

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

VERSION 7 - ARIZONA

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Authors Note:

This document reflects Commodity Specific Food Safety Guidelines for the Production and Harvest of Leafy Greens for Arizona. It is based on the Commodity Specific Food Safety Guidelines for the Production and Harvest of Leafy Greens accepted for use by the California Leafy Greens Handler Marketing Agreement and contains minor, non-substantive modifications recommended by the Arizona Leafy Greens Marketing Committee. Arizona law supersedes any requirements in this document that may be in conflict.

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Active Compost	Compost feedstock that is in the process of being rapidly decomposed and is unstable. Active compost is generating temperatures of at least 50 degrees Celsius (122 degrees Fahrenheit) during decomposition; or is releasing carbon dioxide at a rate of at least 15 milligrams per gram of compost per day, or the equivalent of oxygen uptake.
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.
animal hazard	Feeding, skin, feathers, fecal matter or signs of animal presence in an area to be harvested in sufficient number and quantity to suggest to a reasonable person the crop may be contaminated.
adenosine tri-phosphate (ATP)	A high energy phosphate molecule required to provide energy for cellular function.
agricultural material	Material of plant or animal origin, which result from the production and processing of farm, ranch, agricultural, horticultural, aquacultural, silvicultural, floricultural, vermicultural, or viticultural products, including manures, orchard and vineyard prunings, and crop residues.
ATP test methods	Exploits knowledge of the concentration of ATP as related to viable biomass or metabolic activity; provides an estimate of cleanliness.
Biofertilizers	Fertilizer materials/products that contain microorganisms such as bacteria, fungi, and cyanobacteria that shall promote soil biological activities.
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) either consisting of single cells or groups of cells, capable of growth under the prescribed conditions (medium, atmosphere, time and temperature) to develop into visible colonies (colony forming units) which are counted.
Concentrated Animal Feeding Operation (CAFO)	A lot or facility where animals have been, are or will be stabled or confined and fed or maintained for a total of 45 days or more in any 12 month period and crops, vegetation forage growth, or post-harvest residues are not sustained in the normal growing season over any portion of the lot or facility. In addition, there must be more than 1,000 'animal units' (as defined in 40 CFR 122.23) confined at the facility; or more than 300 animal units confined at the facility if either one of the following conditions are met: pollutants are discharged into navigable waters through a

	man-made ditch, flushing system or other similar man-made device; or pollutants are discharged directly into waters of the United States which originate outside of and pass over, across, or through the facility or otherwise come into direct contact with the animals confined in the operation.
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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.
Co-management	An approach to conserving soil, water, air, wildlife, and other natural resources while simultaneously minimizing microbiological hazards associated with food production.
cross contamination	The transfer of microorganisms, such as bacteria and viruses, from one place to another.
E. coli	<i>Escherichia coli</i> 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 producer’s control that is reasonably likely to contain microorganisms of significant public health concern and is reasonably likely to cause adulteration of edible portions of fresh produce in that field.
food contact surface	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 personnel	Person trained in basic food safety principles and/or working under the auspices of a food safety professional.
food safety professional	Person entrusted with management level responsibility for conducting food safety assessments before food reaches consumers; requires documented training in scientific principles and a solid understanding of the principles of food safety as applied to agricultural production. See appendix B for more details.
geometric mean	Mathematical def.: the n-th root of the product of n numbers, or: Geometric Mean = n-th root of $(X_1)(X_2)\dots(X_n)$, where X_1 , X_2 , etc. represent the individual data points, and n is the

	total number of data points used in the calculation. Practical def.: the average of the logarithmic values of a data set, converted back to a base 10 number.
green waste	"Green Waste" means any plant material that is separated at the point of generation, contains no greater than 1.0 percent of physical contaminants by weight, and meets the requirements of section 17868.5. Green material includes, but is not limited to, yard trimmings ("Yard Trimmings" means any wastes generated from the maintenance or alteration of public, commercial or residential landscapes including, but not limited to, yard clippings, leaves, tree trimmings, prunings, brush, and weeds), untreated wood wastes, natural fiber products, and construction and demolition wood waste. Green material does not include food material, biosolids, mixed solid waste, material processed from commingled collection, wood containing lead-based paint or wood preservative, mixed construction or mixed demolition debris. "Separated At The Point of Generation" includes material separated from the solid waste stream by the generator of that material. It may also include material from a centralized facility as long as that material was kept separate from the waste stream prior to receipt by that facility and the material was not commingled with other materials during handling. ¹
Hobby Farm	A small farm, or rural residence with 25 or fewer animals per acre that is operated without expectation of being the primary source of income.
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, cabbage (green, red and savoy), kale, arugula and chard.
Monthly	Because irrigation schedules and delivery of water is not always in a growers control "monthly" for purposes of water sampling means within 35 days of the previous sample.
most probable number (MPN)	Estimated values that are statistical in nature; a method for enumeration of microbes in a sample, particularly when present in small numbers.
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.

¹ CCR Title 1: Natural Resources. Division 7, CIWMB. **Chapter 3.1: Compostable Materials Handling Operations and Facilities Regulatory Requirements.** Article 1: General. Section 17852: Definitions. <http://www.calrecycle.ca.gov/laws/Regulations/Title14/ch31.htm#Article1>

Ready to eat (RTE) food (excerpted from USFDA 2005 Model Food Code)	<p>(1) "Ready-to-eat food" means FOOD that:</p> <ul style="list-style-type: none"> (a) Is in a form that is edible without additional preparation to achieve FOOD safety, as specified under one of the following: 3-401.11(A) or (B), § 3-401.12, or § 3-402.11, or as specified in 3-401.11(C); or (d) May receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. <p>(2) "Ready-to-eat food" includes:</p> <ul style="list-style-type: none"> (b) Raw fruits and vegetables that are washed as specified under § 3-302.15; (c) Fruits and vegetables that are cooked for hot holding, as specified under § 3-401.13; (e) Plant FOOD for which further washing, cooking, or other processing is not required for FOOD safety, and from which rinds, peels, husks, or shells, if naturally present are removed;
synthetic crop treatments (chemical fertilizers)	Any crop inputs that may be refined, and/or chemically synthesized and/or transformed through a chemical process (e.g. gypsum, lime, sulfur, potash, ammonium sulfate etc.).
oxidation reduction potential (ORP)	An intrinsic property that indicates the tendency of a chemical species to acquire electrons 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
soil amendment	Elements added to the soil, such as compost, peat moss, or fertilizer, to improve its capacity to support plant life.
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 through a statistically-based study, literature, or regulatory guidance.
water distribution system	Distribution systems -- consisting of pipes, pumps, valves, storage tanks, reservoirs, meters, fittings, and other hydraulic appurtenances – canals, ditches and rivers -- to carry water from its primary source to a lettuce and leafy green crop.

95 Acronyms and Abbreviations
96
97 AFOs: Animal feeding operations
98 AOAC: AOAC International (formerly the Association of Official Analytical Chemists)
99 BAM: Bacteriological Analytical Manual
100 CAFOs: Concentrated animal feeding operations
101 CSG2: *Commodity Specific Guidance for Leafy Greens and Lettuce, 2nd Edition*
102 CFU: colony forming units
103 cGMP: current good manufacturing practices
104 COA: Certificate of Analysis
105 DL: Detection Limit
106 FDA: Food and Drug Administration
107 GAPS: good agricultural practices
108 GLPs: good laboratory practices
109 HACCP: hazard analysis critical control point
110 MPN: most probable number
111 NGO: nongovernmental organization
112 NRCS: Natural Resources Conservation Service
113 ORP: Oxidation reduction potential
114 PPM: parts per million
115 RTE: ready-to-eat
116 SSOPs: Sanitation Standard Operating Procedures
117 TMECC: Test Methods for the Examination of Composting and Compost USEPA: United States
118 Environmental Protection Agency
119 UV: ultraviolet
120 WHO: World Health Organization
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129 **LIST OF APPENDICES**

130 [Appendix A](#): Sanitary Survey [Appendix B](#): Technical Basis Document
131 [Appendix C](#): Crop Sampling Protocol [Appendix Z](#): AZ LGMA Resource Agency Contacts
132 [Appendix D](#): Kinetics of Microbial Inactivation for Alternative Food Processing Technologies
133 [Appendix E](#): Environmental Health Standards for Composting Operations (California Code of
134 Regulations)
135

136 **INTRODUCTION**

137

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

151

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

159

160 In response to continued concerns regarding the microbial safety of fresh produce, this edition of the
161 guidelines (which focuses solely on production and harvest practices) was prepared to provide more
162 specific and quantitative measures of identified best practices. A key focus of this revision was to
163 identify, where possible and practical, metrics and measures that could be used to assist the industry
164 with compliance with the guidelines. In preparing this document, metrics were researched for three
165 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:

166

- 167 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.
- 168 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.
- 169 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.

170

171 In the last 10 years, the focus of food safety efforts has been on the farm, initial cooling and
172 distribution points, and value-added processing operations. Fruit and vegetable processing operations
173 have developed sophisticated food safety programs largely centered on current Good Manufacturing
174 Practices (cGMPs) and the principles of Hazard Analysis Critical Control Point (HACCP) programs.
175 As we develop a greater understanding of food safety issues relative to the full spectrum of supply and
176 distribution channels for fruits and vegetables, it has become clear that the next generation of food
177 safety guidance needs to encompass the entire supply chain.

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

187 **SCOPE**

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

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

205
206 Lettuce/leafy greens present multiple opportunities to employ food safety risk management practices
207 to enhance the safety of lettuce/leafy greens. In the production and harvest of lettuce and leafy greens
208 as raw agricultural commodities, GAPs are commonly employed in order to produce the safest
209 products possible. In a processing operation, the basic principles of cGMPs, HACCP, sanitation and
210 documented operating procedures are commonly employed in order to produce the safest products
211 possible. Lettuce/leafy greens are highly perishable and it is strongly recommended that they be
212 distributed, stored and displayed under refrigeration.

213
214 Safe production, packing, processing, distribution and handling of lettuce/leafy greens depend upon a
215 myriad of factors and the diligent efforts and food safety commitment of many parties throughout the
216 distribution chain. No single resource document can anticipate every food safety issue or provide
217 answers to all food safety questions. These guidelines focus on minimizing only the microbial food
218 safety hazards by providing suggested actions to reduce, control or eliminate microbial contamination
219 of lettuce/leafy greens in the field to fork distribution supply chain.

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

226

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

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

244 Due to the close association between production blocks and environmentally sensitive areas in many
245 locations, it recommended to review Appendix Z when any mitigation strategies that may impact
246 these areas are employed. Producers should implement strategies that not only protect food safety but
247 also support co-management. All parties involved with implementing the practices outlined in this
248 document should be aware that these metrics are not meant to be in conflict with or discourage co-
249 management practices and principles.

250

251 Users are encouraged to utilize the services of their trade associations, the U.S. Food and Drug
252 Administration, the Center for Produce Safe, the U.S. Department of Agriculture, the U.S.
253 Environmental Protection Agency, the Centers for Disease Control and Prevention, and state
254 agricultural, environmental, academic, wildlife and natural resources management agencies and/or
255 public health authorities.

256 The Sanitary Survey and Technical Basis Documents prepared as Appendices to these guidelines are
257 considered to be additional resources. They are intended to provide clarification, assist with
258 interpretation and provide additional guidance as users develop food safety programs based on these
259 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.

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.
- Shippers shall have an up to date producers list with contact and location information on file.
- The shipper shall comply with the requirements of The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (farms are exempt from the Act) including those requirements for recordkeeping (traceability) and registration.
- Each producer and shipper shall designate an individual responsible for their operation's food safety program. Twenty-four hour contact information shall be available for this individual in case of food safety emergencies.

3. ISSUE: ENVIRONMENTAL ASSESSMENTS

This section addresses assessments that shall be completed and documented prior to the first seasonal planting, within one week prior to harvesting and during harvest operations. These environmental assessments are intended to identify any issues related to the produce field, adjacent land uses, and/or animal hazards that may present a risk to the production block or crop (see Table 5).

The Best Practices Are:

- Prior to the first seasonal planting and within one week prior to harvest, perform and document an environmental risk assessment of the production field and surrounding area. Focus these assessments on evaluating the production field for

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

305 ○ Assessment of Produce Field

306 ■ Evaluate all produce fields for evidence of animal hazards and/or
307 feces. If any evidence is found, follow procedures identified in
308 the “Production Locations - Encroachment by Animals and Urban
309 Settings.”

310 ○ Assessment of Adjacent Land Use

311 ■ Evaluate all land and waterways adjacent to all production fields
312 for possible sources of human pathogen of concern. These
313 sources include, but are not limited to, manure storage, compost
314 storage, CAFO’s, grazing/open range areas, surface water,
315 sanitary facilities, and composting operations (see Table 6 for
316 further detail). If any possible uses that might result in produce
317 contamination are present consult with the metrics and refer to
318 Appendix Z.

319 ○ Assessment of Historical Land Use

320 ■ To the degree practical, determine and document the historical
321 land uses for production fields and any potential issues from these
322 uses that might impact food safety (i.e., hazardous waste sites,
323 landfills, etc.).

324 ○ Assessment of Flooding

325 ■ Evaluate all produce fields for evidence of flooding. If any
326 evidence is found, follow procedures identified in the “Flooding”
327 section below.

328 **4. ISSUE: WATER**

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

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

339 The current metrics are intended to provide standards associated with water uses; however, it
340 is known that various water sources have different microbial qualities, and each source
341 should be monitored accordingly. Typical microbial values associated with various sources
342 can be found in the Sanitary Survey document (Appendix A). During the sanitary survey that

346 is performed prior to each growing season expected microbial values and historical
347 monitoring data should be used to evaluate the quality of the water source.

348

349 **The Best Practices Are:**

- 350 • A water system description shall be prepared. This description can use maps,
351 photographs, drawings or other means to communicate the location of permanent
352 fixtures and the flow of the water system (including any water captured for re-
353 use.). Permanent fixtures include wells, gates, reservoirs, valves, returns and
354 other above ground features that make up a complete irrigation system should be
355 documented in such a manner as to enable location in the field. Water sources
356 and the production blocks they may serve should be documented.
- 357 • Water systems that convey untreated human or animal waste must be separated
358 from conveyances utilized to deliver irrigation water.
- 359 • Use irrigation water and water in harvest operations that is of appropriate
360 microbial quality for its intended use; see Table 1 and Decision Trees (1A, 1B
361 and 1C) for specific numerical criteria. Appendix B provides the basis for these
362 water quality metrics.
- 363 • Perform a sanitary survey prior to use of water in agricultural operations and if
364 water quality microbial tests are at levels that exceed the numerical values set
365 forth in Table 1. The sanitary survey is described in Appendix A.
- 366 • Test water as close to the point-of-use as practical, and if microbial levels are
367 above specific action levels, take appropriate remedial and corrective actions.
- 368 • Retain documentation of all test results and/or Certificates of Analysis available
369 for inspection for a period of at least 2 years.

370 Other Considerations for water

- 371 ○ Evaluate irrigation methods (drip irrigation, overhead sprinkler, furrow, etc.)
372 for their potential to introduce, support or promote the growth of human
373 pathogens on lettuce and leafy greens. Consider such factors as the potential
374 for depositing soil on the crop, presence of pooled or standing water that
375 attracts animals, etc.
- 376 ○ When waters from various sources are combined, consider the potential for
377 pathogen growth in the water.
- 378 ○ For surface water sources, consider the impact of storm events on irrigation
379 practices. Bacterial loads in surface water are generally much higher after a
380 storm than normal, and caution shall be exercised when using these waters for
381 irrigation.
- 382 ○ Use procedures for storing irrigation pipes and drip tape that reduce or
383 eliminate potential pest infestations. Develop procedures to provide for
384 microbiologically safe use of irrigation pipes and drip tape if a pest
385 infestation does occur.
- 386 ○ Reclaimed water shall be subject to applicable state and federal regulations
387 and standards. Use of this water for agricultural purposes must meet the most
388 stringent standard as defined by the following: state and federal regulation or

Table 1 of this document. Water sample results and analysis provided by the water district or provider may be utilized as records of water source testing for verification and validation audits.

392

393 5. **ISSUE: WATER USAGE TO PREVENT PRODUCT DEHYDRATION**

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

398

399 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.

407 TABLE 1. WATER USE

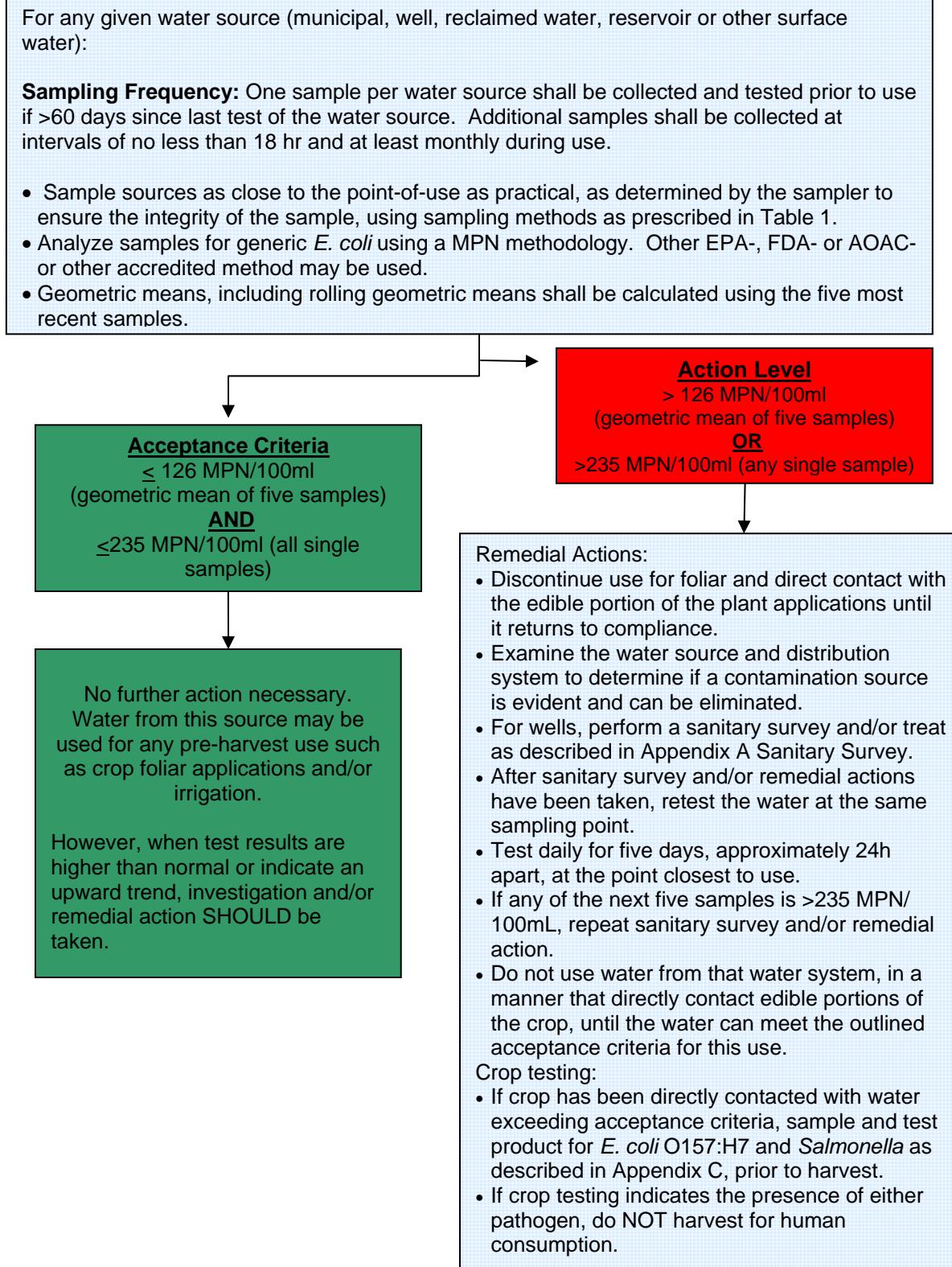
Use	Metric	Rationale /Remedial Actions
PREHARVEST Foliar Applications Whereby Edible Portions of the Crop ARE Contacted by Water (e.g. overhead sprinkler irrigation, pesticides/fungicide application, etc.)	Target Organism: generic <i>E. coli</i> . Sampling Procedure: 100 mL sample collected aseptically at the point of use; i.e., one sprinkler head per water source for irrigation, water tap for pesticides, etc. Water utilized in preseason irrigation operations may be tested and utilized. 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 <i>E. coli</i> are below detection limits for five consecutive samples, the sampling frequency may be decreased to no less than once every 180 days and the requirements for 60 and monthly sampling are waived. Closed systems with records to demonstrate that all samples of generic <i>E. coli</i> are below detection limits for the two preceding seasons may decrease sampling to a single sample per season. This exemption is void if there is a significant source or distribution system change.	For any given water source (municipal, well, reclaimed water, reservoir or other surface water), samples for microbial testing shall be taken at a point as close to the point of use as practical (as determined by the sampler, to ensure the integrity of the sample, using sampling methods as prescribed in Table 1) where the water contacts the crop, so as to test both the water source and the water distribution system. In a closed water system (meaning no connection to the outside) water samples may be collected from any point within the system but are still preferred as close to point of use as practical. No less than one sample per month per distribution system is required under these metrics unless a system has qualified for an exemption. If there are multiple potential point-of-use sampling points in a distribution system, then samples 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. However, a rolling geometric mean of five samples is not necessarily required prior to irrigation or harvest. If less than five samples are collected prior to irrigation, the acceptance criteria depends on the number of samples taken. If only one sample has been taken, it must be below 126 CFU/100 mL. Once two samples are taken, a geometric mean can be calculated and the normal acceptance criteria apply. If the acceptance criteria are exceeded during this time period, additional samples may be collected to reach a 5 sample rolling geometric mean (as long as the water has not been used for irrigation). The <i>rolling</i> geometric mean calculation starts after 5 samples have been collected. If the water source has not been tested in the past 60 days, the first water sample shall be tested prior to use, to avoid using a contaminated water source. After the first sample is shown to be within acceptance criteria, subsequent samples shall be collected no less frequently than monthly at points of use within the distribution system. Ideally, preharvest water should not contain generic <i>E. coli</i> , 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 <i>E. coli</i> levels are within acceptance criteria: <ul style="list-style-type: none"> 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).

	<p>Test Method: FDA BAM method or any U.S. EPA approved or AOAC accredited for quantitative monitoring of water for generic <i>E. coli</i>. Presence/absence testing with a similar limit of detection may be used as well.</p> <p>Acceptance Criteria: ≤ 126 MPN (or CFU*)/100 mL (rolling geometric mean n=5) and ≤ 235 MPN/100mL for any single sample.</p> <p>*for the purposes of water testing, MPN and CFU shall be considered equivalent.</p>	<ul style="list-style-type: none"> For wells, perform a sanitary survey and/or treat as described in Appendix A Sanitary Survey. Retest the water after conducting the sanitary survey and/or taking remedial actions to determine if it meets the outlined microbial acceptance criteria for this use. This sample should represent the conditions of the original water system, if feasible this test should be as close as practical to the original sampling point. A more aggressive sampling program (i.e., sampling once per week instead of once per month) shall be instituted if an explanation for the exceedence is not readily apparent. This type of sampling program should also be instituted if an upward trend is noted in normal sampling results. <p>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 <i>E. coli</i> O157:H7 and <i>Salmonella</i> 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.</p> <p>Records: Information requirements: Each water sample and analysis shall record: the type of water (canal, reservoir, well, etc) date, time and location of the sample and the method of analysis and detection limit. Records of the analysis of source water may be provided by municipalities, irrigation districts or other water providers. All test results and remedial actions shall be documented and available for verification from the grower/shipper who is the responsible party for a period of two years.</p>
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	<p>Target Organism, Sampling Procedure, Sampling Frequency Test Method and Municipal Well Exemption: as described for foliar application.</p> <p>Acceptance Criteria: ≤ 126 MPN /100 mL (rolling geometric mean n=5) and ≤ 576 MPN /100 mL for any single sample.</p>	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.

is not necessary)		
POSTHARVEST Direct Product Contact or Food Contact Surfaces	<p><u>Microbial Testing</u></p> <p>Target Organism, Sampling Procedure, and Test Method: as described for foliar application.</p> <p>Sampling Frequency: One sample per water source shall be collected and tested prior to use if >60 days since last test of the water source. Additional samples shall be collected at intervals of no less than 18 hr and at least monthly during use.</p> <p>Municipal & Well Exemption: For wells and municipal water sources, if generic <i>E. coli</i> are below detection limits for five consecutive samples, the sampling frequency may be decreased to no less than once every 180 days and the requirements for 60 and monthly sampling are waived. Closed systems with records to demonstrate that all samples of generic <i>E. coli</i> are below detection limits for the two preceding seasons may decrease sampling to a single sample per season. This exemption is void if there is a significant source or distribution system change.</p> <p>Acceptance Criteria: Negative or below DL for all samples</p> <p><u>Physical/Chemical Testing</u></p> <p>Target Variable: Water disinfectant (e.g. chlorine or other disinfectant compound, ORP)</p>	<p>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 <i>E. coli</i> 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. No less than one sample per month per distribution system is required under these metrics unless a system has qualified for an exemption.</p> <p>Single Pass vs. Multiple Pass Systems</p> <ul style="list-style-type: none"> • Single pass use – Water must have non-detectable levels of <i>E. coli</i> or breakpoint disinfectant present at point of entry • Multi-pass use – Water must have non-detectable levels of <i>E. coli</i> and/or sufficient disinfectant to insure returned water has no detectable <i>E. coli</i> (minimally 1 ppm chlorine) <p>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 <i>E. coli</i> levels are within acceptance criteria:</p> <ul style="list-style-type: none"> • 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. <p>For example, if a water sample for water used to clean food contact surfaces has detectable <i>E. coli</i>, 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 <i>E. coli</i>, repeat remedial actions and DO NOT use that system until the source of contamination can be corrected.</p> <p>Records: All test results and remedial actions shall be documented and available for verification from the</p>

	<p>Multi Pass Water Acceptance Criteria:</p> <ul style="list-style-type: none"> • <u>Chlorine</u> ≥1 ppm free chlorine after application and pH 6.5 – 7.5 OR • ORP ≥ 650 mV, and pH 6.5 – 7.5 • <u>Other approved treatments</u> per product EPA label for human pathogen reduction in water. <p>Testing Procedure:</p> <ul style="list-style-type: none"> • Chemical reaction based colorimetric test, or • Ion specific probe, or • ORP, or • Other as recommended by disinfectant supplier. <p>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.</p>	<p>user of the water for a period of two years.</p>
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408 **Figure 1A. Decision Tree for PRE-HARVEST WATER USE – Foliar Applications**
409 whereby edible portions of the crop are contacted by water (e.g. overhead irrigation,
410 pesticide/fungicide applications)

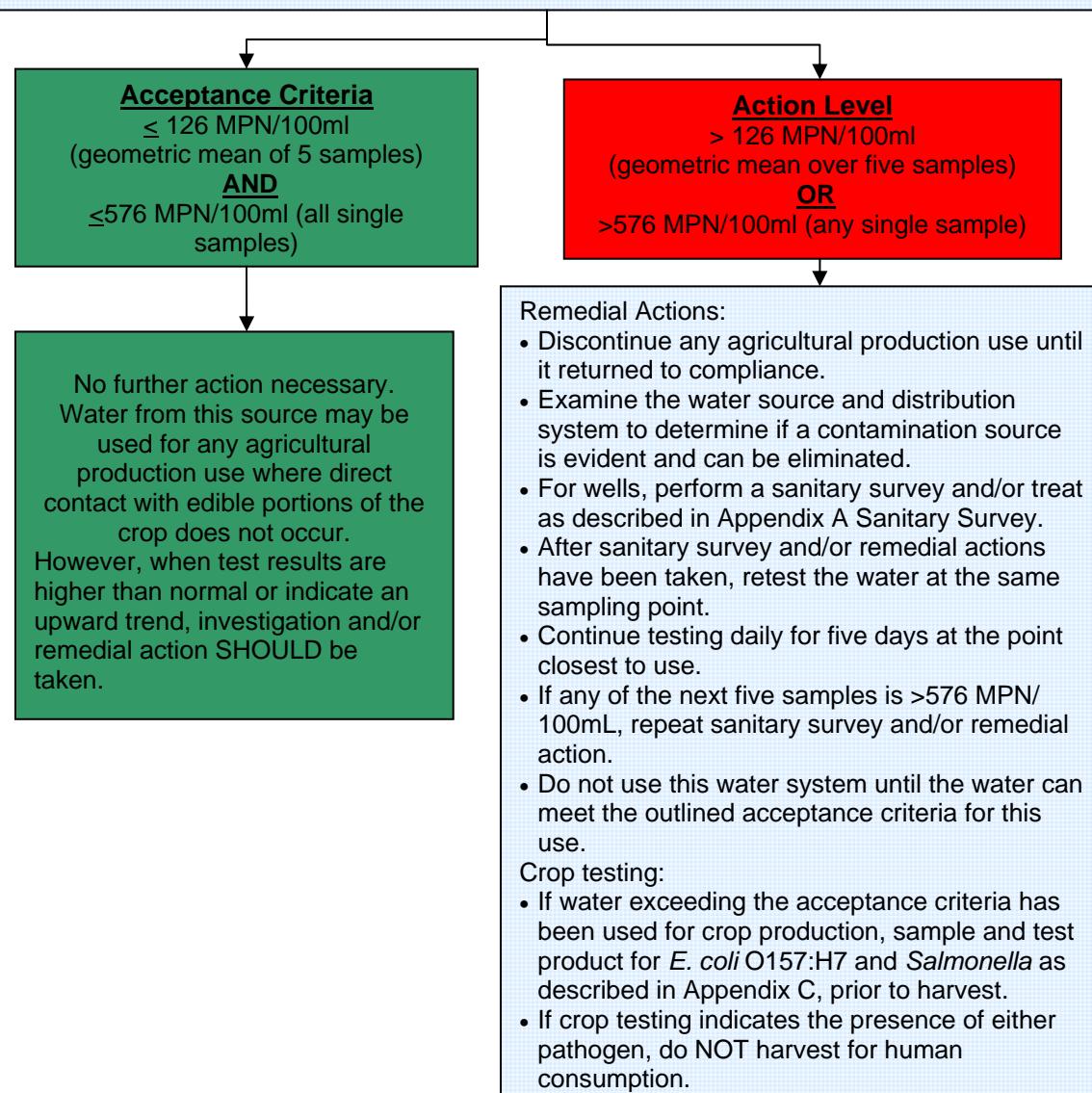


413 **Figure 1B. Decision Tree for PRE-HARVEST WATER USE – Non-Foliar Applications**
 414 whereby edible portions of the crop are NOT contacted by water (e.g. furrow or drip
 415 irrigation, dust abatement water)
 416

For any given water source (municipal, well, reclaimed water, reservoir or other surface water):

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.

- Sample sources as close to the point-of-use as practical using sampling methods as prescribed in Table 1.
- Analyze samples for generic *E. coli* using a MPN methodology. Other EPA-, FDA- or AOAC International -accredited method may be used.
- Geometric means, including rolling geometric means shall be calculated using the five most recent samples.



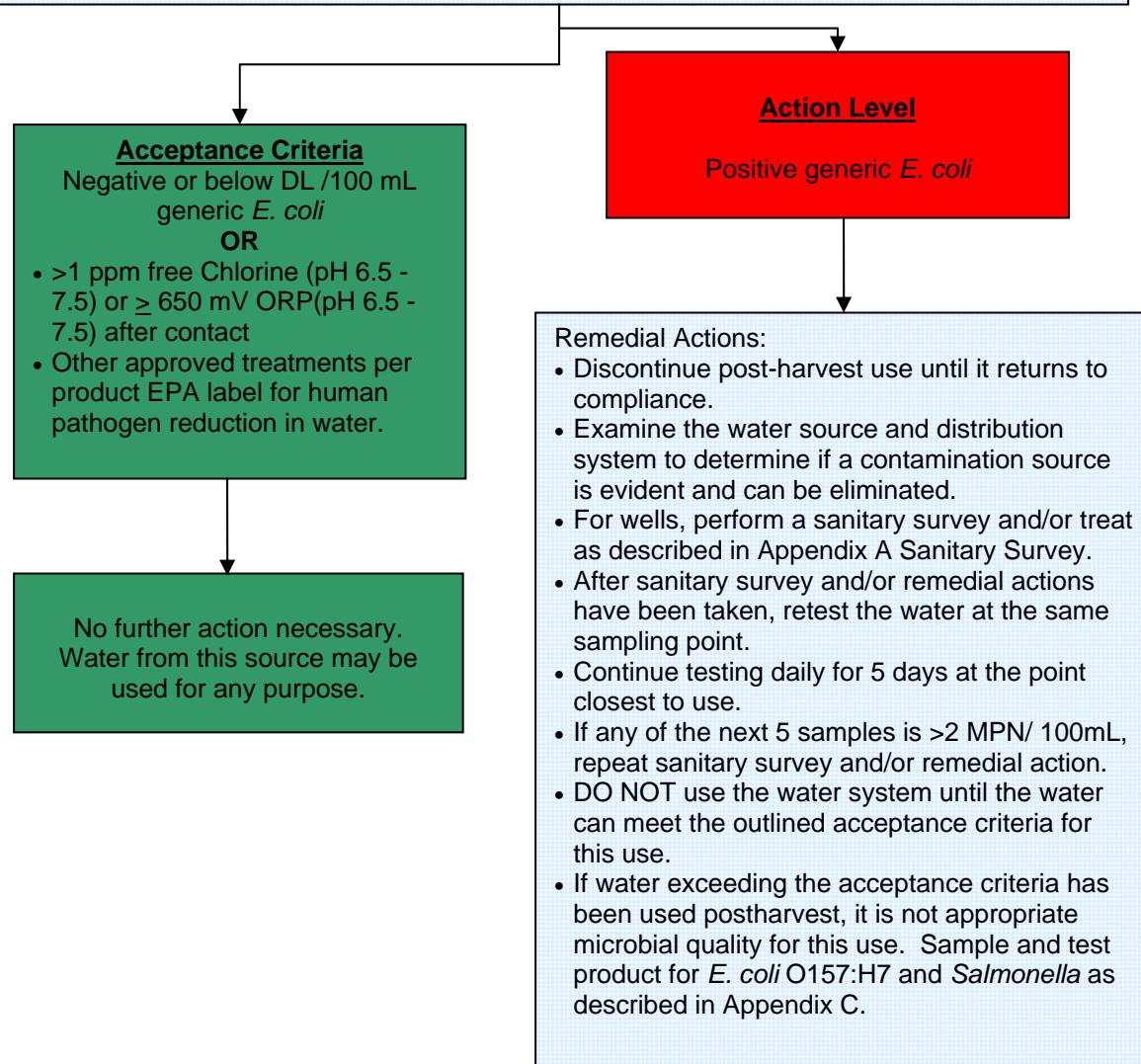
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Figure 1C. POSTHARVEST WATER USE – Direct product contact (e.g. re-hydration, core in field, etc.)

For any given water source (municipal, well, reservoir or other surface water):
Water that directly contacts edible portions of harvested crop, shall meet microbial standards set forth in U.S. EPA National Drinking Water Regulations, and/or contain an approved disinfectant at sufficient concentration to prevent cross contamination.

Sampling Frequency: One sample per water source shall be collected and tested prior to use if >60 days since last test of the water source. Additional samples shall be collected no less than 18 hr apart and a least monthly during use. No less than one sample per month per distribution system is required under these metrics unless a system has qualified for an exemption.

- Sample sources as close to the point-of-use as practical using sampling methods as prescribed in Table 1.
- Analyze samples for generic *E. coli* using a MPN methodology. Other EPA-, FDA- or AOAC International -accredited method may be used.
- Geometric means, including rolling geometric means shall be calculated using the 5 most



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423 **6. ISSUE: SOIL AMENDMENTS**

424 Soil amendments are commonly but not always incorporated prior to planting into
425 agricultural soils used for lettuce/leafy greens production to add organic and inorganic
426 nutrients to the soil as well as intended to improve the physical, chemical, or biological
427 characteristics of soil.. Human pathogens may persist in animal manures for weeks or even
428 months (Fukushima *et al.* 1999; Gagliardi and Karns 2000). Proper composting of animal
429 manures via thermal treatment will reduce the risk of potential human pathogen survival.
430 However, the persistence of many human pathogens in agricultural soils depends on many
431 factors (soil type, relative humidity, UV index, etc.) and the effects of these factors is under
432 extensive investigation (Jiang *et al.* 2003; Islam *et al.* 2004).

433
434 Field soil contaminated with human pathogens may provide a means of lettuce and leafy
435 greens contamination. Studies of human pathogens conducted in cultivated field vegetable
436 production models point towards a rapid initial die-off from high pathogen populations but a
437 characteristic and prolonged low level survival. Readily detectable survival is typically less
438 than 8 weeks following incorporation, but has been documented to exceed 12 weeks (Jiang *et*
439 *al.* 2001; Islam *et al.* 2005).. Recoverable pathogen populations, using highly sensitive
440 techniques, have been reported to persist beyond this period under some test conditions. The
441 detection of introduced pathogens on mature lettuce plants from these low levels of surviving
442 pathogens was not possible, and the risk was concluded to be negligible. Human pathogens
443 do not persist for long periods of time in high UV index and low relative humidity
444 conditions, but may persist for longer periods of time within aged manure or inadequately
445 composted soil amendments. Therefore, establishing suitably conservative pre-plant
446 intervals, appropriate for specific regional and field conditions, is an effective step towards
447 minimizing risk (Suslow *et al.* 2003).

448
449 **The Best Practices Are:**

450 • DO NOT USE raw manure or soil amendment that contain un-composted,
451 incompletely composted animal manure and/or green waste or non-thermally
452 treated animal manure to fields which will be used for lettuce and leafy green
453 production.

454 • See Table 2 and Decision Trees (Figures 2A and 2B) for numerical criteria and
455 guidance for compost and soil amendments used in lettuce and leafy greens
456 production fields. The “Technical Basis Document” (Appendix B) describes the
457 process used to develop these metrics.

458 • Any soil amendment that does not contain animal manure must have a document
459 (e.g., ingredient list, statement of identity, letter of guaranty, etc.) from the
460 producer or seller demonstrating that it is manure free. This document must
461 indicate in some way that manure is not an ingredient used in the production of
462 the amendment or provide the ingredients of the product. A statement of identity
463 or product is sufficient for single-chemical amendments (i.e., “calcium
464 carbonate” or “gypsum”). If “inert ingredients” are listed as part of an
465 amendment, then a document from the producer or seller is necessary indicating
466 manure has not been added. The manure free document must be available for
467 verification before harvest begins and it must be saved and available for
468 inspection for 2 years. A new document is required every two years unless there
469 is a significant process or ingredient change.

- 470 • Implement management plans (e.g., timing of applications, storage location,
471 source and quality, transport, etc.) that significantly reduce the likelihood that soil
472 amendments being used contain human pathogens.
- 473 • Verify that the time and temperature process used during the composting process
474 reduces, controls, or eliminates the potential for human pathogens being carried
475 in the composted materials, as applicable to regulatory requirements.
- 476 • Maximize the time interval between soil amendment application and time to
477 harvest.
- 478 • Implement practices that control, reduce or eliminate likely contamination of
479 lettuce/leafy green fields in close proximity to on-farm stacking of manure.
- 480 • Use soil amendment application techniques that control, reduce or eliminate
481 likely contamination of surface water and/or edible crops being grown in adjacent
482 fields.
- 483 • Segregate equipment used for soil amendment handling, preparation, distribution,
484 applications or use effective means of equipment sanitation before subsequent use
485 that effectively reduce the potential for cross contamination.
- 486 • Minimize the proximity of wind-dispersed or aerosolized sources of
487 contamination (e.g., water and manure piles) that may potentially contact growing
488 lettuce/leafy greens or adjacent edible crops. Segregate equipment used for soil
489 amendment applications or use effective means of equipment sanitation before
490 subsequent use.
- 491 • Compost suppliers shall have written Standard Operating Procedures to prevent
492 cross-contamination of finished compost with raw materials through equipment,
493 runoff, or wind, and producers shall obtain proof that these documents exist.
- 494 • Compost operations supplying compost to leafy greens crops shall maintain
495 temperature monitoring and turning records for at least two years, and producers
496 shall obtain proof that this documentation exists. This applies to composting
497 operations regulated under Title 14 CCR as well as smaller operations that do not
498 fall under Title 14.
- 499 • Perform microbiological testing of soil amendments prior to application (Table
500 2).
- 501 • Do not use biosolids as a soil amendment for production of lettuce or leafy
502 greens.
- 503 • Retain documentation of all processes and test results by lot (at the supplier)
504 and/or Certificates of Analysis available for inspection for a period of at least two
505 years.

TABLE 2. SOIL AMENDMENTS

Amendment	Metric/Rationale
Raw Manure or Not Fully Composted green waste and/or Animal Manure Containing Soil Amendments (see composted manure process definition below)	<p>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.</p>
Composted Soil Amendments (containing animal manure or animal products) *Composted soil amendments should not be applied after emergence of plants.	<p>Please see Figure 2A: Decision Tree for Use of Composted Soil Amendments.</p> <p>Composting Process Validation:</p> <p><u>Enclosed or within-vessel composting:</u> Active compost must maintain a minimum of 131°F for 3 days</p> <p><u>Windrow composting:</u> Active compost must maintain aerobic conditions for a minimum of 131°F or higher for 15 days or longer, with a minimum of five turnings during this period.</p> <p><u>Aerated static pile composting:</u> Active compost must be covered with at least 12 inches of insulating materials and maintain a minimum of 131°F for 3 days</p> <p>Target Organisms:</p> <ul style="list-style-type: none"> • Fecal coliforms • <i>Salmonella</i> spp • <i>E. coli</i> O157:H7 <p>Acceptance Criteria:</p> <ul style="list-style-type: none"> • Fecal coliforms <1000 MPN/gram • <i>Salmonella</i>: Negative or < DL (<1/ 30 grams) • <i>E. coli</i> O157:H7: Negative or < DL (<1/ 30 grams)

Amendment	Metric/Rationale
	<p>Recommended Test Methods:</p> <ul style="list-style-type: none"> • Fecal coliforms: 9 tube MPN • <i>Salmonella spp</i>: U.S. EPA Method 1682 • <i>E. coli</i> O157:H7: Any laboratory validated method for compost sampling. • Other U.S. EPA, FDA, AOAC, TMECC or, accredited methods may be used as appropriate. <p>Sampling Plan:</p> <ul style="list-style-type: none"> • A composite sample shall be representative and random and obtained as described in the California state regulations.¹ • Sample may be taken by the supplier if trained by a testing laboratory or state authority. • Laboratory must be certified/accredited for microbial testing by an appropriate process authority <p>Testing Frequency:</p> <ul style="list-style-type: none"> • 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. <p>Application Interval:</p> <ul style="list-style-type: none"> • Must be applied >45 days before harvest <p>Documentation:</p> <ul style="list-style-type: none"> • All test results and/or Certificates of Analysis shall be documented and available for verification from the producer (the responsible party) for a period of two years. <p>Rationale:</p> <ul style="list-style-type: none"> • The microbial metrics and validated processes for compost are based on allowable levels from California state regulations (CCR Title 14 - Chapter 3.1 - Article 7 2007), with the addition of testing for <i>E. coli</i> 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.

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, TMECC or, other accredited methods may be used as appropriate

Sampling Plan:

- Extract at least 12 equivolume samples (identify 12 separate locations from which to collect the sub-sample, in case of bagged product 12 individual bags).
- Sample may be taken by the supplier if trained by a testing laboratory or state authority.
- 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.
 - In lieu of the above analysis requirement a Certificate of Process Validity Issued by a recognized *Process Authority* can be substituted. This certificate will attest to the process validity as determined by either a documented (included w/Certificate)) inoculated pack study

of the standard process or microbial inactivation calculations of organisms of significant risk (included w/Certificate) as outlined in FDA CFSAN publication **“Kinetics of Microbial Inactivation for Alternative Food Processing Technologies. Overarching Principles: Kinetics and Pathogens of Concern for All Technologies”** (Incorporated for reference in Appendix E Thermal Process Overview)

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 and meets 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 and/or Certificates of Process Validation shall be documented and available for verification from the producer 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 producer for a period of two years.

Rationale:

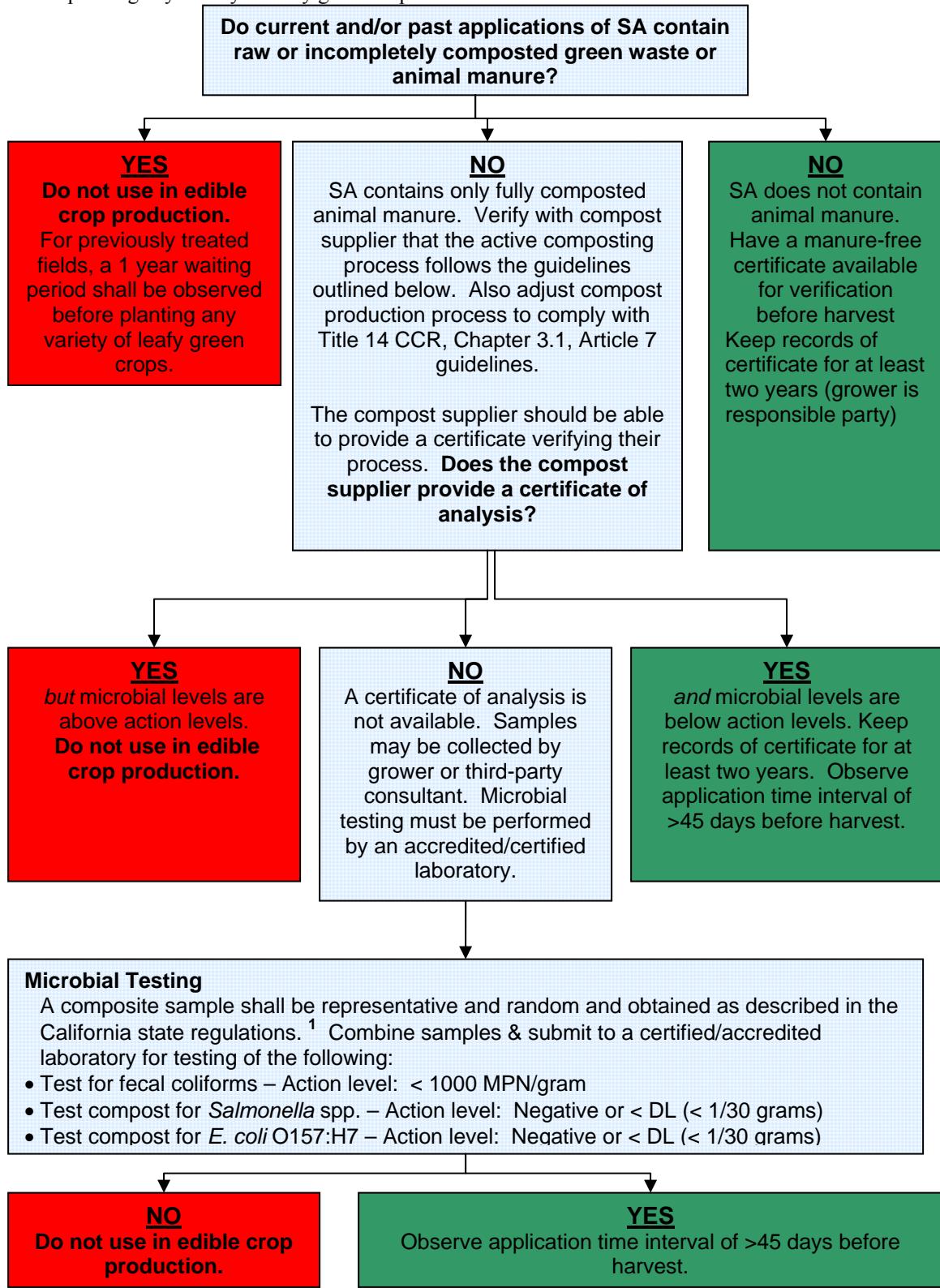
- The microbial metrics and validated processes for compost are based on allowable levels from California state regulations (CCR Title 14 - Chapter 3.1 - Article 7 2007), with the addition of testing for *E. coli* O157:H7 as the microbe of particular concern. A more stringent level of fecal coliform was also included to address the much more controlled nature of 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.
- FDA has established the validity of D-values and Z-values for key pathogens of concern in foods. This method of process validation is currently acceptable to US regulators. Alternatively, results of an inoculated test pack utilizing the specific process is also an acceptable validation of the lethality of the process.

Soil Amendments Not Containing Animal Manure	<ul style="list-style-type: none">• 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 producer who is the responsible party for a period of two years.
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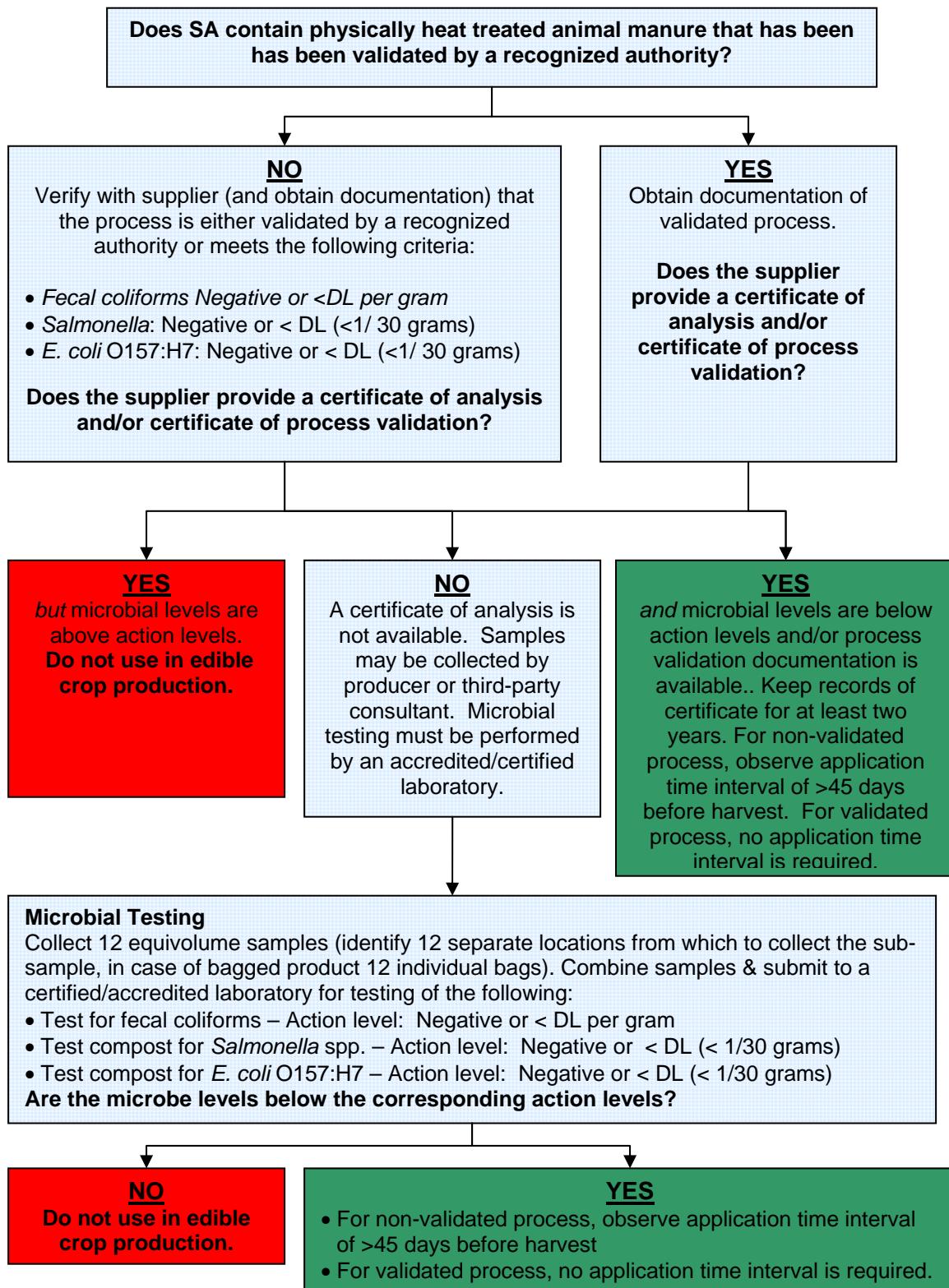
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Figure 2A. Decision Tree for Composted Soil Amendments (SA)

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.



514

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

521 7. **ISSUE: NONSYNTHETIC CROP TREATMENTS**

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

530 **The Best Practices Are:**

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

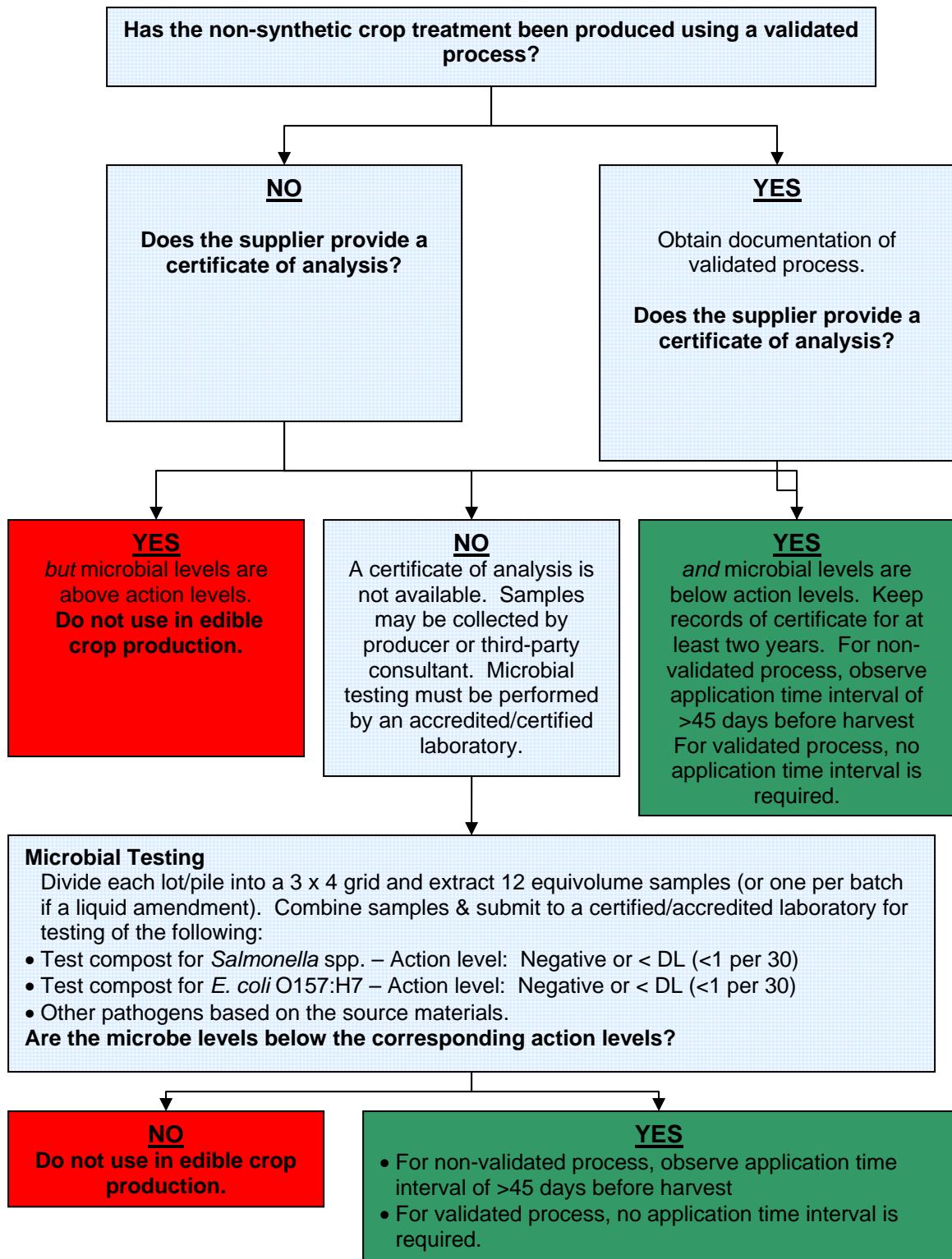
TABLE 3. NONSYNTHETIC CROP TREATMENTS

Treatment	Metric/Rationale
<p><i>Any crop input that contains animal manure, an animal product, and/or an animal by-product that is reasonably likely to contain human pathogens.</i></p> <p>Examples include but are not limited to:</p> <ul style="list-style-type: none"> • Compost teas, • Fish emulsions • Fish meal • Blood meal • "Bio-fertilizers" commonly used for pest control, greening, disease control, fertilizing. <p>Suppliers of these products shall disclose on labels, certificates of analysis, or other companion paperwork whether the product contains any animal manure or products.</p>	<p>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.</p> <p>Please see Figure 3: Decision Tree for Use of Nonsynthetic Crop Treatments.</p> <p>Process Validation:</p> <ul style="list-style-type: none"> • The physical, chemical and/or biological treatment process(es) used to render the crop input safe for application to edible crops must be validated. <p>Target Organism:</p> <ul style="list-style-type: none"> • <i>Salmonella</i> spp • <i>E. coli</i> O157:H7 <p>Acceptance Criteria (at point of use):</p> <ul style="list-style-type: none"> • <i>Salmonella</i>: Negative or < DL (<1/ 30 grams) • <i>E. coli</i> O157:H7: Negative or < DL (<1/ 30 grams) • Other pathogens appropriate for the source material <p>Recommended Test Methods:</p> <ul style="list-style-type: none"> • <i>Salmonella</i> spp: U.S. EPA Method 1682 • <i>E. coli</i> O157:H7: Any laboratory validated method for the non synthetic material to be tested. • Other U.S. EPA, FDA, AOAC, TMECC or, accredited methods may be used as appropriate <p>Sampling Plan:</p> <ul style="list-style-type: none"> • 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 <p>Testing Frequency:</p> <ul style="list-style-type: none"> • Each lot before application to production fields.

Treatment	Metric/Rationale
	<p>Application Interval:</p> <ul style="list-style-type: none"> • 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. <p>Documentation:</p> <ul style="list-style-type: none"> • All test results and/or Certificates of Analysis shall be documented and available from the producer for verification for a period of 2 years. The producer the party responsible party for maintaining the appropriate records. <p>Rationale:</p> <ul style="list-style-type: none"> • 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 <i>E. coli</i> 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.

561

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



568 **Note: Mixtures of soil amendment materials**

569

570 For soil amendments that contain mixtures of materials each component must meet the
571 requirements of its respective class of materials. The usages allowed will conform to that of
572 the most stringent class of materials utilized in the mixture.

573

574 For example; Soil amendments containing animal manure that has been physically heat
575 treated or processed by other equivalent methods mixed with soil amendments not containing
576 animal manure would require a process certification for the physically heat treated or
577 processed by other equivalent methods materials and the components from non-animal
578 manure would require documentation attesting to its manure free status. The resulting
579 mixture could then be applied in accordance with the guidelines associated with the
580 physically heated treated class of materials (most stringent limits).

581 **8. ISSUE: HARVEST EQUIPMENT**

582 This section addresses harvest and harvest aid equipment used for lettuce/leafy greens.
583 Mechanical or machine harvest has become increasingly prevalent and provides opportunity
584 for increased surface contact exposure. This includes field cored lettuce operations that use
585 various harvest equipment and aids.

586

587 **The Best Practices Are:**

- 588 • Prepare an SOP for harvest equipment that addresses the following:
 - 589 ○ Sanitation verification
 - 590 ○ Daily inspection
 - 591 ○ Proper cleaning, sanitation and storage of hand harvest equipment (knives,
592 scythes, etc.)
 - 593 ○ Control procedures when equipment is not in use, including policy for
594 removal of equipment from the work area or site and the use of scabbards,
595 sheathes or other storage equipment.
- 596 • Prepare an SOP for handling and storage of product containers that addresses the
597 following:
 - 598 ○ Overnight storage
 - 599 ○ Contact with the ground
 - 600 ○ Container assembly (RPC, fiber bin, plastic bin, etc)
 - 601 ○ Damaged containers
 - 602 ○ Use of containers only as intended
- 603 • Prepare an SOP for sanitary operation of equipment which addresses:
 - 604 ○ Spills and leaks
 - 605 ○ Inoperative water sprays
 - 606 ○ Exclusion of foreign objects (including glass, plastic, metal and other
607 debris)

608 ○ Establish and implement cleaning and sanitation schedules for containers
609 and equipment that will be used in hydration.

610 ○ Maintain logs documenting cleaning and sanitation, and retain these
611 records for at least two years.

612 ○ Establish policies for the storage and control of water tanks and
613 equipment used for hydration operations when not in use.

614

615 ● Establish appropriate measures that reduce and control the potential introduction
616 of human pathogens at the cut surface during and after mechanical harvest
617 operations. Due to the cut surface being more vulnerable to microbial
618 contamination, this best practice is extremely important and all practical means
619 should be taken to reduce the possibility of introduction of contamination at this
620 process step.

621 ● If re-circulated rinse or antioxidant solutions are used on the cut surface, take all
622 practicable precautions to prevent them from becoming a source of
623 contamination.

624 ● Design equipment to facilitate cleaning by using materials and construction that
625 facilitate cleaning and sanitation of equipment food contact surfaces (e.g.,
626 transportation tarps, conveyor belts, etc.).

627 ● Establish the frequency of equipment cleaning and sanitation by developing
628 Sanitation Standard Operating Procedures (SSOPs) and a sanitation schedule for
629 machine harvest operations.

630 ● Evaluate the use of cleaning verification methods for harvesting equipment (e.g.,
631 ATP test methods).

632 ● Locate equipment cleaning and sanitizing operations away from product and other
633 equipment to reduce the potential for cross contamination.

634 ● Establish equipment storage and control procedures to minimize the potential for
635 contamination when not in use. Establish policies and sanitary design options that
636 facilitate frequent and thorough cleaning and sanitizing of food contact surfaces.

637 ● Develop and implement appropriate cleaning, sanitizing, storage and handling
638 procedures of all food contact surfaces to reduce and control the potential for
639 microbial cross contamination.

640 ● Allow adequate distance for the turning and manipulation of harvest equipment to
641 prevent cross contamination from areas or adjacent land, that may pose a risk.

642

643 9. **ISSUE: HARVEST PERSONNEL - DIRECT CONTACT WITH SOIL DURING HARVEST**
644 **(FIELD SANITATION)**

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

649

650 **The Best Practices Are:**

651 • Evaluate appropriate measures that reduce and control the potential introduction
652 of human pathogens through soil contact at the cut surface after harvest (e.g.
653 frequency of knife sanitation, no placement of cut surfaces of harvested product
654 on the soil, container sanitation, single use container lining, etc.).

655 • Do not stack soiled bins on top of each other if the bottom of one bin has had
656 direct contact with soil unless a protective barrier (*i.e.*, liner, cover, *etc.*) is used
657 to separate the containers..

658

659 **10. ISSUE: FIELD AND HARVEST PERSONNEL - TRANSFER OF HUMAN PATHOGENS**
660 **BY WORKERS (FIELD SANITATION)**

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

665 **The Best Practices Are:**

666 • Use appropriate preventive measures outlined in GAPs such as training in appropriate
667 and effective hand washing, glove use and replacement, and mandatory use of
668 sanitary field latrines to reduce and control potential contamination.

669 • Establish a written worker practices program (*i.e.*, an SOP) that can be used to verify
670 employee compliance with company food safety policy. This program shall establish
671 the following practices for field and harvest employees as well as visitors.

672 ○ Prior to harvest, an individual should be designated as responsible for
673 harvesting food safety

674 ○ Use, storage, record keeping, and proper labeling of chemicals

675 ○ Training on proper sanitation and hygiene practices

676 ○ Requirements for workers to wash their hands before beginning or returning
677 to work

678 ○ Confinement of smoking, eating and drinking of beverages other than water
679 to designated areas.

680 ○ Prohibitions on spitting, urinating or defecating in the field.

681 ○ Personal item storage

682 • A written physical hazard prevention program should be developed for leafy green
683 products that are intended for further processing. The program must address the
684 following:

685 ○ Employee clothing and jewelry (head and hair restraints, aprons, gloves,
686 visible jewelry, etc.)

687 ○ Removal of all objects from upper pockets

688 ○ Foreign objects in the field.

689 • Establish a worker health practices program (i.e., an SOP) that address the following
690 issues:
691 ○ Workers with diarrhea disease or symptoms of other infectious disease are
692 prohibited from handling fresh produce.
693 ○ Workers with open cuts or lesions are prohibited from handling fresh produce
694 without specific measures to prevent cross contamination of product.
695 ○ Actions for employee to take in the event of injury or illness.
696 ○ A policy describing procedures for handling/disposition of produce or food
697 contact surfaces that have come into contact with blood or other body fluids.
698 • A field sanitary facility program (i.e., an SOP) shall be implemented, and it should
699 address the following issues: the number, condition, and placement of field sanitation
700 units, the accessibility of the units to the work area, facility maintenance, facility
701 supplies (i.e., hand soap, water, paper towels, toilet paper, etc.), facility signage,
702 facility cleaning and servicing, and a response plan for major leaks or spills.
703 ○ Sanitary facilities should be placed such that the location minimizes the
704 impact from potential leaks and/or spills while allowing access for cleaning
705 and service.
706 ○ The location and sanitary design of toilets and hand wash facilities should be
707 optimized to facilitate the control, reduction and elimination of human
708 pathogens from employee hands. Evaluate the location of worker hygiene
709 facilities to maximize accessibility and use, while minimizing the potential
710 for the facility to serve as a source of contamination.
711 ○ Establish the frequency of toilet and hand washing facility
712 maintenance/sanitation.
713 ○ Establish equipment and supply storage and control procedures when not in
714 use.
715 ○ Maintain documentation of maintenance and sanitation schedules and any
716 remedial practices for a period of two years.

717 **11. ISSUE: EQUIPMENT FACILITATED CROSS CONTAMINATION (FIELD**
718 **SANITATION)**

719 When farm equipment has had direct contact with raw untreated manure, untreated compost,
720 waters of unknown quality, animals, or other potential human pathogen reservoirs it may be a
721 source of cross contamination. Such equipment should not be used in proximity to or in
722 areas where it may contact edible portions of lettuce and or leafy greens without proper
723 sanitation.

724
725 **The Best Practices Are:**

726 • Identify any field operations that may pose a risk for cross-contamination. These
727 include management personnel in the fields, vehicles used to transport workers,
728 as well as many other possibilities.
729 • Segregate equipment used in high-risk operations or potentially exposed to high
730 levels of contamination.

731 • Use effective means of equipment cleaning and sanitation before subsequent
732 equipment use in lettuce/leafy greens production, if it was previously used in a
733 high-risk operation.

734 • Develop appropriate means of reducing and controlling the possible transfer of
735 human pathogens to soil and water that may directly contact edible lettuce/leafy
736 green tissues through use of equipment.

737 • Maintain appropriate records related to equipment cleaning and possible cross-
738 contamination issues for a period of two years.

739

740 **12. ISSUE: FLOODING**

741 Flooding for purposes of this document is defined as the flowing or overflowing of a field
742 with water outside of a producer's control, that is reasonably likely to contain
743 microorganisms of significant public health concern and is reasonably likely to cause
744 adulteration of the edible portions of fresh produce in that field. Pooled water (e.g., rainfall)
745 that is not reasonably likely to contain microorganisms of significant public health concern
746 and is not reasonably likely to cause adulteration of the edible portion of fresh produce
747 should not be considered flooding.

748

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

753

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

763

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

770

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

776

777 **The Best Practices For Product That Has Come Into Contact With Flood Water**
778 **Are:**

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

787

788

789

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 producer's control that is reasonably likely to contain microorganisms of significant public health concern and is reasonably likely to cause adulteration of edible portions of fresh produce in that field. Additional discussion of this definition and implications for production is provided in the text portion of this document.
Allowable Harvest Distance from Flooding	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 <i>Soil Screening Guidance: Technical Background Document</i> (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	<ul style="list-style-type: none"> • 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.

790

791

792 **The Best Practices for Product in Proximity to a Flooded Area But Not Contacted**
793 **By Flood Water Are:**

794 • Prevent cross contamination between flooded and non-flooded areas (e.g.
795 cleaning equipment, eliminating contact of any farming or harvesting equipment
796 or personnel with the flooded area during growth and harvest of non-flooded
797 areas).

798 • To facilitate avoiding contaminated/adulterated produce, place markers
799 identifying both the high-water line of the flooding and an interval 30 feet beyond
800 this line. If 30 feet is not sufficient to prevent cross contamination while turning
801 harvesting or other farm equipment in the field, use a greater appropriate interval.
802 Take photographs of the area for documentation. Do not harvest product within
803 the 30 foot buffer zone.

804

805 **The Best Practices For Formerly Flooded Production Ground Are:**

806 • Prior to replanting or soil testing, the designated food safety professional for the
807 producer shall perform a detailed food safety assessment of the production field.
808 This designated professional will be responsible for assessing the relative merits
809 of testing versus observing the appropriate time interval for planting, and also
810 will coordinate any soil testing plan with appropriate third-party consultants
811 and/or laboratories that have experience in this type of testing.

812 • Evaluate the source of flood waters (e.g., drainage canal, river, irrigation canal,
813 etc.) for potential significant upstream contributors of human pathogens at levels
814 that pose a significant threat to human health.

815 • Allow soils to dry sufficiently and be reworked prior to planting subsequent crops
816 on formerly flooded production ground.

817 • Do not replant formerly flooded production ground for at least 60 days following
818 the receding of floodwaters. This period or longer and active tillage of the soil
819 provide additional protection against the survival of pathogenic organisms.

820 • If flooding has occurred in the past on the property, soil clearance testing may be
821 conducted prior to planting leafy greens. Soil testing may be used to shorten the
822 clearance period to 30 days. If performed, testing must indicate soil levels of
823 microorganisms lower than the standards for processed compost. Suitable
824 representative samples should be collected for the entire area suspected to have
825 been exposed to flooding.

826 • Sample previously flooded soil for the presence of microorganisms of significant
827 public health concern or appropriate indicator microorganisms. Microbial soil
828 sampling can provide valuable information regarding relative risks; however,
829 sampling by itself does not guarantee that crops grown within the formerly
830 flooded production area will be free of the presence of human pathogens.

831 • Evaluate the field history and crop selection on formerly flooded production
832 ground.

833 • Assess the time interval between the flooding event, crop planting, and crop
834 harvest. Comparative soil samples may be utilized to assess relative risk if

835 significant reductions in indicator microorganisms have occurred within this time
836 interval.

837 • Prevent cross-contamination by cleaning or sanitizing any equipment that may
838 have contacted previously flooded soil (also see the section on Equipment
839 Facilitated Cross Contamination above).

840 **13. ISSUE: PRODUCTION LOCATIONS - CLIMATIC CONDITIONS AND ENVIRONMENT**

841 Lettuce/leafy greens are grown in varying regions but generally in moderate weather
842 conditions. Cool, humid conditions favor human pathogen persistence (Takeuchi and Frank
843 2000; Takeuchi *et al.* 2000) while drier climates may present other problems such as
844 requirements for additional water that may increase the potential for introduction of human
845 pathogens. Heavy rains in certain areas may also cause lettuce/leafy greens to be exposed to
846 contaminated soil due to rain splashing. It is important to tailor practices and procedures
847 designed to promote food safety to the unique environment in which each crop may be
848 produced

849 **The Best Practices Are:**

850 • Consider harvest practices such as removing soiled leaves, not harvesting soiled
851 heads, etc., when excessive soil or mud builds up on lettuce/leafy greens.

852 • Take care to reduce the potential for windborne soil, including soil from roads
853 adjacent to fields, water, or other media that may be a source of contamination to
854 come into direct contact with the edible portions of lettuce and leafy greens. Do not
855 allow runoff from adjacent properties to come into contact with produce.

856 • Evaluate and implement practices to reduce the potential for the introduction of
857 pathogens into production blocks by wind or runoff. Such practices may include but
858 are not limited to berms, windbreaks, diversions ditches and vegetated filter strips.

859 • When soil has accumulated on plants, remove soil during the harvest or further
860 processing.

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

863 Lettuce/leafy greens are generally grown in rural areas that may have adjacent wetlands,
864 wildlands, parks and/or other areas where animals may be present. Some animal species are
865 known to be potential carriers of various human pathogens (Fenlon 1985; Gorski *et al.* 2011;
866 jay *et al.* 2007; keene *et al.* 1997; LeJeune *et al.* 2008; perz *et al.* 2001). In addition, extensive
867 development in certain farming communities has also created situations with urban
868 encroachment and unintentional access by domestic animals and/or livestock which may also
869 pose varying degrees of risk. Finally, it is possible that some land uses may be of greater
870 concern than others when located near production fields. Table 6 provides a list of these uses
871 and recommended buffer distances.

875 **The Best Practices Are:**

- 876 • See Tables 5 and 6 and Decision Tree (Figure 5) for numerical criteria and
877 guidance applicable to animal encroachment and adjacent land uses. The
878 “Technical Basis Document” (Appendix B) describes the process used to develop
879 these metrics.
- 880 • During the Environmental Assessments discussed in Section 2, the location of
881 any adjacent land uses that are likely to present a food safety risk should be
882 documented. In addition, as specified in Table 6, any deviations from the
883 recommended buffer distances due to mitigation factors or increased risk should
884 be documented.
- 885 • Evaluate and monitor animal activity in and proximate to lettuce/leafy greens
886 fields and production environments. Conduct and document periodic monitoring,
887 and pre-season, pre-harvest, and harvest assessments. If animals present a
888 probable risk (medium/high hazard), make particular efforts to reduce their
889 access to lettuce and leafy green produce.
- 890 • Fencing, vegetation removal, and destruction of habitat may result in adverse
891 impacts to the environment. Potential adverse impacts include loss of habitat to
892 beneficial insects and pollinators; wildlife loss; increased discharges of sediment
893 and other pollutants resulting from the loss of vegetative filtering; and increased
894 air quality impacts if bare soil is exposed to wind. It is recommended that
895 producers check for local, state, and federal laws and regulations that protect
896 riparian habitat and wetland areas, restrict removal of vegetation or habitat, or
897 regulate wildlife deterrence measures, including hazing, harassment, lethal and
898 non-lethal removal, etc.
- 899 • Evaluate the risk to subsequent crop production on production acreage that has
900 experienced recent postharvest grazing with or by domesticated animals that used
901 field culls as a source of animal feed.
- 902 • Document any probable risk (medium/high hazard) during production and/or
903 harvest periods and take appropriate corrective action per Table 5 in LGMA
904 metrics.
- 905 • Locate production blocks to minimize potential access by animals and maximize
906 distances to possible sources of microbial contamination. For example, consider
907 the proximity to water (i.e., riparian areas), animal harborage, open range lands,
908 non-contiguous blocks, urban centers, etc. Periodically monitor these factors and
909 assess during preseason and pre-harvest assessments as outlined in Tables 5 and
910 6. If the designated food safety professional deems that there is the potential for
911 microbial contamination from adjacent areas, a risk assessment shall be
912 performed to determine the risk level as well as to evaluate potential strategies to
913 control or reduce the introduction of human pathogens.
- 914 • DO NOT harvest areas of fields where unusually heavy activity by animals
915 occurred. If animal intrusions are common on a particular production field,
916 consider fencing, barriers, noisemakers, and other practices that may reduce
917 intrusions.

918 • Train harvest employees to recognize and report evidence (e.g., feces) of animal
919 activity.

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

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

925 • Producers are encouraged to contact the relevant agencies (e.g., the Regional
926 Water Quality Control Board and state and federal fish and wildlife agencies) to
927 confirm the details of these requirements. In addition, producers may wish to
928 consult with local NRCS to evaluate the food safety risks associated with
929 wildlife, livestock, domestic animals and other adjacent land uses and to develop
930 and document strategies to control or reduce the introduction of human pathogens
931 for each production block.

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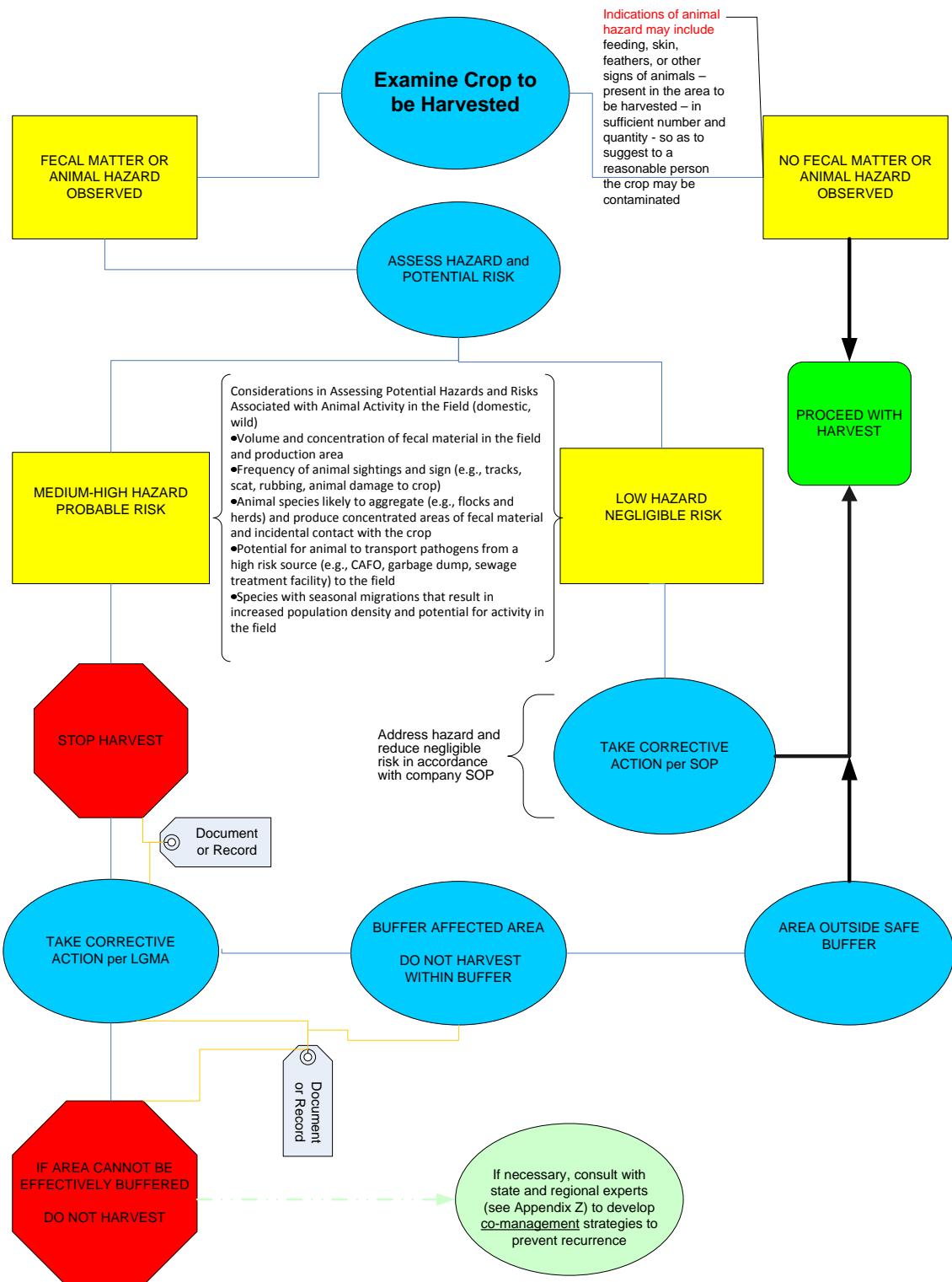
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Figure 5. PRE-HARVEST and HARVEST Assessment – Animal Hazard/Fecal Matter Decision Tree



953

TABLE 5. ANIMAL HAZARD IN FIELD (WILD OR DOMESTIC)

When evidence of animal intrusion in a production block occurs.

Issue	Metric	Remedial Actions
Evidence of Intrusion	<u>Frequency</u> <ul style="list-style-type: none"> There shall be a periodic monitoring plan in place for production fields. There shall be Pre Season, Pre Harvest, and Harvest Assessments <u>Variables</u> <ul style="list-style-type: none"> Physical observation of animals in the field Downed fences Animal tracks in production block Animal feces or urine in production block Damaged or eaten plants in production block 	<ul style="list-style-type: none"> If there is evidence of intrusion by animals, the production block must undergo a detailed food safety assessment by appropriately trained food safety personnel (see Glossary) prior to harvest, as defined in the text of this document. Animal intrusion events shall be categorized as low or medium/high hazard. An example of a low hazard might be a sign of animal intrusion into the leafy green production area by a single animal or solitary bird with minimal to no fecal deposition. Corrective actions for “Low hazard” animal intrusion shall be carried out according to company SOP. Corrective actions for “medium/high hazard” animal intrusion shall be carried out per the accepted LGMA metrics and must include food safety buffers and do not harvest areas. In developing preventive remedial and corrective actions, consider consulting with wildlife and/or domestic animal experts as appropriate. If remedial actions, such as appropriate no harvest buffers, cannot be formulated to control or eliminate the identified risk, do not harvest and instead destroy the contaminated crop. Equipment used to destroy crop must be cleaned and sanitized upon exiting the field. Formulate effective corrective actions. Prior to taking action that may affect natural resources, producers should check local, state and federal laws and regulations that protect riparian habitat and wetland areas, restrict removal of vegetation or habitat, or restrict construction of wildlife deterrent fences in riparian areas or wildlife corridors. Food safety assessments and corrective actions shall be documented and available for verification for a period of two years.

Issue	Metric	Remedial Actions
Allowable Harvest Distance from Evidence of Intrusion	<p>Please see Figure 5. Decision Tree for Conducting Pre-Harvest and Harvest Assessments.</p> <p><u>Monitoring</u> Conduct periodic monitoring and, pre-season, pre-harvest and harvest assessments. Evaluate and monitor animal activity in and proximate to lettuce/leafy greens fields and production environments.</p> <p><u>Pre Harvest Assessment and Daily Harvest Assessment</u></p> <ul style="list-style-type: none"> Conduct the pre-harvest assessment not more than one week prior to harvest. Conduct the daily harvest assessment on each day of harvest. 	
	<p>Fecal Material</p> <ul style="list-style-type: none"> Do not harvest any produce that has come into direct contact with fecal material. If evidence of fecal material is found, conduct a food safety assessment using qualified personnel. Do not harvest any crop found within a minimum 5 foot radius buffer distance from the spot of the contamination unless remedial action can be found that adequately control the risk. The food safety professional can increase this buffer distance if deemed appropriate. <p>Intrusion</p> <ul style="list-style-type: none"> If evidence of animal intrusion is found in a production field, conduct a visual food safety assessment to determine whether the intrusion is a probable (medium/high hazard) or negligible (low hazard) risk. Low hazard (negligible risk) can be corrected by following a company SOP. Medium/high hazard (probable risk) intrusion should include a three foot buffer radius where the impacted crop has been isolated. <p><u>Daily Harvest Assessment ONLY</u></p> <p>If evidence of medium/high hazard risk animal intrusion into the production block is not discovered until harvest operations:</p> <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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		<ul style="list-style-type: none"> The basis of these metrics is qualitative assessment of the relative risk from a variety of intrusions. Some animal feces and some signs of intrusion (feces vs. tracks) are considered to be of more concern than others. Because it is difficult to develop quantitative metrics for these types of risks, a food safety assessment is considered appropriate for this issue. Individual companies need to make the determination as to the level of hazard after considering the following risk factors: the concentration and volume of fecal matter, frequency of animals (observed or indicators) in the field, density of animal population and surrounding area risk – all identified during a risk assessment. A trained food safety professional should be involved in decisions related to animal intrusion. See Appendix B for more details on the qualifications for this person. Appendix B describes in detail the process used to develop these metrics

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TABLE 6. CROP LAND AND WATER SOURCE ADJACENT LAND USE

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)	<p>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.</p> <p>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.</p>	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)	<p>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.</p> <p>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.</p>	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)	<p>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.</p> <p>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.</p>	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	√	

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
	For non-synthetic crop treatments that have been heat treated using a validated process an interim guidance distance of 30 feet from the edge of the crop is proposed	Covering on pile to prevent wind dispersion		✓
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	At least 100 feet separation for sandy soil and 200 feet	Topography: Uphill from manure		✓

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
Untreated Manure	separation for loamy or clay soil (slope less than 6%; increase distance to 300 feet if slope greater than 6%) is recommended.	Topography: Downhill from manure	√	
		Opportunity for water runoff from or through untreated manure to surface waters.	√	
		Opportunity for soil leaching	√	
		Presence of physical barriers such as windbreaks, diversion ditches, vegetative strips		√
Rationale	<ul style="list-style-type: none"> 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. 			

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

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968 15. **DETAILED BACKGROUND GUIDANCE INFORMATION**

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970 **Required Reference Documents**

971

972 1. FDA Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables
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974 2. UFFVA Food Safety Auditing Guidelines: Core Elements of Good Agricultural Practices for Fresh
 975 Fruits and Vegetables

976 3. UFFVA Food Safety Questionnaire for Fresh Fruits and Vegetables

977 4. National GAPs Program Cornell University: Food Safety Begins on the Farm: A Grower Self
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