 for specific numerical criteria. Decision trees (Figures 1, 2, 3, 4, and 5) provide guidance on the water quality evaluation process. The "Technical Basis Document" (Appendix 1) describes the process used to develop these metrics.
- Perform a sanitary survey prior to use of water in agricultural operations and during the investigation of any exceedences of action levels as outlined in Table 1 and Decision trees (Figures 1, 2, 3, 4 and 5). The sanitary survey is described in Appendix 2.
- 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.
- 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.
- Use procedures for storing irrigation pipes and drip tape that reduce potential pest infestations. Develop procedures to provide for safe use of irrigation pipes and drip tape if a pest infestation does occur.

TABLE 1. WATER SOURCES

Source	Metric	Remedial Actions/Rationale

Municipal Water Source	Must meet the standards for *E. coli* set forth in U.S. EPA National Drinking Water Regulations (or similar national levels in other countries).
	
	Target Organism:
	• Generic *E. coli*
	
	Action Level 1:
	• Non Detect; <2MPN/100ml (average n≥5 samples)
	Action Level 2:
	• 2 – 576 MPN/100ml (average n≥5 samples)
	Action Level 3:
	• >576 MPN/100ml (average n≥5 samples)
	
	Recommended Test Methods:
	• 15 tube MPN
	• Other U.S. EPA, FDA, or AOAC-accredited methods may be used as appropriate.
	
	Testing Frequency:
	Annual Testing or Annual Certificate of Analysis from supplier. Testing of distribution system prior to production and monthly.
		• In general, if water from a municipal water source does not meet the *E. coli* standards set forth in U.S. EPA National Drinking Water Regulations, it should not be used for any purpose that requires water of drinking water quality. Exceeding these levels triggers additional testing actions that are outlined in Figure 1: Decision Tree for Municipal Water Sources.
		  • Action Level 1: No further action.
		  • Action Level 2: Implement additional testing and Sanitary Survey.
		  • Action Level 3: Stop using water immediately; implement additional testing and Sanitary Survey.
		• The initial five samples shall be taken before production begins with at least 24 hours between each sample. Samples should be taken in the distribution system as far from the source (and close to the point-of-use) as practicable. The timing of sampling shall be long enough before planting so that results are obtained prior to planting begins.
		
		• All test results and corrective actions shall be documented and available for verification for a period of two years.
		
		• Rationale: The requirements for this water source are based on regulations promulgated by the U.S. EPA for drinking water.

Source	Metric	Remedial Actions/Rationale
Well Head	**Target Organism:** • Generic *E. coli* **Action Level 1:** • Non Detect; <2MPN/100ml (average n≥5 samples) **Action Level 2:** • 2 – 576 MPN/100ml (average n≥5 samples) **Action Level 3:** • >576 MPN/100ml (average n≥5 samples) **Recommended Test Methods:** • 15 tube MPN • Other U.S. EPA, FDA, or AOAC-accredited methods may be used as appropriate. **Testing Frequency:** Before production beings and monthly. Testing is not required during non-production periods.	• In general, if a well tests positive for the presence of generic *E. coli*, additional testing actions should be initiated as specified in Figure 2: Decision Tree for Wells. If greater than 576 MPN generic *E. coli* is detected, then the water should not be used for any purpose until remedial actions have been completed and levels are lower than 576 MPN. • Action Level 1: No further action. • Action Level 2: Implement additional testing and Sanitary Survey. • Action Level 3: Stop using water immediately; implement additional testing and Sanitary Survey. • The initial five samples shall be taken before production begins with at least 24 hours between each sample. Samples should be taken in the distribution system as far from the source (and close to the point-of-use) as practicable. The timing of sampling shall be long enough before planting so that results are obtained prior to planting begins. • All test results and corrective actions shall be documented and available for verification for a period of two years. • Rationale: The requirements for this water source are based on the knowledge that wells typically do not contain any detectable levels of *E. coli*; thus, any detection is a sign that the well may be contaminated and should be evaluated. *E. coli* is currently considered the most appropriate indicator organism by U.S. EPA and other scientists.

Well Reservoir	**Target Organism:** • Generic *E. coli* **Action Level 1:** • <126 MPN/100ml (average n≥5 samples) **Action Level 2:** • 126 – 576 MPN/100ml (average n≥5 samples) **Action Level 3:** • >576 MPN/100ml (average n≥5 samples) **Recommend Test Methods:** • 15 tube MPN • Other U.S. EPA, FDA, or AOAC-accredited methods may be used as appropriate. **Testing Frequency:** Before production begins and monthly. Testing is not required during non-production periods.	• In general, if a well reservoir tests positive for greater than 126 MPN of generic *E. coli*, additional testing actions should be initiated as specified in Figure 3: Decision Tree for Well Reservoir Sources. If greater than 576 MPN generic *E. coli* is detected, then the water should not be used for any purpose until remedial actions have been completed and levels are lower than 576 MPN. • Action Level 1: No further action. • Action Level 2: Implement additional testing and Sanitary Survey. • Action Level 3: Stop using water immediately; implement additional testing and Sanitary Survey. • The initial five samples shall be taken before production begins with at least 24 hours between each sample. Samples should be taken in the distribution system as far from the source (and close to the point-of-use) as practicable. The timing of sampling shall be long enough before planting so that results are obtained prior to planting begins. • All test results and corrective actions shall be documented and available for verification from the grower who is the responsible party for a period of two years. • Rationale: The requirements for this water source are based on several sources including scientific information (Suslow, 2005) and current Arizona irrigation water standards (Ariz. Admin. Code R18-11-109). *E. coli* is currently considered the most appropriate indicator organism by U.S. EPA and other scientists.
Surface Water/Canal	**Target Organism:** • Generic *E. coli* **Action Level 1:** • <126 MPN/100ml (average n≥5 samples) **Action Level 2:** • 126 – 576 MPN/100ml (average n≥5 samples) **Action Level 3:** • >576 MPN/100ml (average n≥5 samples) **Recommended Test Methods:** • 15 tube MPN • Other U.S. EPA, FDA, or AOAC-accredited methods may be used as appropriate.	• In general, if a surface water source tests positive for greater than 126 MPN of generic *E. coli,* additional testing actions should be initiated as specified in Figure 4: Decision Tree for Surface Water Sources. If greater than 576 MPN generic *E. coli* is detected, then the water should not be used for any purpose until remedial actions have been completed and levels are lower than 576 MPN. • Action Level 1: No further action. • Action Level 2: Implement additional testing and Sanitary Survey. • Action Level 3: Stop using water immediately; implement additional testing and Sanitary Survey. • The initial five samples shall be taken before production begins with at least 24 hours between each sample. Samples should be taken in the distribution system as far from the source (and close to the point-of-use) as practicable. The timing of sampling shall be long enough before planting so that results are obtained prior to planting begins. • All test results and corrective actions shall be documented and available for verification for a period of two years.

	Testing Frequency: Before production begins and monthly. Testing is not required during non-production periods.	• Rationale: The requirements for this water source are based on the several sources including scientific information (Suslow, 2005) and current Arizona irrigation water standards (Ariz. Admin. Code R18-11-109). *E. coli* is currently considered the most appropriate indicator organism by U.S. EPA and other scientists.
Reclaimed Water For Irrigation on Edible Crops* *Growers should check for state-specific regulations regarding the use of reclaimed water prior to using it for agricultural purposes.	Reclaimed Water means wastewater that is oxidized, coagulated, filtered, and disinfected adequately. **Target Organism:** • Generic *E. coli* **Action Level 1:** • Generic *E. coli*: Non Detect <2MPN/100ml **Action Level 2:** • Generic *E. coli*: 2 – 576 MPN/100ml **Action Level 3:** • Generic *E. coli*: >576 MPN/100ml **Recommended Test Methods:** • Generic *E coli:* 15 tube MPN • Other U.S. EPA, FDA, or AOAC-accredited methods may be used as appropriate. **Testing Frequency:** Before production begins and monthly and appropriate Certificates of Analysis for the same time periods.	• For reclaimed water use, it must be demonstrated that at some point in the reclaiming process, state-specific levels of generic *E. coli* have been obtained. Once this has been adequately demonstrated (generally via a COA from the supplier), the "source" testing criteria most applicable to its method of delivery to the grower shall be used. For instance, if the reclaimed water is transported via open canal to the grower, then the "Surface Water" testing and metric table and decision tree shall be used to test and conduct remedial actions. If it is transported via closed pipe, then the "Municipal Water Supply" metric table and decision tree shall be used to conduct testing and remedial actions. • All test results and corrective actions shall be documented and available for verification from the grower who is the responsible party for a period of two years. • Rationale: The requirements for this water source are based on U.S. EPA requirements for reclaimed water.
Tail Water	Shall meet microbial quality standards as specified for surface water or well reservoir water if used for any purpose that might contact produce.	• Corrective actions are identical to those outlined for surface or well reservoir water. • Rationale: This requirement is based on the specific use for tail water, which was determined to be the most appropriate basis.

TABLE 2. WATER USE

Use	Metric	Remedial Actions/Rationale
Irrigation Water	Water used for this application must be tested in accordance with the microbial action levels outlined for various water sources. (See Table 1.) These source waters can be used for any type of irrigation (e.g., overhead sprinkler, furrow, drip).	• Water from a source that does not meet the acceptable source criteria above shall not be used except as specified in the accompanying decision trees. • Find a water source that meets the acceptable source criteria outlined above. • Take remedial action(s) to bring the water source into compliance with acceptable microbial criteria for that water source type as outlined above. • All test results and corrective actions shall be documented and available for verification from the grower who is the responsible party for a period of two years.
PreHarvest Foliar Applications (*e.g.* pesticides, fungicides, etc.)	Water used for this application must be tested in accordance with the microbial action levels outlined for various water sources. (See Table 1. Water Sources)	
Postharvest Water Used for Direct Product Contact or Food Contact Surfaces (*e.g.* Re-hydration, Core In Field, harvest equipment cleaning)	Water used for this application, must meet microbial standards set forth in U.S. EPA National Drinking Water Regulations. (See Table 1. Water Sources)	

Use	Metric	Remedial Actions/Rationale
Postharvest Re-circulated Water Used for Direct Product Contact (*e.g.* hydro-vac cooler water, hydro coolers, etc)	**Criteria:** • Source Water Criteria Source water used for this application, must meet microbial standards set forth in U.S. EPA National Drinking Water Regulations. (See Table 1. Municipal Water Source Criteria) • Re-circulated Water Criteria Re-circulated water used for this application must be routinely monitored to assure that sufficient water disinfectant is present to prevent cross contamination. **Target Variable:** • Approved water disinfectant (e.g. chlorine) **Acceptance Criteria:** • 1 -4 ppm free chlorine @ pH 6.5 - 7.5 OR an ORP of ≥ 650 mV. • Other approved disinfectants may be utilized applied according to label and documented **Test:** • Chemical reaction based colorimetric test. • Ion specific probe. • ORP **Testing Frequency:** • Continuous monitoring OR • Routine hourly monitoring	• Water from a source that does not meet the acceptable source criteria above shall not be used in a manner that may contaminate food crops. • Find a water source that meets the acceptable source criteria outlined above. • Take remedial action(s) to bring the water source into compliance with acceptable microbial criteria for that water source type as outlined above. • All test results and corrective actions shall be documented and available for verification from the grower who is the responsible party for a period of two years.

Dust Abatement Water	**Criteria:** Water used for this application, must meet the aforementioned microbial acceptance criteria outlined for various water sources. (See Table 1. Water Sources)	

Figure 1. Decision Tree for Municipal Water Sources

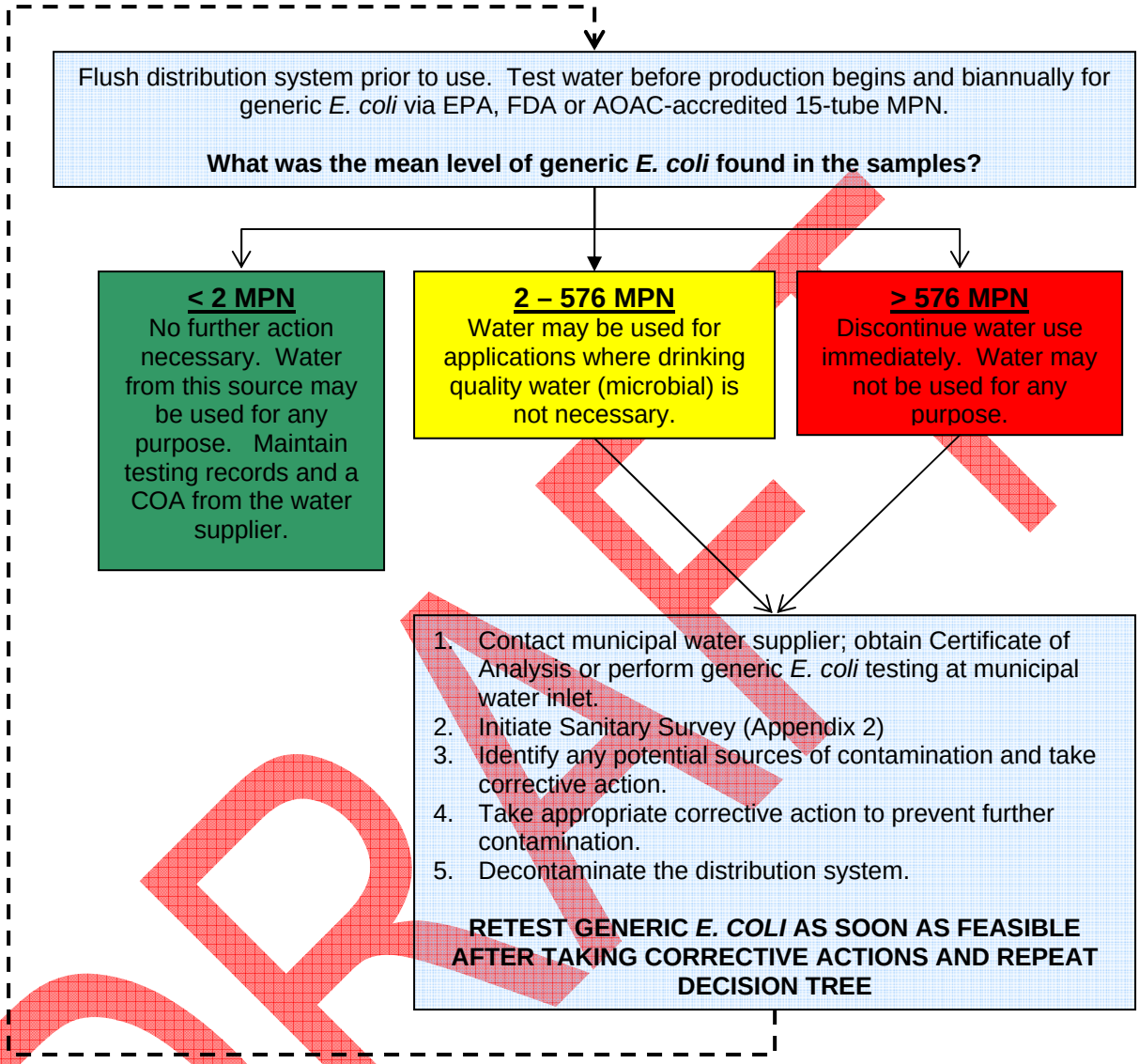


Figure 2. Decision Tree for Wells

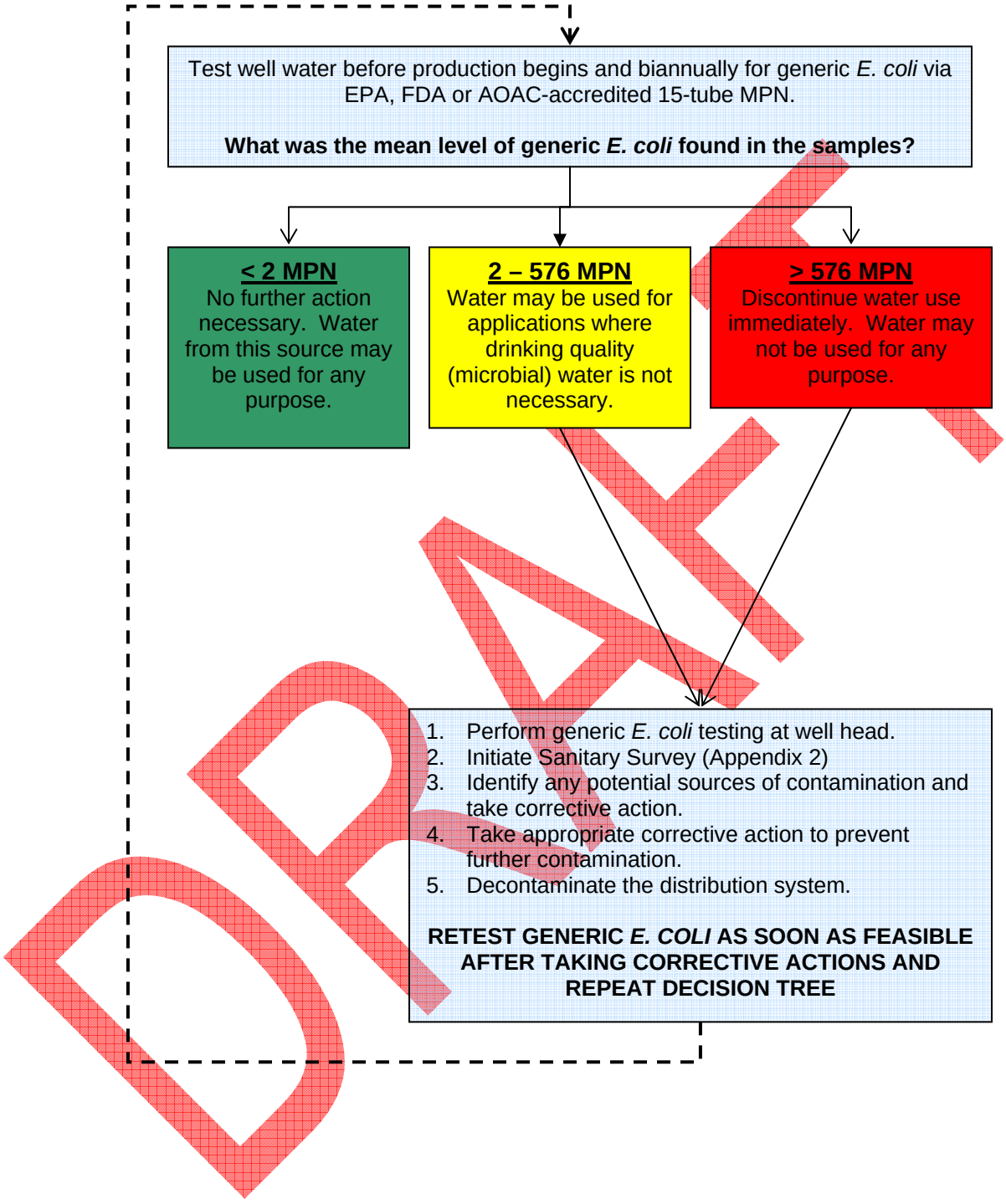


Figure 3. Decision Tree for Well Reservoirs

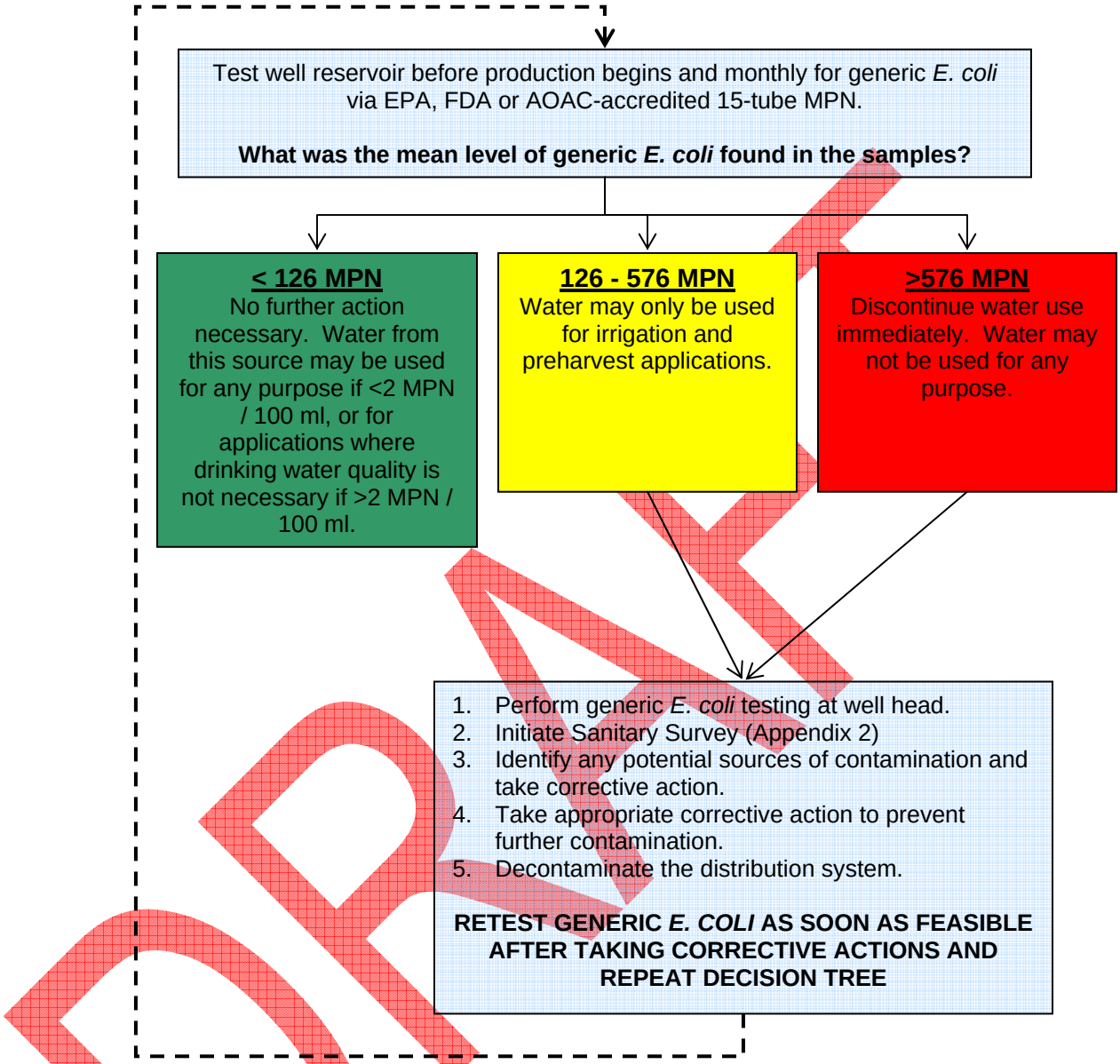


Figure 4. Decision Tree for Surface Water Sources

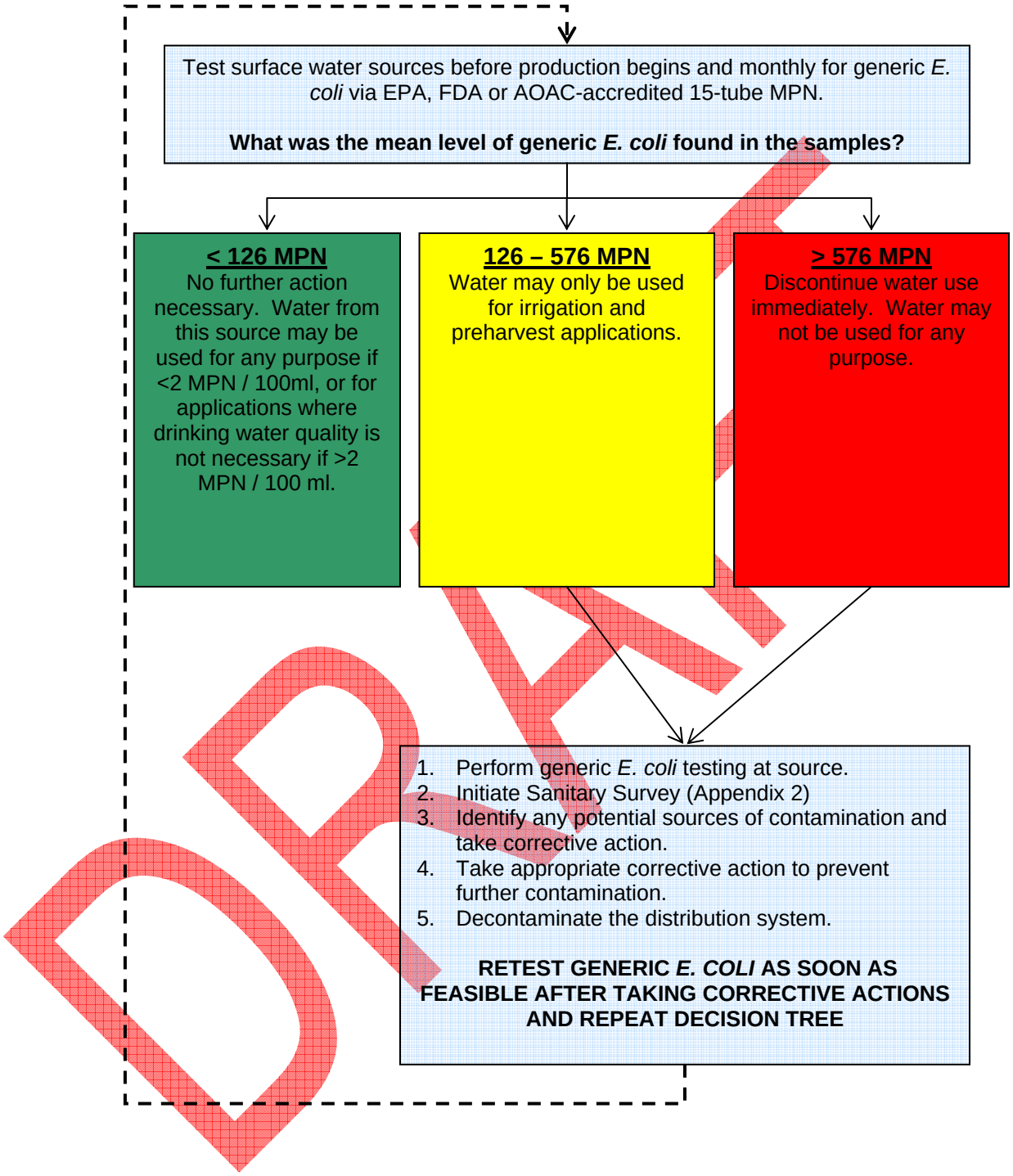
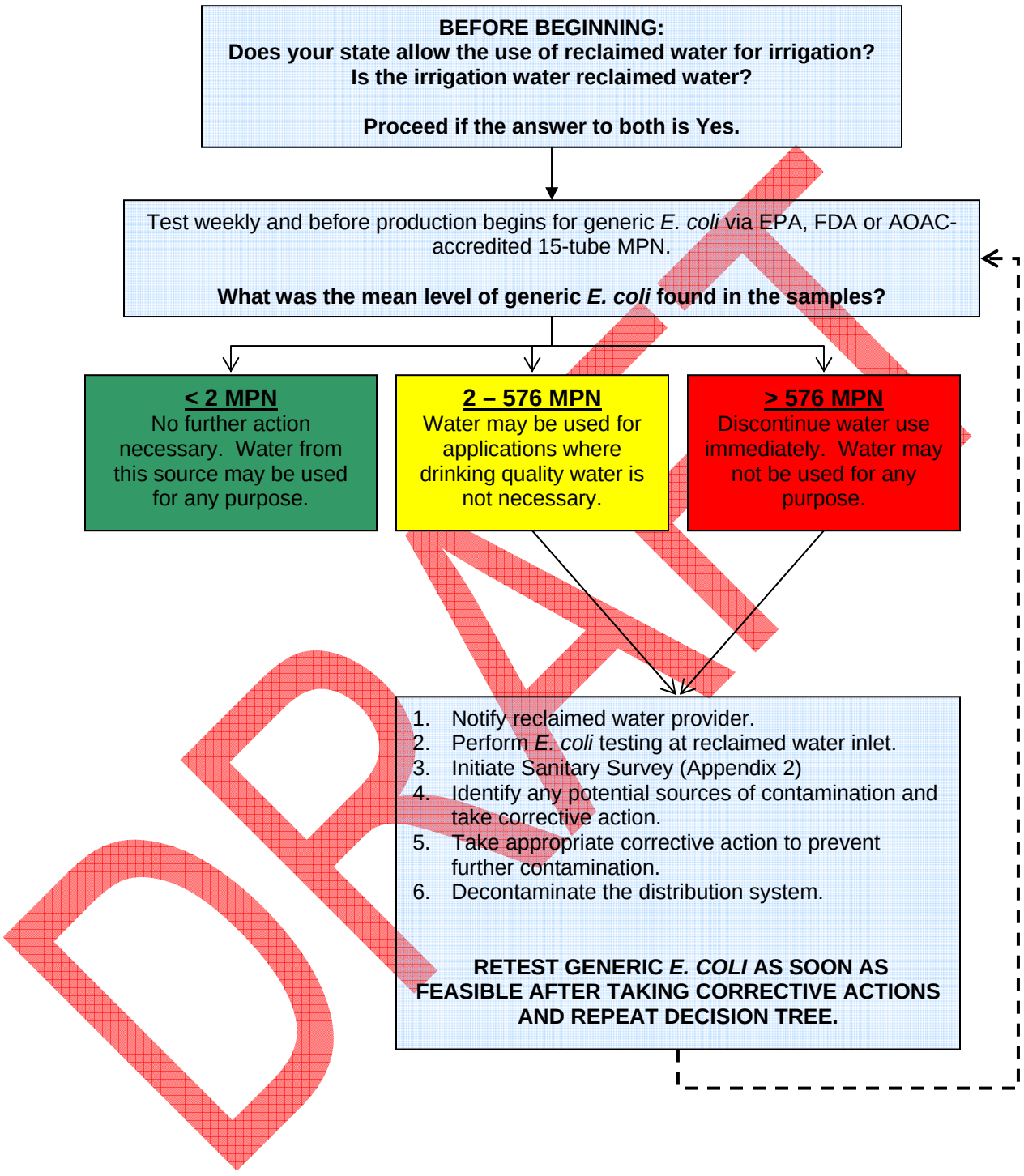


Figure 5. Decision Tree for Reclaimed Water



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 untreated agricultural soils is currently unknown and under extensive investigation (Jiang *et al.* 2003a;2003b; 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 2001).

THE BEST PRACTICES ARE:

- Do not use raw animal manure with any lettuce/leafy greens crop.
- See Table 3 and Decision Trees (Figures 6 and 7) for numerical criteria and guidance for compost and soil amendments used in lettuce and leafy greens production fields. The "Technical Basis Document" (Appendix 1) describes the process used to develop these metrics.
- Perform microbiological testing as close to application time as practicable.
- Do not use biosolids for lettuce or leafy green produce.
- Retain documentation of all test results and/or Certificates of Analysis available for inspection for a period of at least 2 years.
- Implement management plans (e.g., timing of applications, storage location, source and quality, transport, etc.) that assure use of soil amendments does not pose a significant human pathogens hazard.
- 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.
- 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.
- Reduce human pathogen contamination of soil which may in turn contaminate water and/or edible portions of lettuce and leafy greens (e.g., solarization, fumigation, etc.).

TABLE 3. 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 animal manure to fields which will be used for edible crop production. If these materials have been applied to a field, wait one year prior to producing leafy greens.
Composted Soil Amendments *Composted soil amendments should not be applied after emergence of plants.	**Please see Figure 6: 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 3-6 weeks 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 3-6 weeks before application to fields. • Aerated static pile composting: • Active compost must be covered with 6 to 12 inches of insulating materials and maintain a minimum of 131°F for 3 days, with a curing/aging period of 3-6 weeks before application to fields. **Target Organisms:** • Fecal coliforms • *Salmonella spp.* • *E. coli* O157:H7 **Acceptance Criteria:** • Fecal coliforms <1000 MPN/gram • *Salmonella spp.*: Negative <3/ 4 grams • *E. coli* O157:H7: Negative <1/ 4 grams **Recommended Test Methods:** • Fecal coliforms: 9 tube MPN • *Salmonella spp:* U.S. EPA Method 1682 • *E. coli* O157:H7: BAM Chapter 4

Amendment	Metric/Rationale
	• Other U.S. EPA, FDA, or AOAC-accredited methods may be used as appropriate. **Sampling Plan:** • 12 point sampling plan composite sample • Sample may be taken by the supplier if trained by the testing laboratory • Laboratory must be certified/accredited **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 who is 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 (Title 14 CCR, Chapter 3.1, Article 5), with the addition of testing for *E. coli* 0157:H7 as microbe of particular concern. A 45-day (as opposed to 120-day) application interval was deemed appropriate due to the three hurdle metric design. Raw manure must be composted with an approved process and pass testing requirements before an application interval is observed. Because the 120-day period is specific to raw (uncomposted) manure, it was judged that the application interval could be shortened safely.
Physically Heat Treated Animal Manure Containing Soil Amendments	**Please see Figure 7: Decision Tree for Use of Physically Heat Treated Soil Amendments.** **Physical Heat Process Validation** • The physical heat treatment processes applied to the animal manure containing soil amendment shall be validated by a process authority to assure that bacteria is reduced to acceptable levels .

Amendment	Metric/Rationale
	Target Organism: • Fecal coliforms • *Salmonella spp.* • *E. coli* O157:H7 **Acceptance Criteria:** • Fecal coliforms <10 MPN/gram • *Salmonella*: Negative <3/ 4 grams • *E. coli* O157:H7: Negative <1/ 4 grams **Recommended Test Methods:** • Fecal coliforms: 9 tube MPN • *Salmonella spp.:* BAM Chapter 5 • *E. coli* O157:H7: BAM Chapter 4 • Other U.S. EPA, FDA, or AOAC-accredited methods may be used as appropriate. **Sampling Plan:** • 12 point sampling plan composite sample • 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 "pasteurize" the animal manure containing soil amendment is validated and meets the microbial acceptance criteria outlined below, no time interval is needed between application and harvest. • If the physical heat treatment process used to "pasteurize" the animal manure containing soil amendment is not validated but will likely significantly reduce microbial populations of human pathogens (minimum temperature: 300^{o}F (150 ^{o}C) for 60 minutes resulting in a moisture content <30% dry weight) and meets that microbial acceptance criteria outlined above, a 45 day interval between application and harvest is required.

Amendment	Metric/Rationale
	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 also be validated 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 (Title 14 CCR, Chapter 3.1, Article 5), with the addition of testing for *E. coli* 0157: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. A 45-day (as opposed to 120-day) application interval was deemed appropriate due to the three hurdle metric design. Raw manure must be composted with an approved process and pass testing requirements before an application interval is observed. Because the 120-day period is specific to raw (uncomposted) manure, it was judged that the application interval could be shortened safely.
Soil Amendments Not Containing Animal Manure	• Any organic (i.e. chemically organic) soil amendment that DOES NOT contain animal manure must have a certificate that it is manure-free. • The certificate must be available for verification before harvest begins. • 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.

Figure 6. Decision Tree for Composted Soil Amendments (SA)

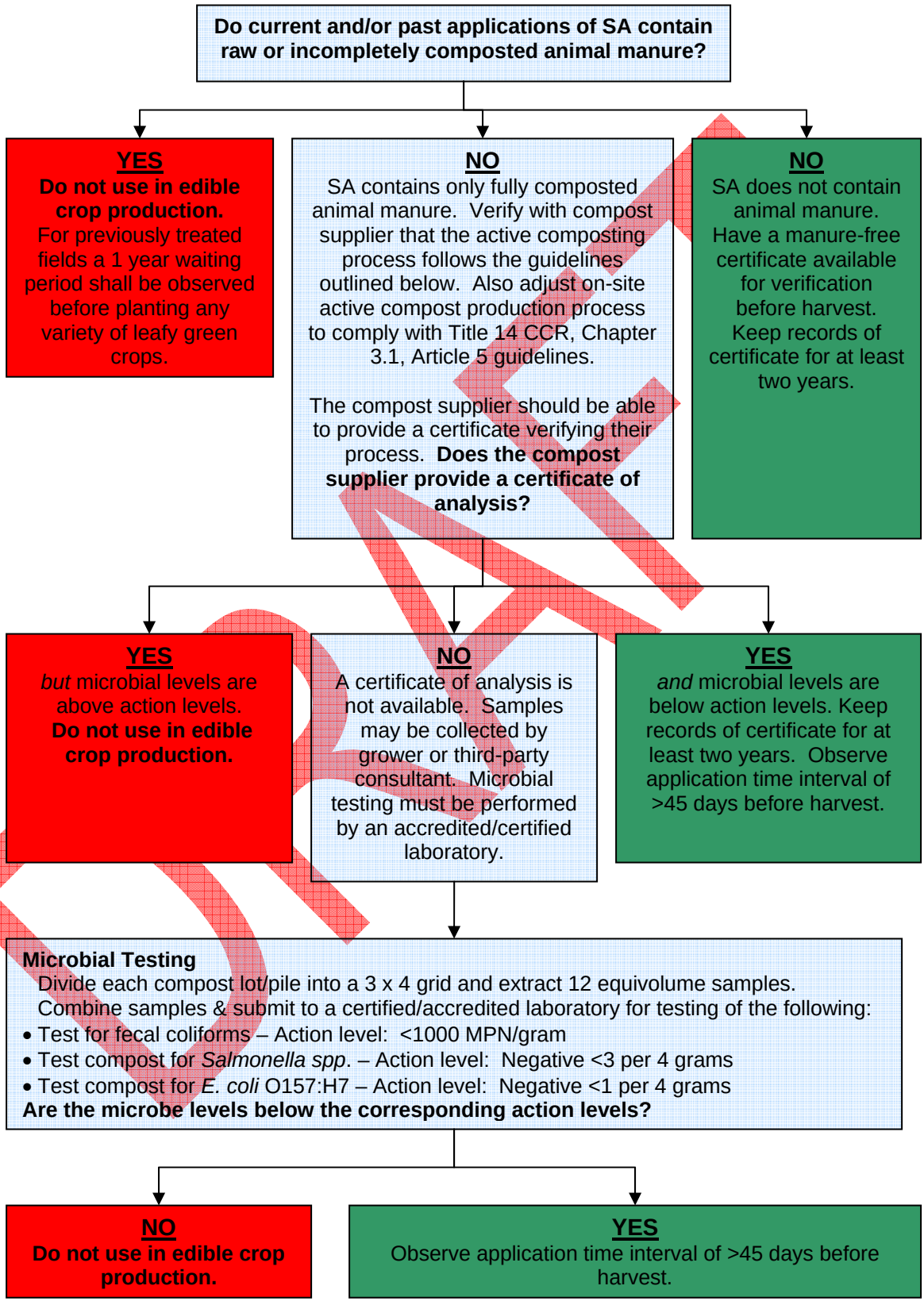
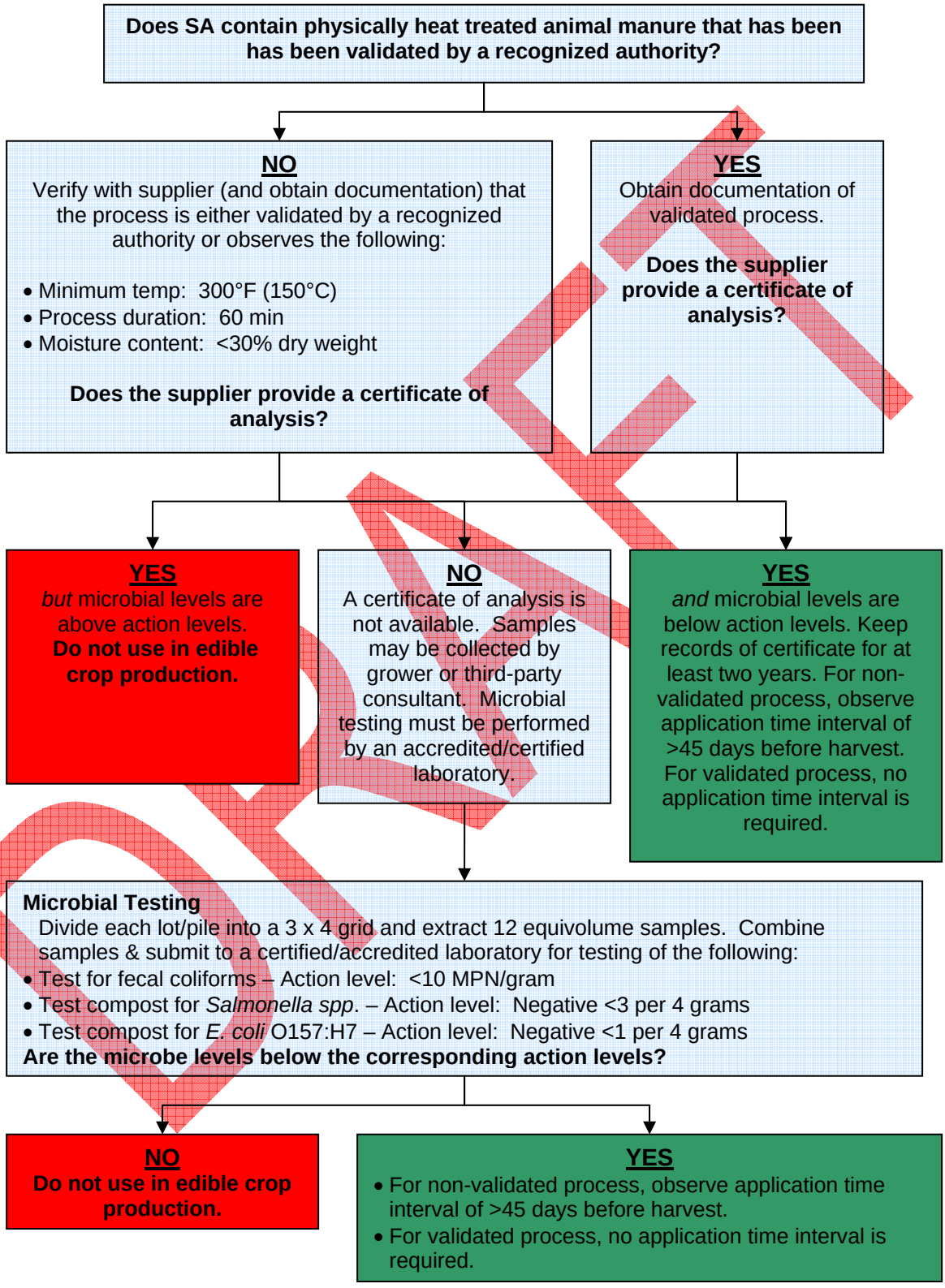


Figure 7. Decision Tree for Physically Heat Treated Animal Manure Containing Soil Amendments (SA)



ISSUE: *Nonsynthetic Crop Treatments*

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

THE BEST PRACTICES ARE:

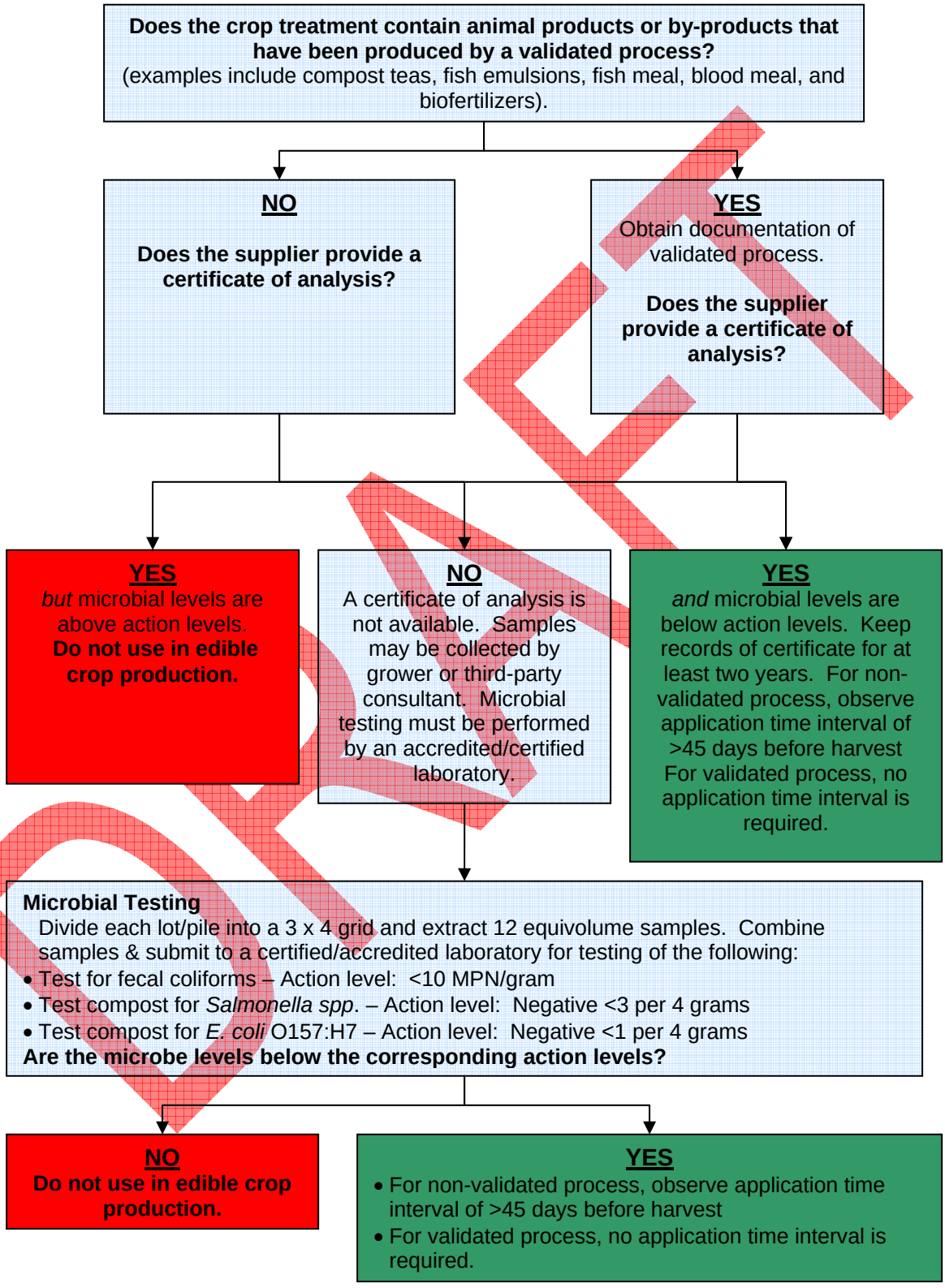
- See Table 4 and Decision Tree (Figure 8) for numerical criteria and guidance for nonsynthetic crop treatments used in lettuce and leafy greens production fields. The "Technical Basis Document" (Appendix 1) describes the process used to develop these metrics.
- Do not use crop treatments that contain raw manure for lettuce or leafy green produce.
- Retain documentation of all test results available for inspection for a period of at least 2 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 potential human pathogens 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.

TABLE 4. 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.	**Please see Figure 8: 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 by a recognized process authority. **Target Organism:** • Fecal coliforms • *Salmonella spp.* • *E. coli* O157:H7 **Acceptance Criteria:** • Fecal coliforms <10 MPN/gram • *Salmonella*: Negative <3/ 4 grams • *E. coli* O157:H7: Negative <1/ 4 grams **Recommended Test Methods:** • Fecal coliforms: 9 tube MPN • *Salmonella spp.:* BAM Chapter 5 • *E. coli* O157:H7: BAM Chapter 4 • Other U.S. EPA, FDA, or AOAC-accredited methods may be used as appropriate. **Sampling Plan:** • 12 point sampling plan composite sample • 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, 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 below, no

Treatment	Metric/Rationale
	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 for verification from the grower who is 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 (Title 14 CCR, Chapter 3.1, Article 5), with the addition of testing for *E. coli* 0157:H7 as the microbe of particular concern. A 45-day (as opposed to 120-day) application interval was deemed appropriate due to the three hurdle metric design. Raw manure must be composted with an approved process and pass testing requirements before an application interval is observed. Because the 120-day period is specific to raw (uncomposted) manure, it was judged that the application interval could be shortened safely.

Figure 8. Decision Tree for Nonsynthetic Crop Treatments



ISSUE: *Machine Harvest*
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.

THE BEST PRACTICES ARE:

- Establish appropriate measures that reduce and control the potential introduction of human pathogens at the cut surface during and after mechanical harvest operations.
- 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.

ISSUE: *Hand Harvest* - 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 and Frank 2001).

THE BEST PRACTICES ARE:

- Evaluate appropriate measures that reduce and control the potential introduction of human pathogens through soil contact at the cut surface after harvest (e.g.

frequency of knife sanitation, no placement of cut surfaces of harvested product on the soil, container sanitation, single use container lining, etc.).

- Avoid stacking soiled bins on top of each other.

ISSUE: *Hand Harvest* - Transfer of Human Pathogens by Field 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.

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 programs that can be used to verify employee compliance with company food safety policy.
- Prohibit eating, drinking or smoking in close proximity to unharvested product to reduce potential for product contamination.
- Optimize the location and sanitary design of field latrines and hand wash facilities to facilitate the control and reduction of human pathogens from employee hands. Evaluate the location of field sanitation and 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 facility maintenance/sanitation.
- Establish equipment storage and control procedures when not in use.
- Establish policies and sanitary design options that facilitate frequent and thorough cleaning and sanitizing of food contact surfaces (e.g., policies that prohibit employees from taking tools such as knives from the work area and require the use of knife scabbards that can be easily cleaned and sanitized).
- Do not harvest 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. Either remove the decayed portions or do not use at all.

ISSUE: *Equipment Facilitated Cross Contamination*
Farm equipment that has direct contact with soil, soil amendments, or water that is likely to contain microorganisms of significant concern to public health may spread microbial contamination to other production lands or water sources. Of particular attention is equipment that may come into contact with raw untreated manure, untreated compost, waters of unknown quality, wildlife or domestic animals, and other potential human pathogen reservoirs. Higher risk activity may entail the use of this equipment in proximity to or in areas where it may contact edible portions of lettuce and or leafy greens.

THE BEST PRACTICES ARE:

- Identify any field operations that may pose a risk for cross-contamination.
- Segregate equipment used in high-risk operations.
- 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.

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 5.

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

- See Table 5 for numerical criteria for lettuce and leafy greens production fields that have possibly come into contact with flood waters. The "Technical Basis Document" (Appendix 1) 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.

TABLE 5. FLOODING

When evidence of flooding in a production block occurs.

Practice	Metric/Rationale
Flooding Defined	The flowing or overflowing of a field with water outside a 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 high water mark of flooding. • Required buffer distance may be greater than 30 ft based on risk analysis. • In developing remedial and corrective actions, consult with food safety experts as appropriate.
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 a Flooding Event	• 60 days. • 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* (U.S. 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.

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. Appropriately document the flooded area and corrective measures taken to prevent cross contamination. Destroy produce within the 30 foot buffer zone prior to harvesting any remaining produce in the field.

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.
- If flooding has occurred in the past on the property, soil clearance testing may be conducted prior to planting leafy greens. A clearance period of 60 days or greater and active tillage of the soil provide additional confidence that pathogenic organisms are not present. 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.
- 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.
- 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 all raw agricultural commodities grown within the formerly flooded production area are free of the presence of human pathogens.

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

THE BEST PRACTICES ARE:

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

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

THE BEST PRACTICES ARE:

- 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, 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.
- When soil has accumulated on plants, remove soil during the harvest or further processing.

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. Many wildlife species (deer, pigs, birds, insects, amphibians and snakes) are known to be potential carriers of human pathogens (Fenlon

1985). Extensive development in certain farming communities has also created situations with urban encroachment and unintentional access by domestic animals.

THE BEST PRACTICES ARE:

- See Tables 6 and 7 and Decision Tree (Figure 9) for numerical criteria and guidance applicable to animal encroachment. The "Technical Basis Document" (Appendix 1) describes the process used to develop these metrics.
- 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. 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.
- Monitor animal encroachment immediately prior to and during production periods.
- Evaluate and monitor domestic animal and wildlife activity in and proximate to lettuce/leafy greens fields and production environments. Conduct periodic monitoring, pre-plant, pre-harvest, and harvest assessments. Because cattle, deer, feral pig, and geese are of particular concern related to microbial contamination, make particular efforts to reduce their access to lettuce and leafy green produce. Other animals are likely to pose a lower risk of contamination.
- Evaluate the risk to subsequent crop production on production acreage that has experienced recent postharvest grazing of domesticated animals that used field culls as a source of animal feed.
- Locate production blocks to minimize potential access by wildlife and maximize distances to possible sources of microbial contamination. For example, consider the proximity to water, wildlife harborage, open range lands, non-contiguous blocks, urban centers, etc. Periodically monitor these factors and assess during preharvest and harvest assessments as outlined in Tables 6 and 7.
- Consider production field locations and proximity to wildlife especially if the production block location is isolated from other non contiguous production areas, for example in foothill locations adjacent to open lands.
- If unusually heavy wildlife pest activity or evidence of wildlife pest activity (e.g. presence of extensive tracks or feces) occurs, consider whether or not to harvest affected portions of the field.
- If animal intrusions are common on a particular production field, consider fencing the field to reduce intrusions.
- Train harvest employees to recognize and report evidence (e.g., feces) of wildlife activity or infestations.

- 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.

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

When evidence of wild or domestic animal intrusion in a production block occurs.

Issue	Metric	Remedial Actions
Evidence of Intrusion *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.	Frequency • Formal vs. Informal • Pre Planting, Pre Harvest, and Harvest Assessment 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 <u>Wild Animals of Significant Risk</u> • Deer • Geese • Wild Pigs <u>Domestic Animals of Significant Risk</u> • Cattle • Goats and Sheep	• If there is evidence of intrusion, 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 and assess the extent of intrusion and impact on crop food risk. • Formulate effective corrective actions. • Evidence of intrusion and corrective actions shall be documented and available for verification for a period of two years.

Allowable Harvest Distance from Evidence of Intrusion	**Please see Figure 9. Decision Tree for Conducting Pre-Harvest and Harvest Assessments.**
	
	Monitoring
	• Evaluate and monitor domestic animal and wildlife activity in and proximate lettuce/leafy greens fields and production environments. Conduct periodic monitoring, pre-plant, 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 distance of one crop row from the spot of the contamination, unless remedial actions can be found that adequately control the risk.
	• **Intrusion**
	  • If evidence of animal 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 radius non-harvest area should be applied (*e.g.*, wide areas of wild pig rooting and tracks).	

Issue	Metric	Remedial Actions
	Harvest Assessment If evidence of animal intrusion into the production block is not discovered until harvest operations: • Stop harvest operations. • Initiate an intensified block assessment for evidence of further contamination and take appropriate actions per the aforementioned actions. • If evidence of intrusion is discovered during production block harvest operations and the harvest rig has come with 30 feet of contamination, 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 sanitize the container sanitized before reuse.	
Verification	• Archive documentation 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.	
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.	

TABLE 7. CROP LAND AND WATER SOURCE ADJACENT LAND USE

Land Use/Water Source	Metric (Proximal Safe Distance– 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	400 ft from the edge of crop.	Topography: Uphill from crop	√	
		Topography: Downhill from crop		√
		Downwind from crop		√
		Upwind from crop	√	
		Opportunity for water run off (creeks, streams, etc)	√	
		Opportunity for soil leaching	√	
		Physical Barriers such as windbreaks, diversion ditches, vegetative strips		√
Concentrated Animal Feeding Operations (Medium or Large size, as defined in 40 CFR 122.23)	400 ft from the edge of crop.	Fencing/barriers adequate to prevent intrusion of domestic animals.		√
		Topography: Uphill from crop	√	
		Topography: Downhill from crop		√
		Downwind from crop		√
		Upwind from crop	√	
		Opportunity for water run off (creeks, streams, etc)	√	
		Opportunity for soil leaching	√	
		Manure Management Program utilized		√
Non-synthetic Soil Amendment Pile	400 ft from the edge of crop.	Access and review COA for materials in question.		√
		Topography: Uphill from crop	√	
		Topography: Downhill from crop		√
		Downwind from crop		√
		Upwind from crop	√	

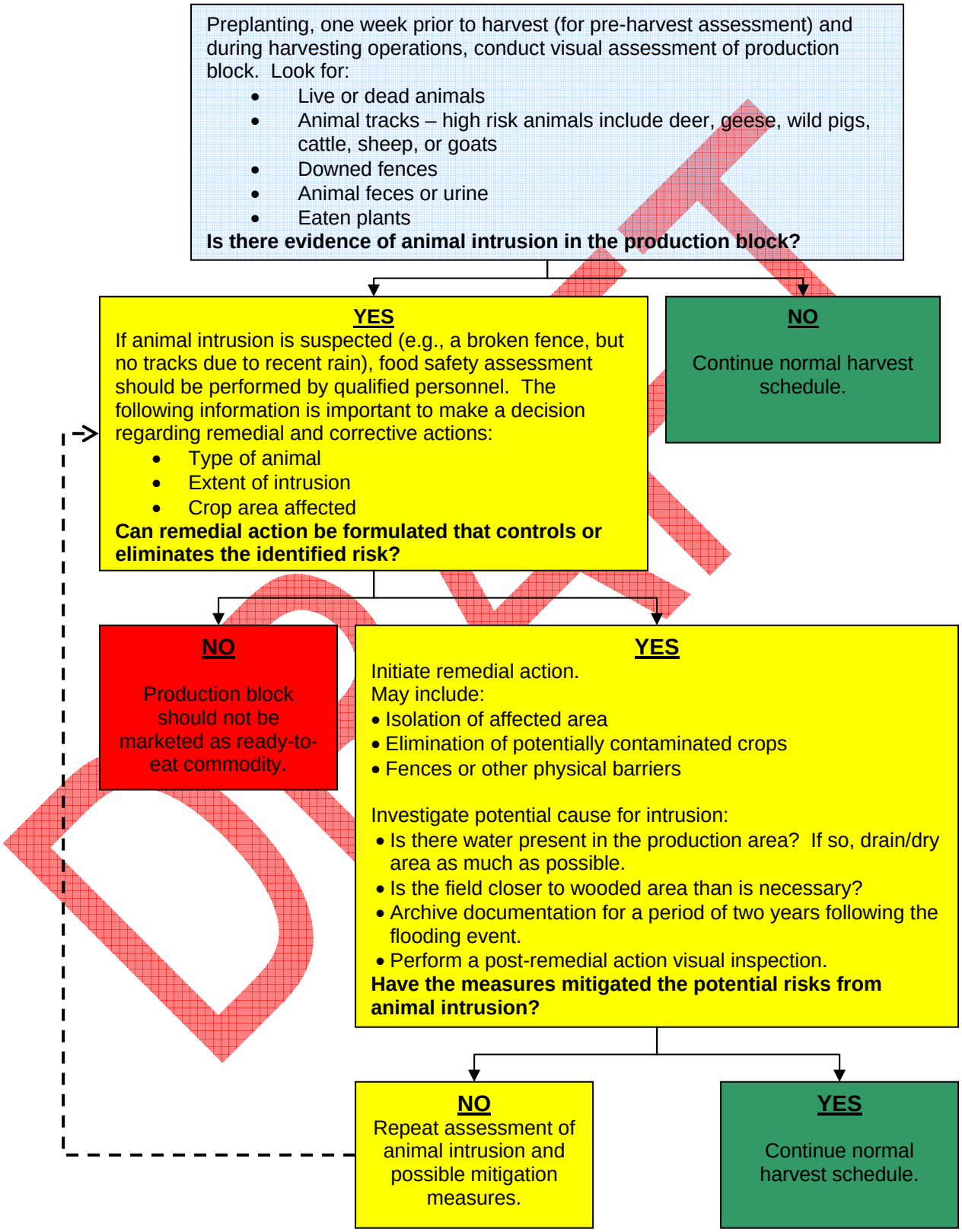
Land Use/Water Source	Metric (Proximal Safe Distance– This distance may be either increased or decreased depending on risk and mitigation factors.)	Considerations for Risk Analysis*		
		Risk/Mitigation Factors	Increase Distance	Decrease Distance
		Opportunity for water run off (creeks, streams, etc)	√	
		Opportunity for soil leaching	√	
		Covering on pile to prevent wind dispersion.		√
Grazing Lands/Domestic Animals/Small AFOs includes homes with hobby farms, and non commercial livestock)	30 ft from the edge of crop.	Fencing/barriers adequate to prevent intrusion of domestic animals.		√
		Topography: Uphill from crop	√	
		Topography: Downhill from crop		√
		Downwind from crop		√
		Upwind from crop	√	
		Opportunity for water run off (creeks, streams, etc)	√	
		Opportunity for soil leaching	√	
Homes or other building with a septic leach field.	30 ft from the edge of crop.	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		√
Undisturbed open non farmed land with evidence of wildlife (including wildlife buffer strips).	30 ft from the edge of crop.	High level of wildlife activity (*e.g.* amphibians, birds, mammals and reptiles).	√	
		Low level of wildlife activity (*e.g.*, amphibians, birds, mammals and reptiles).		√

Land Use/Water Source	Metric (Proximal Safe Distance– 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
		Wildlife type contamination potential: feces deposition potential (animal size X number of animals), propensity to carry human pathogens, feces dispersion.	√	
		Evidence of activity = tracks, feces, crop damage.	√	
		Noise makers (*e.g.*, carbide cannons) deter wildlife intrusion.		√
		Fencing/barriers that are adequate to deter wildlife intrusion.		√
Ponds, Sloughs, Rivers, Lakes, Wetlands, Creeks,	30 ft from the edge of crop.	High level of wildlife activity (*e.g.*, amphibians, birds, mammals and reptiles).	√	
		Low level of wildlife activity (*e.g.*, amphibians, birds, mammals and reptiles).		√
		Wildlife type contamination potential: feces deposition potential (animal size X number of animals), propensity to carry human pathogens, feces dispersion.	√	
		Evidence of activity = tracks, feces, crop damage.	√	
		Noise makers (*e.g.* carbide cannons) deter wildlife intrusion.		√
		Fencing/barriers that are adequate to deter wildlife intrusion.		√
Well Head Distance from Untreated Manure (also see Section 1.1.1 of Appendix 2 for additional well head guidance)	200 ft separation of untreated manure from wells, although less distance may be sufficient.	Topography: Uphill from manure		√
		Topography: Downhill from manure	√	
		Downwind from manure	√	
		Upwind from manure		√
		Opportunity for water run off (creeks, streams, etc)	√	

Land Use/Water Source	Metric (Proximal Safe Distance– 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	√	
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	√	
		Downwind from manure	√	
		Upwind from manure		√
		Opportunity for water run off (creeks, streams, etc)	√	
		Opportunity for soil leaching	√	
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 (2002) 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. The distances above are the best practices for general production; however, each individual grower must take care to determine which practices are practicable and sufficient for their particular fields.			

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



ISSUE: *Environmental Assessments*

This section addresses assessments that shall be completed by all growers within one week prior to planting and one week prior to harvesting. These two environmental assessments are intended to identify any issues related to the produce field, adjacent land uses, or wildlife intrusion that might impact produce quality or cause microbial contamination.

THE BEST PRACTICES ARE:

- Within one week prior to planting and 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 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 intrusion and/or feces. If any evidence is found, follow procedures identified in the "Production Locations - Encroachment by Animals and Urban Settings" section above.
    - 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. If any possible uses that might result in produce contamination are present, follow management practices identified in the sections above related to environmental and land use concerns.
    - Assessment of Flooding
        - Evaluate all produce fields for evidence of flooding. If any evidence is found, follow procedures identified in the "Flooding" section above.
    - Use the self-audit form attached to this document or a suitable alternative to conduct the assessments. Keep completed forms for a period of at least two years after completion.

DETAILED BACKGROUND GUIDANCE INFORMATION

REQUIRED REFERENCE DOCUMENTS

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

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