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

AUGUST 2, 2013

Authors Note: This document supersedes all previously published versions of the Commodity Specific Food Safety Guidelines for the Production and Harvest of Leafy Greens including those dated March 23, 2007, April 18, 2007 June 5, 2007, October 16, 2007, June 13, 2008, July 10, 2009, January 29, 2010, August 4, 2010, July 22, 2011, January 20, 2012 and August 31,2012

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87 GLOSSARY

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.
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.
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.
<i>E. coli</i>	<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 grower’s control that is reasonably likely to contain microorganisms of significant public health concern and is reasonably likely to cause adulteration of edible portions of fresh produce in that field.
food contact surface	A surface of equipment or a utensil with which food normally comes into contact, or from which food may drain, drip or splash into a food or onto a surface normally in contact with food.
food safety assessment	A standardized procedure that predicts the likelihood of harm resulting from exposure to chemical, microbial and physical agents in the diet.
food safety personnel	Person trained in basic food safety principals 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 $(X_1)(X_2)...(X_n)$, 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. 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
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.
Ready To Eat (RTE) food <i>(excerpted from USFDA 2005 Model Food Code)</i>	(1) "Ready-to-eat food" means FOOD that: (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. (2) "Ready-to-eat food" includes: (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 -- to carry water from its primary source to a lettuce and leafy green crop.

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

128 [Appendix A](#): Sanitary Survey [Appendix B](#): Technical Basis Document

129 [Appendix C](#): Crop Sampling Protocol [Appendix Z](#): CA Resource Agency Contacts

130 [Appendix D](#): Kinetics of Microbial Inactivation for Alternative Food Processing Technologies

131 Appendix E: Environmental Health Standards for Composting Operations (California Code of

132 Regulations)

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134 **INTRODUCTION**

135
136 In 1998, the U.S. Food and Drug Administration (FDA) issued its “Guide to Minimize Microbial
137 Food Safety Hazards for Fresh Fruits and Vegetables.” The practices outlined in this and other
138 industry documents are collectively known as Good Agricultural Practices or GAPs. GAPs provide
139 general food safety guidance on critical production steps where food safety might be compromised
140 during the growing, harvesting, transportation, cooling, packing and storage of fresh produce. More
141 specifically, GAP guidance alerts fruit and vegetable growers, shippers, packers and processors to the
142 potential microbiological hazards associated with various aspects of the production chain including:
143 land history, adjacent land use, water quality, worker hygiene, pesticide and fertilizer use, equipment
144 sanitation and product transportation. The vast majority of the lettuce/leafy greens industry has
145 adopted GAPs as part of normal production operations. Indeed the majority of lettuce/leafy greens
146 producers undergo either internal or external third-party GAP audits on a regular basis to monitor and
147 verify adherence to their GAPs programs. These audit results are often shared with customers as
148 verification of the producer’s commitment to food safety and GAPs.

149
150 While the produce industry has an admirable record of providing the general public with safe,
151 nutritious fruits and vegetables, it remains committed to continuous improvement with regard to food
152 safety. In 2004, the FDA published a food safety action plan that specifically requested produce
153 industry leadership in developing the next generation of food safety guidance for fruit and vegetable
154 production. These new commodity-specific guidelines focus on providing guidance that enhances the
155 safe growing, processing, distribution and handling of commodities from the field to the end user.
156 The 1st Edition of these new voluntary guidelines were published by the industry in April 2006.

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

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

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

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

185 SCOPE

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

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

203
204 Lettuce/leafy greens present multiple opportunities to employ food safety risk management practices
205 to enhance the safety of lettuce/leafy greens. In the production and harvest of lettuce and leafy greens
206 as raw agricultural commodities, GAPs are commonly employed in order to produce the safest
207 products possible. In a processing operation, the basic principles of cGMPs, HACCP, sanitation and
208 documented operating procedures are commonly employed in order to produce the safest products
209 possible. Lettuce/leafy greens are highly perishable and it is strongly recommended that they be
210 distributed, stored and displayed under refrigeration.

211
212 Safe production, packing, processing, distribution and handling of lettuce/leafy greens depend upon a
213 myriad of factors and the diligent efforts and food safety commitment of many parties throughout the
214 distribution chain. No single resource document can anticipate every food safety issue or provide
215 answers to all food safety questions. These guidelines focus on minimizing only the microbial food
216 safety hazards by providing suggested actions to reduce, control or eliminate microbial
217 contamination of lettuce/leafy greens in the field to fork distribution supply chain.

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

224
225 These guidelines are intended only to convey the best practices associated with the industry. The
226 Produce Marketing Association, the United Fresh Produce Association, Western Growers, and all
227 other contributors and reviewers make no claims or warranties about any specific actions contained
228 herein. It is the responsibility of any purveyor of food to maintain strict compliance with all local,
229 state and federal laws, rules and regulations. These guidelines are designed to facilitate inquiries and
230 developing information that must be independently evaluated by all parties with regard to compliance
231 with legal and regulatory requirements. The providers of this document do not certify compliance
232 with these guidelines and do not endorse companies or products based upon their use of these
233 guidelines.

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

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

249
250 Users are encouraged to utilize the services of their trade associations, the U.S. Food and Drug
251 Administration, the Center for Produce Safety, the U.S. Department of Agriculture, the U.S.
252 Environmental Protection Agency, the Centers for Disease Control and Prevention, and state
253 agricultural, environmental, academic, wildlife and natural resources management agencies and/or
254 public health authorities.

255 The Sanitary Survey and Technical Basis Documents prepared as Appendices to these guidelines are
256 considered to be additional resources. They are intended to provide clarification, assist with
257 interpretation and provide additional guidance as users develop food safety programs based on these
258 Guidelines. They are not intended for measurement or verification purposes.

259 **Lettuce/Leafy Greens Commodity Specific Guidance**
260 **Production & Harvest Unit Operations**
261

262 **1. PURPOSE**

263 The issues identified in this document are based on the core elements of Good Agricultural Practices.
264 The specific recommendations contained herein are intended for lettuce and leafy greens only. If
265 these specific recommendations are effectively implemented this would constitute the best practices
266 for a GAP program for the production and harvest unit operations of lettuce and leafy greens.
267

268 **2. ISSUE: GENERAL REQUIREMENTS**

269 In addition to the area-specific requirements discussed in latter sections, there are several general
270 requirements that are part of an effective best practices program. These requirements are outlined
271 below.
272

273 **2.1. The Best Practices Are:**

- 274 • A written Leafy Greens Compliance Plan which specifically addresses the Best Practices
275 of this document shall be prepared. This plan shall address at least the following areas:
276 water, soil amendments, environmental factors, work practices, and field sanitation.
- 277 • Handlers shall have an up to date growers list with contact and location information on
278 file.
- 279 • The handler shall comply with the requirements of The Public Health Security and
280 Bioterrorism Preparedness and Response Act of 2002 (farms are exempt from the Act)
281 including those requirements for recordkeeping (traceability) and registration.
- 282 • Each grower and handler shall designate an individual responsible for their operation’s
283 food safety program. Twenty-four hour contact information shall be available for this
284 individual in case of food safety emergencies.

285
286 **3. ISSUE: ENVIRONMENTAL ASSESSMENTS**

287 This section addresses assessments that shall be completed and documented prior to the first seasonal
288 planting, within one week prior to harvesting and during harvest operations. These environmental
289 assessments are intended to identify any issues related to the produce field, adjacent land uses, and/or
290 animal hazards that may present a risk to the production block or crop (see Table 5).
291

292 **3.1. The Best Practices Are:**

- 293 • Prior to the first seasonal planting and within one week prior to harvest, perform and
294 document an environmental risk assessment of the production field and surrounding area.
295 Focus these assessments on evaluating the production field for possible animal hazards or
296 other sources of human pathogens of concern, assessing adjacent land uses for possible

297 sources that might contaminate the production field, and evaluating nearby water sources
298 for the potential of past or present flooding.

- 299 ○ Assessment of Produce Field
- 300 ▪ Evaluate all produce fields for evidence of animal hazards and/or feces. If
301 any evidence is found, follow procedures identified in the “Production
302 Locations - Encroachment by Animals and Urban Settings.”
- 303 ○ Assessment of Adjacent Land Use
- 304 ▪ Evaluate all land and waterways adjacent to all production fields for
305 possible sources of human pathogen of concern. These sources include,
306 but are not limited to manure storage, compost storage, CAFO’s,
307 grazing/open range areas, surface water, sanitary facilities, and
308 composting operations (see Table 6 for further detail). If any possible
309 uses that might result in produce contamination are present, consult with
310 the metrics and refer to Appendix Z.
- 311 ○ Assessment of Historical Land Use
- 312 ▪ To the degree practical, determine and document the historical land uses
313 for production fields and any potential issues from these uses that might
314 impact food safety (i.e., hazardous waste sites, landfills, etc.).
- 315 ○ Assessment of Flooding
- 316 Evaluate all produce fields for evidence of flooding. If any evidence is found,
317 follow procedures identified in the “Flooding” section below.
318

319 **4. ISSUE: WATER**

320 Water used for production and harvest operations may contaminate lettuce and leafy greens if water
321 containing human pathogens comes in direct contact with the edible portions of lettuce/leafy greens.
322 Contamination may also occur by means of water-to-soil followed by soil-to-lettuce/leafy greens
323 contact. Irrigation methods may have varying potential to introduce human pathogens or promote
324 human pathogen growth on lettuce and leafy greens (Stine *et al.*, 2005).
325

326 There are several different approaches and values that can be utilized to ensure that water is of
327 appropriate quality for its intended use. The metrics applied in this edition of the Commodity
328 Specific Guidance should be considered a starting point in industry efforts to continuously improve
329 the quality of water used in production of these commodities.
330

331 The current metrics are intended to provide standards associated with water uses; however, it is
332 known that various water sources have different microbial qualities, and each source should be
333 monitored accordingly. Typical microbial values associated with various sources can be found in the
334 Sanitary Survey document ([Appendix A](#)). During the sanitary survey that is performed prior to each
335 growing season expected microbial values and historical monitoring data should be used to evaluate
336 the quality of the water source.
337

338 **4.1. The Best Practices Are:**

- 339 • A water system description shall be prepared. This description can use maps,
340 photographs, drawings or other means to communicate the location of permanent fixtures

341 and the flow of the water system (including any water captured for re-use.). Permanent
342 fixtures include wells, gates, reservoirs, valves, returns and other above ground features
343 that make up a complete irrigation system should be documented in such a manner as to
344 enable location in the field. Water sources and the production blocks they may serve
345 should be documented.

- 346 • Water systems that convey untreated human or animal waste must be separated from
347 conveyances utilized to deliver irrigation water.
- 348 • Use irrigation water and water in harvest operations that is of appropriate microbial
349 quality for its intended use; see Table 1 and Decision Trees (1A, 1B and 1C) for specific
350 numerical criteria. Appendix B provides the basis for these water quality metrics.
- 351 • Perform a sanitary survey prior to use of water in agricultural operations and if water
352 quality microbial tests are at levels that exceed the numerical values set forth in Table 1.
353 The sanitary survey is described in [Appendix A](#).
- 354 • Test water as close to the point-of-use as practical, and if microbial levels are above
355 specific action levels, take appropriate remedial and corrective actions.
- 356 • Retain documentation of all test results and/or Certificates of Analysis available for
357 inspection for a period of at least 2 years.

358 Other Considerations for water

- 359 ○ Evaluate irrigation methods (drip irrigation, overhead sprinkler, furrow, etc.) for their
360 potential to introduce, support or promote the growth of human pathogens on lettuce
361 and leafy greens. Consider such factors as the potential for depositing soil on the
362 crop, presence of pooled or standing water that attracts animals, etc.
- 363 ○ When waters from various sources are combined, consider the potential for pathogen
364 growth in the water.
- 365 ○ For surface water sources, consider the impact of storm events on irrigation practices.
366 Bacterial loads in surface water are generally much higher after a storm than normal,
367 and caution shall be exercised when using these waters for irrigation.
- 368 ○ Use procedures for storing irrigation pipes and drip tape that reduce or eliminate
369 potential pest infestations. Develop procedures to provide for microbiologically safe
370 use of irrigation pipes and drip tape if a pest infestation does occur.
- 371 ○ Reclaimed water shall be subject to applicable state and federal regulations and
372 standards. Use of this water for agricultural purposes must meet the most stringent
373 standard as defined by the following: state and federal regulation or Table 1 of this
374 document. Water sample results and analysis provided by the water district or
375 provider may be utilized as records of water source testing for verification and
376 validation audits.

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

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

- Due to the timing of application of water that directly contacts edible portions of lettuce/leafy greens, assure the water is of appropriate microbial quality (e.g., meets U.S. EPA microbial standards for drinking water).
- Test the water source periodically to demonstrate it is of appropriate microbial quality for its intended purpose (e.g., meets U.S. EPA or WHO microbial standards for drinking water) or assure that it has appropriate disinfection potential as described in Table1.

391 TABLE 1. WATER USE

Use	Metric	Rationale /Remedial Actions
<p>PREHARVEST Foliar Applications Whereby Edible Portions of the Crop ARE Contacted by Water</p> <p>(e.g. overhead sprinkler irrigation, pesticides/fungicide application, etc.)</p>	<p>Target Organism: generic <i>E. coli</i>.</p> <p>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.</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 no less than 18 hr apart and at least monthly during use from points within the distribution system.</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. This exemption is void if there is a significant source or distribution system change.</p> <p>Test Method: FDA BAM method or any U.S. EPA approved or AOAC accredited method</p>	<p>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).</p> <p>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.</p> <p>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.</p> <p>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:</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 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

	<p>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>	<p>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) 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> <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/handler who is the responsible party for a period of two years.</p>
<p>PREHARVEST Non-foliar Applications Whereby Edible Portions of the Crop are NOT Contacted by Water</p> <p>(e.g., furrow or drip irrigation, dust abatement water; if water is not used in the vicinity of produce, then testing is not necessary)</p>	<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>	<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.</p>
<p>POSTHARVEST Direct Product Contact or Food Contact Surfaces</p>	<p>Microbial Testing 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</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.</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

<p>samples shall be collected at intervals of no less than 18 hr and at least monthly during use.</p> <p>Acceptance Criteria: Negative or below DL for all samples</p>	<p>at point of entry</p> <ul style="list-style-type: none"> 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><u>Physical/Chemical Testing</u></p> <p>Target Variable: Water disinfectant (e.g. chlorine or other disinfectant compound, ORP).</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>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 user of the water for a period of two years.</p>

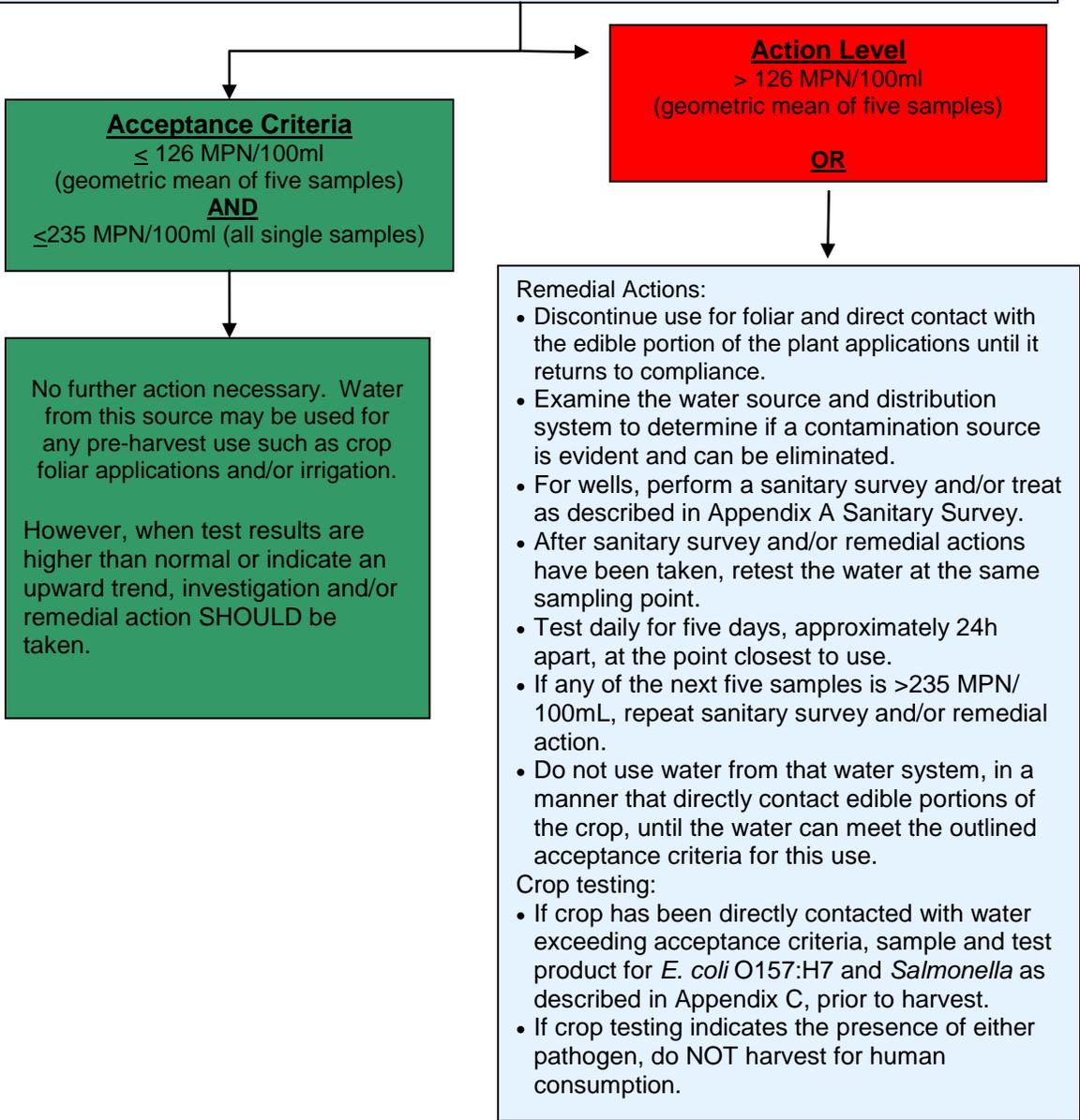
392 **Figure 1A. Decision Tree for PRE-HARVEST WATER USE – Foliar Applications whereby**
 393 **edible portions of the crop are contacted by water (e.g. overhead irrigation, pesticide/fungicide**
 394 **applications)**

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

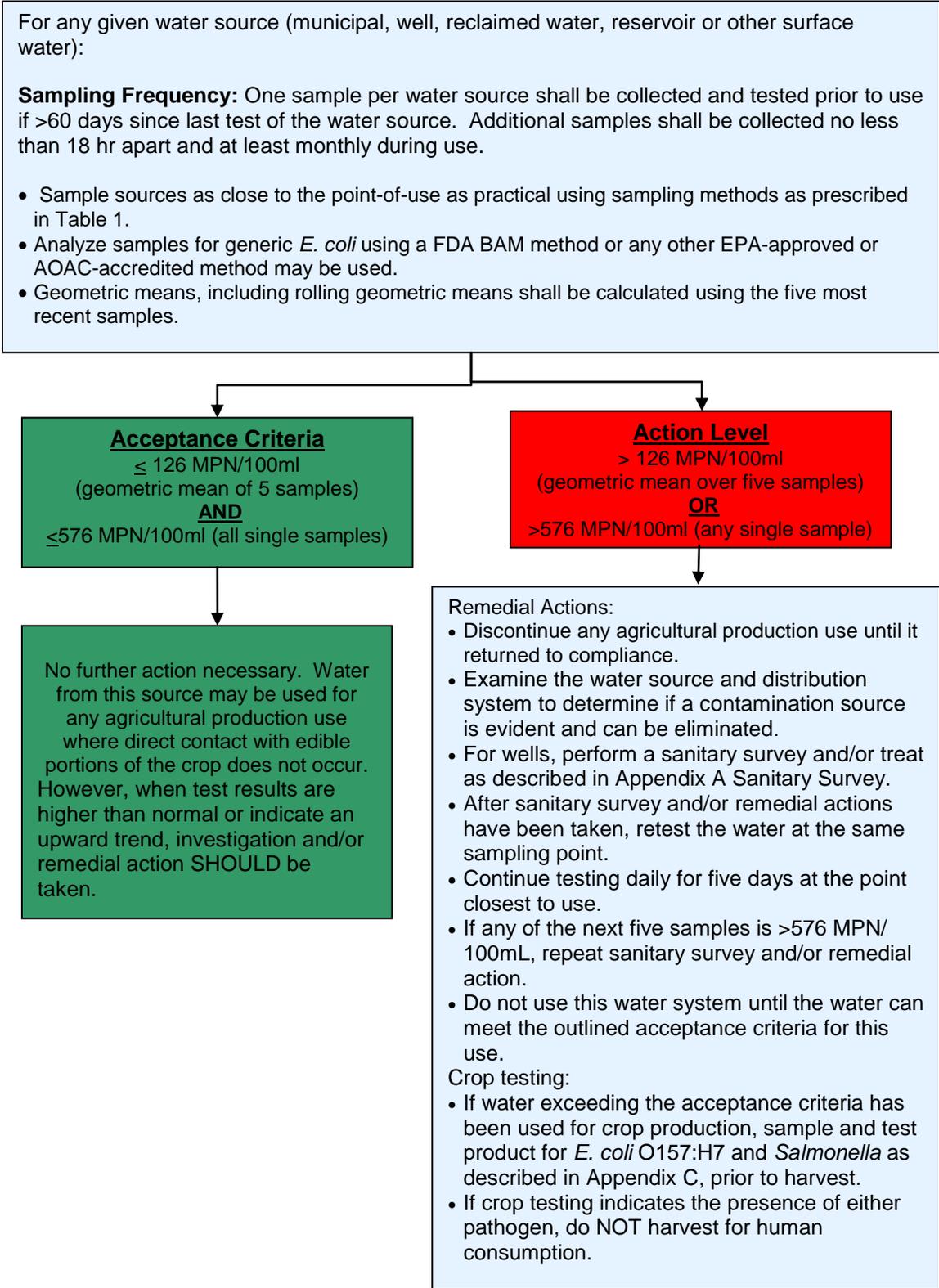
Sampling Frequency: One sample per water source shall be collected and tested prior to use if >60 days since last test of the water source. Additional samples shall be collected at intervals of no less than 18 hr and at least monthly during use.

- Sample sources 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.
- Analyze samples for generic *E. coli* using a FDA BAM method or any other EPA- approved or AOAC-accredited method may be used.
- Geometric means, including rolling geometric means shall be calculated using the five most recent samples.

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397 **Figure 1B. Decision Tree for PRE-HARVEST WATER USE – Non-Foliar Applications**
 398 **whereby edible portions of the crop are NOT contacted by water (e.g. furrow or drip**
 399 **irrigation, dust abatement water)**
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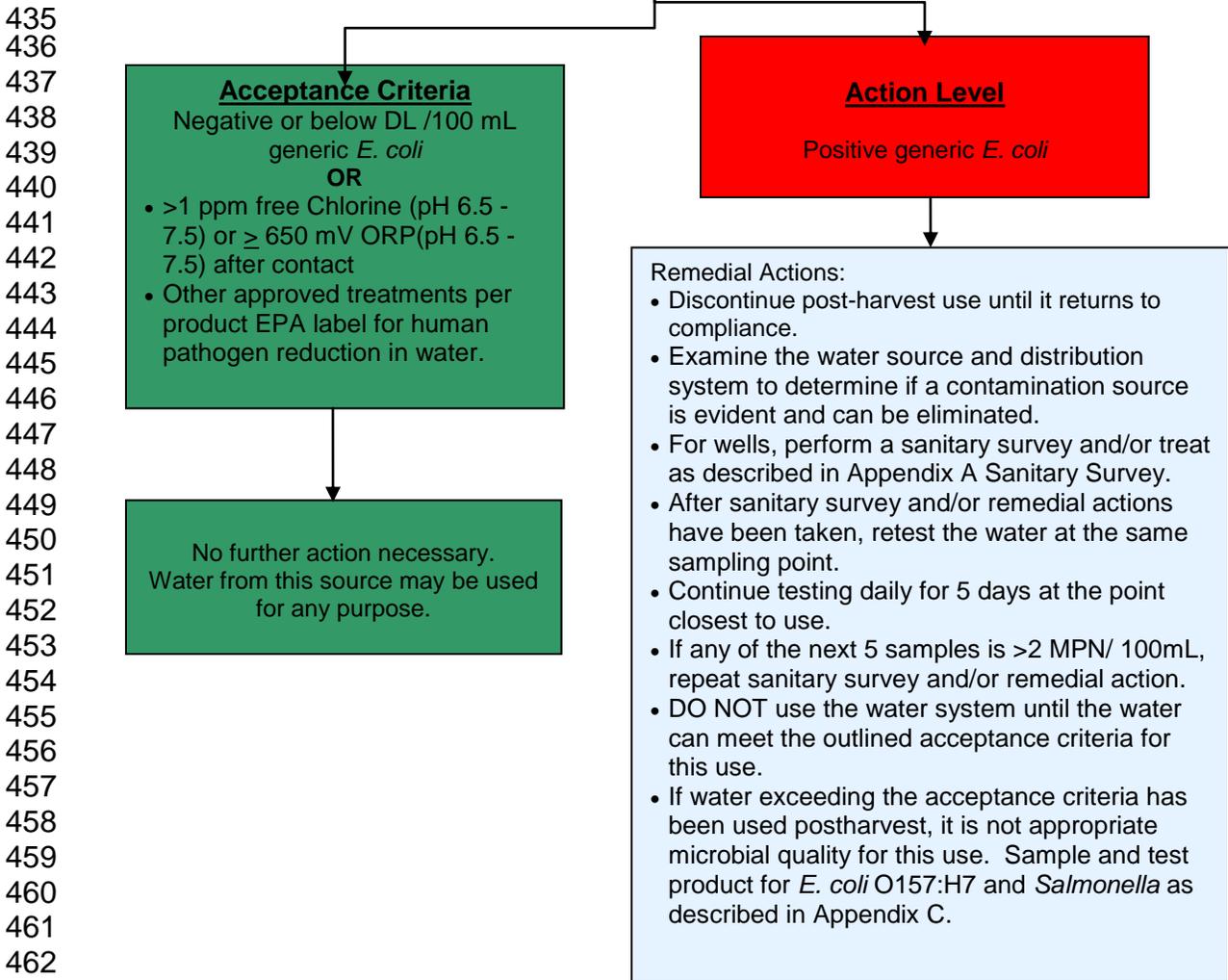
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 432 **Figure 1C. POSTHARVEST WATER USE – Direct product contact (e.g. re-hydration, core in**
 433 **field, etc.)**
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For any given water source (municipal, well, reservoir or other surface water):
 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.

- 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 FDA BAM method or any other EPA-approved or AOAC-accredited method may be used.
- Geometric means, including rolling geometric means shall be calculated using the 5 most recent samples.



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464 **6. ISSUE: SOIL AMENDMENTS**

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

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

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489 **6.1. The Best Practices Are:**

- 490 • DO NOT USE raw manure or soil amendment that contain un-composted, incompletely
491 composted animal manure and/or green waste or non-thermally treated animal manure to
492 fields which will be used for lettuce and leafy green production.
- 493 • See Table 2 and Decision Trees (Figures 2A and 2B) for numerical criteria and guidance
494 for compost and soil amendments used in lettuce and leafy greens production fields. The
495 “Technical Basis Document” (Appendix B) describes the process used to develop these
496 metrics.
- 497 • Any soil amendment that does not contain animal manure must have a document (e.g.,
498 ingredient list, statement of identity, letter of guaranty, etc.) from the producer or seller
499 demonstrating that it is manure free. This document must indicate in some way that
500 manure is not an ingredient used in the production of the amendment or provide the
501 ingredients of the product. A statement of identity or product is sufficient for single-
502 chemical amendments (i.e., “calcium carbonate” or “gypsum”). If “inert ingredients” are
503 listed as part of an amendment, then a document from the producer or seller is necessary
504 indicating manure has not been added. The manure free document must be available for
505 verification before harvest begins and it must be saved and available for inspection for 2
506 years. A new document is required every two years unless there is a significant process
507 or ingredient change.

- 508 • Implement management plans (e.g., timing of applications, storage location, source and
509 quality, transport, etc.) that significantly reduce the likelihood that soil amendments
510 being used contain human pathogens.
- 511 • Verify that the time and temperature process used during the composting process
512 reduces, controls, or eliminates the potential for human pathogens being carried in the
513 composted materials, as applicable to regulatory requirements.
- 514 • Maximize the time interval between soil amendment application and time to harvest.
- 515 • Implement practices that control, reduce or eliminate likely contamination of
516 lettuce/leafy green fields in close proximity to on-farm stacking of manure.
- 517 • Use soil amendment application techniques that control, reduce or eliminate likely
518 contamination of surface water and/or edible crops being grown in adjacent fields.
- 519 • Segregate equipment used for soil amendment handling, preparation, distribution,
520 applications or use effective means of equipment sanitation before subsequent use that
521 effectively reduce the potential for cross contamination.
- 522 • Minimize the proximity of wind-dispersed or aerosolized sources of contamination (e.g.,
523 water and manure piles) that may potentially contact growing lettuce/leafy greens or
524 adjacent edible crops. Segregate equipment used for soil amendment applications or use
525 effective means of equipment sanitation before subsequent use.
- 526 • Compost suppliers shall have written Standard Operating Procedures to prevent cross-
527 contamination of finished compost with raw materials through equipment, runoff, or
528 wind, and growers shall obtain proof that these documents exist.
- 529 • Compost operations supplying compost to leafy greens crops shall maintain temperature
530 monitoring and turning records for at least two years, and growers shall obtain proof that
531 this documentation exists. This applies to composting operations regulated under Title
532 14 CCR as well as smaller operations that do not fall under Title 14.
- 533 • Perform microbiological testing of soil amendments prior to application (Table 2).
- 534 • Do not use biosolids as a soil amendment for production of lettuce or leafy greens.
- 535 • Retain documentation of all processes and test results by lot (at the supplier) and/or
536 Certificates of Analysis available for inspection for a period of at least two years.
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TABLE 2. SOIL AMENDMENTS

Amendment	Metric/Rationale
<p>Raw Manure or Not Fully Composted green waste and/or Animal Manure Containing Soil Amendments (see composted manure process definition below)</p>	<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>
<p>Composted Soil Amendments (containing animal manure or animal products)</p> <p>*Composted soil amendments should not be applied after emergence of plants.</p>	<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) <p>Recommended Test Methods:</p> <ul style="list-style-type: none"> • Fecal coliforms: 9 tube MPN

Amendment	Metric/Rationale
	<ul style="list-style-type: none"> • <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, or AOAC-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 (See Appendix E) • 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 grower (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.

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¹ CCR Title 14 - Chapter 3.1 - Article 7 - Section 17868.1
<http://www.calrecycle.ca.gov/Laws/Regulations/Title14/ch31a5.htm#article7>

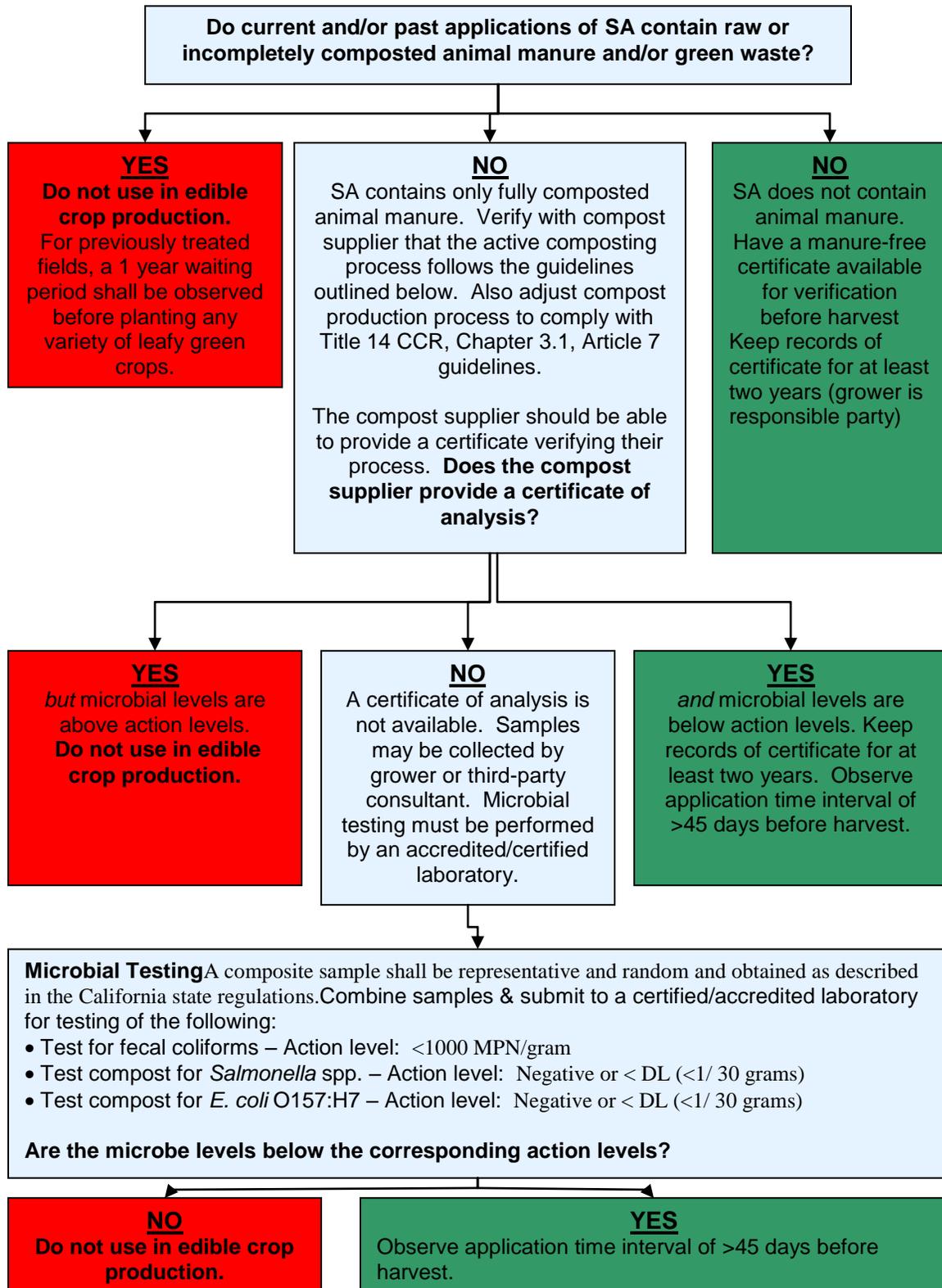
<p>Soil amendments containing animal manure that has been physically heat treated or processed by other equivalent methods.</p>	<p>Please see Figure 2B: Decision Tree for Use of Physically Heat Treated Soil Amendments.</p> <p>Physical Heat Process Validation</p> <ul style="list-style-type: none"> The 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. <p>Target Organism:</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 Negative or < DL per gram <i>Salmonella</i>: Negative or < DL (<1/ 30 grams) <i>E. coli</i> O157:H7: Negative or < DL (<1/ 30 grams) <p>Recommended Test Methods:</p> <ul style="list-style-type: none"> Fecal coliforms: 9 tube MPN <i>Salmonella</i> spp: U.S. EPA Method 1682 <i>E. coli</i> O157:H7: Any laboratory validated method for testing soil amendments. U.S. EPA, FDA, AOAC-or other accredited methods may be used as appropriate <p>Sampling Plan:</p> <ul style="list-style-type: none"> 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. <p>Testing Frequency:</p> <ul style="list-style-type: none"> Each lot before application to production fields. <ul style="list-style-type: none"> In lieu of the above analysis requirement a Certificate of Process Validity Issued by a recognized <i>Process Authority</i> 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
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	<p style="text-align: center;">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)</p> <p>Application Interval:</p> <ul style="list-style-type: none"> • 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 above, then no time interval is needed between application and harvest. • If the physical heat treatment process used to inactivate human pathogens of significant public health concern 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. <p>Documentation:</p> <ul style="list-style-type: none"> • All test results and/or Certificates of Analysis and/or Certificates of Process Validation shall be documented and available for verification from the grower who is the responsible party for a period of two years. The suppliers operation should be validated by a process authority and a record maintained by the grower for a period of two years. <p>Rationale:</p> <ul style="list-style-type: none"> • The microbial metrics 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. 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.
<p>Soil Amendments Not Containing Animal Manure</p>	<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 grower who is the responsible party for a period of two years.

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

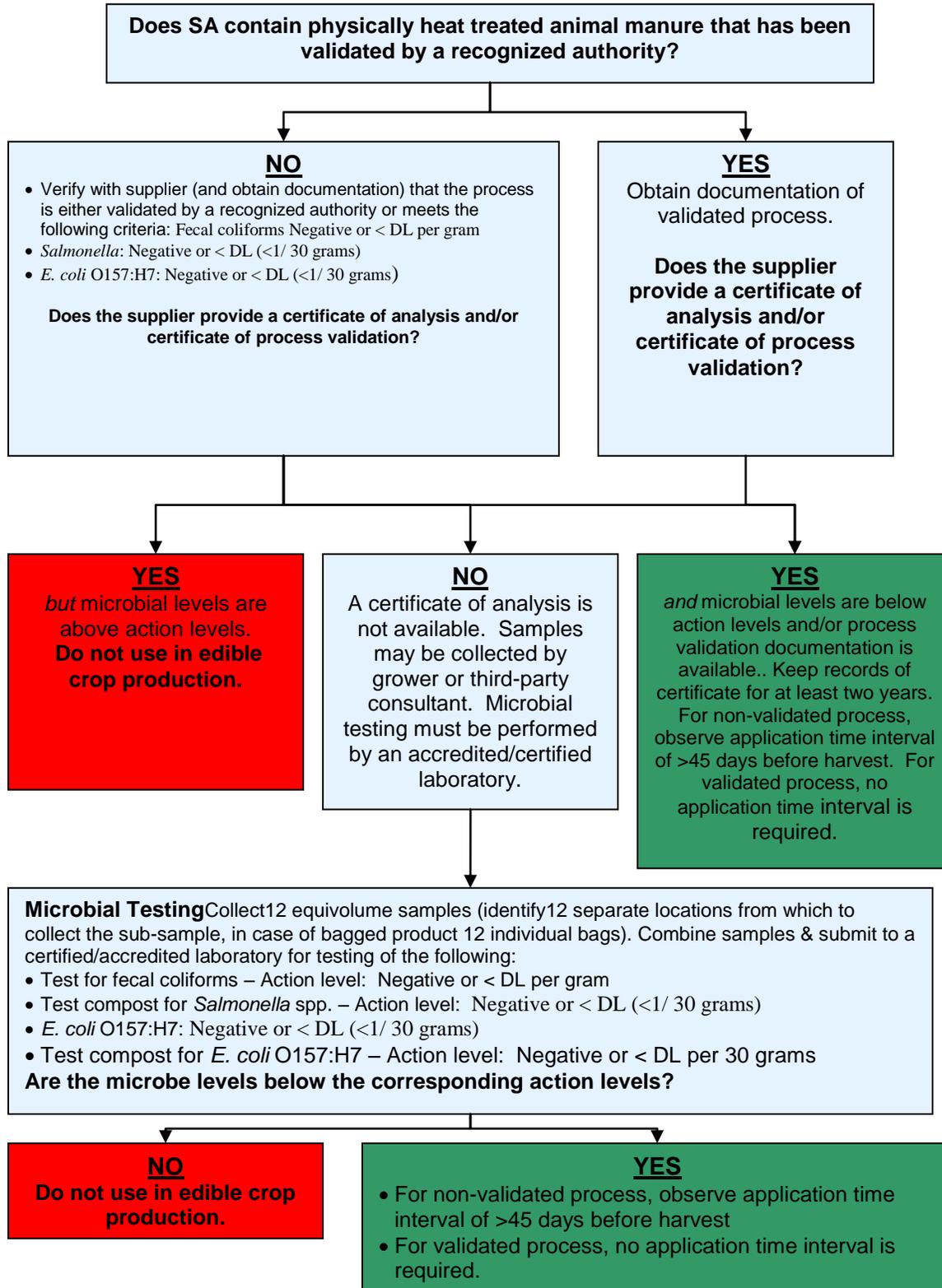
If raw manure has been directly applied to the field in the past, a 1 year waiting period shall be observed before planting any variety of leafy green crops.



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574 **Figure 2B. Decision Tree for Physically Heat Treated Animal Manure Containing Soil**
 575 **Amendments (SA)**
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580 **7. ISSUE: NONSYNTHETIC CROP TREATMENTS**

581 Nonsynthetic crop treatments are commonly applied post-emergence for pest and disease control,
582 greening, and to provide organic and inorganic nutrients to the plant during the growth cycle. For the
583 purposes of this document, they are defined as any crop input that contains animal manure, an animal
584 product, and/or an animal by-product that is reasonably likely to contain human pathogens. Due to
585 the potential for human pathogen contamination, these treatments should only be used under
586 conditions that minimize the risk for crop contamination.
587

588 **7.1. The Best Practices Are:**

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

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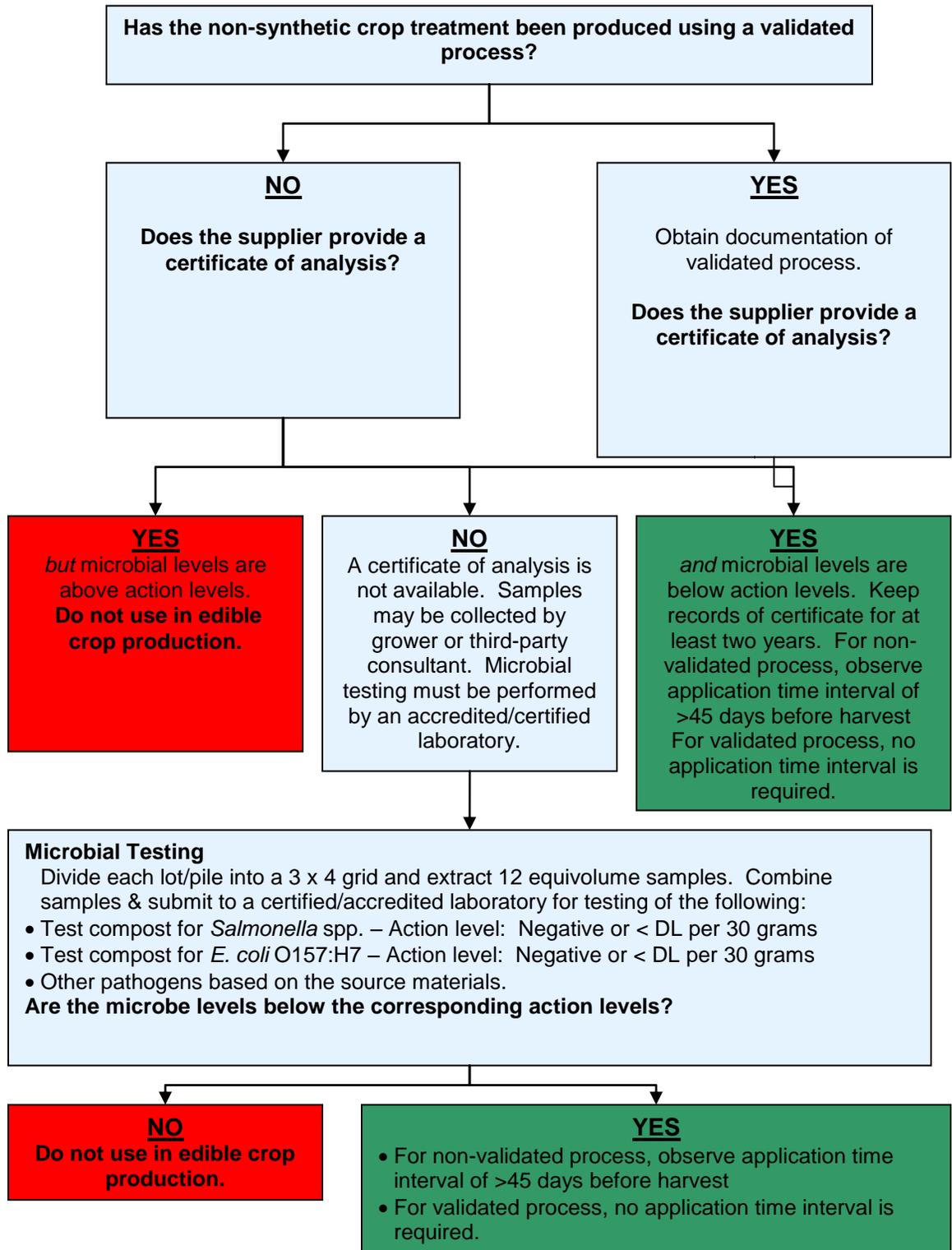
TABLE 3. NONSYNTHETIC CROP TREATMENTS

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, or AOAC-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. <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

Treatment	Metric/Rationale
	<p>between application and harvest.</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 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 grower for verification for a period of 2 years. The grower 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.

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614 **Figure 3. Decision Tree for Nonsynthetic Crop Treatments That Contain Animal Products**
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Note: Mixtures of soil amendment materials

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

647
648 For example; Soil amendments containing animal manure that has been physically heat treated or
649 processed by other equivalent methods mixed with soil amendments not containing animal
650 manure would require a process certification for the physically heat treated or processed by other
651 equivalent methods materials and the components from non-animal manure would require
652 documentation attesting to its manure free status. The resulting mixture could then be applied in
653 accordance with the guidelines associated with the physically heated treated class of materials
654 (most stringent limits).

655 **8. ISSUE: HARVEST EQUIPMENT (FIELD SANITATION)**

656 This section addresses harvest and harvest aid equipment used for lettuce/leafy greens. Mechanical
657 or machine harvest has become increasingly prevalent and provides opportunity for increased surface
658 contact exposure. This includes field cored lettuce operations that use various harvest equipment and
659 aids.
660

661 **8.1. The Best Practices Are:**

- 662 • Prepare an SOP for harvest equipment that addresses the following:
 - 663 ○ Sanitation verification
 - 664 ○ Daily inspection
 - 665 ○ Proper cleaning, sanitation and storage of hand harvest equipment (knives,
666 scythes, etc.)
 - 667 ○ Control procedures when equipment is not in use, including policy for removal of
668 equipment from the work area or site and the use of scabbards, sheathes or other
669 storage equipment.
- 670 • Prepare an SOP for handling and storage of product containers that addresses the
671 following:
 - 672 ○ Overnight storage
 - 673 ○ Contact with the ground
 - 674 ○ Container assembly (RPC, fiber bin, plastic bin, etc)
 - 675 ○ Damaged containers
 - 676 ○ Use of containers only as intended
- 677 • Prepare an SOP for sanitary operation of equipment which addresses:
 - 678 ○ Spills and leaks
 - 679 ○ Inoperative water sprays
 - 680 ○ Exclusion of foreign objects (including glass, plastic, metal and other debris)

- 681 ○ Establish and implement cleaning and sanitation schedules for containers and
682 equipment that will be used in hydration.
- 683 ○ Maintain logs documenting cleaning and sanitation, and retain these records for at
684 least two years.
- 685 ○ Establish policies for the storage and control of water tanks and equipment used
686 for hydration operations when not in use.
- 687
- 688 ● Establish appropriate measures that reduce and control the potential introduction of
689 human pathogens at the cut surface during and after mechanical harvest operations. Due
690 to the cut surface being more vulnerable to microbial contamination, this best practice is
691 extremely important and all practical means should be taken to reduce the possibility of
692 introduction of contamination at this process step.
- 693 ● If re-circulated rinse or antioxidant solutions are used on the cut surface, take all
694 practicable precautions to prevent them from becoming a source of contamination.
- 695 ● Design equipment to facilitate cleaning by using materials and construction that facilitate
696 cleaning and sanitation of equipment food contact surfaces (e.g., transportation tarps,
697 conveyor belts, etc.).
- 698 ● Establish the frequency of equipment cleaning and sanitation by developing Sanitation
699 Standard Operating Procedures (SSOPs) and a sanitation schedule for machine harvest
700 operations.
- 701 ● Evaluate the use of cleaning verification methods for harvesting equipment (e.g., ATP test
702 methods).
- 703 ● Locate equipment cleaning and sanitizing operations away from product and other
704 equipment to reduce the potential for cross contamination.
- 705 ● Establish equipment storage and control procedures to minimize the potential for
706 contamination when not in use. Establish policies and sanitary design options that
707 facilitate frequent and thorough cleaning and sanitizing of food contact surfaces.
- 708 ● Develop and implement appropriate cleaning, sanitizing, storage and handling procedures
709 of all food contact surfaces to reduce and control the potential for microbial cross
710 contamination.
- 711 ● Allow adequate distance for the turning and manipulation of harvest equipment to prevent
712 cross contamination from areas or adjacent land that may pose a risk.

713

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

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

720

- 721 **9.1. The Best Practices Are:**
- 722 • Evaluate appropriate measures that reduce and control the potential introduction of
- 723 human pathogens through soil contact at the cut surface after harvest (e.g. frequency of
- 724 knife sanitation, no placement of cut surfaces of harvested product on the soil, container
- 725 sanitation, single use container lining, etc.).
- 726 • Do not stack soiled bins on top of each other if the bottom of one bin has had direct
- 727 contact with soil unless a protective barrier (*i.e.*, liner, cover, *etc.*) is used to separate the
- 728 containers.
- 729

730 **10. ISSUE: FIELD AND HARVEST PERSONNEL - TRANSFER OF HUMAN PATHOGENS BY**

731 **WORKERS (FIELD SANITATION)**

732 Lettuce/leafy greens are handled by harvest crews during harvest in that each lettuce/leafy greens

733 plant is touched/handled as part of the harvest process. It is possible that persons working with

734 produce in the field may transfer microorganisms of significant public health concern. Workers may

735 be asymptomatic.

736 **10.1. The Best Practices Are:**

- 737 • Use appropriate preventive measures outlined in GAPs such as training in appropriate and
- 738 effective hand washing, glove use and replacement, and mandatory use of sanitary field
- 739 latrines to reduce and control potential contamination. Establish a written worker practices
- 740 program (*i.e.*, an SOP) that can be used to verify employee compliance with company food
- 741 safety policy. This program shall establish the following practices for field and harvest
- 742 employees as well as visitors.
- 743 ○ Prior to harvest, an individual should be designated as responsible for harvesting food
- 744 safety
- 745 ○ Use, storage, record keeping, and proper labeling of chemicals
- 746 ○ Training on proper sanitation and hygiene practices
- 747 ○ Requirements for workers to wash their hands before beginning or returning to work
- 748 ○ Confinement of smoking, eating and drinking of beverages other than water to
- 749 designated areas.
- 750 ○ Prohibitions on spitting, urinating or defecating in the field
- 751 ○ Personal item storage
- 752 • A written physical hazard prevention program should be developed for leafy green products
- 753 that are intended for further processing. The program must address the following:
- 754 ○ Employee clothing and jewelry (head and hair restraints, aprons, gloves, visible
- 755 jewelry, etc.)
- 756 ○ Removal of all objects from upper pockets
- 757 ○ Foreign objects in the field.
- 758 • Establish a worker health practices program (*i.e.*, an SOP) that address the following issues:

- 759 ○ Workers with diarrhea disease or symptoms of other infectious disease are prohibited
760 from handling fresh produce.
- 761 ○ Workers with open cuts or lesions are prohibited from handling fresh produce
762 without specific measures to prevent cross contamination of product.
- 763 ○ Actions for employee to take in the event of injury or illness.
- 764 ○ A policy describing procedures for handling/disposition of produce or food contact
765 surfaces that have come into contact with blood or other body fluids.
- 766 ● A field sanitary facility program (i.e., an SOP) shall be implemented, and it should address
767 the following issues: the number, condition, and placement of field sanitation units, the
768 accessibility of the units to the work area, facility maintenance, facility supplies (i.e., hand
769 soap, water, paper towels, toilet paper, etc.), facility signage, facility cleaning and servicing,
770 and a response plan for major leaks or spills.
 - 771 ○ Sanitary facilities should be placed such that the location minimizes the impact from
772 potential leaks and/or spills while allowing access for cleaning and service.
 - 773 ○ The location and sanitary design of toilets and hand wash facilities should be
774 optimized to facilitate the control, reduction and elimination of human pathogens
775 from employee hands. Evaluate the location of worker hygiene facilities to maximize
776 accessibility and use, while minimizing the potential for the facility to serve as a
777 source of contamination.
 - 778 ○ Establish the frequency of toilet and hand washing facility maintenance/sanitation.
 - 779 ○ Establish equipment and supply storage and control procedures when not in use.
 - 780 ○ Maintain documentation of maintenance and sanitation schedules and any remedial
781 practices for a period of two years.

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

783 When farm equipment has had direct contact with raw untreated manure, untreated compost, waters
784 of unknown quality, animals or other potential human pathogen reservoirs it may be a source of cross
785 contamination. Such equipment should not be used in proximity to or in areas where it may contact
786 edible portions of lettuce and or leafy greens without proper sanitation.
787

788 **11.1. The Best Practices Are:**

- 789 ● Identify any field operations that may pose a risk for cross-contamination. These include
790 management personnel in the fields, vehicles used to transport workers, as well as many
791 other possibilities.
- 792 ● Segregate equipment used in high-risk operations or potentially exposed to high levels of
793 contamination.
- 794 ● Use effective means of equipment cleaning and sanitation before subsequent equipment
795 use in lettuce/leafy greens production, if it was previously used in a high-risk operation.
- 796 ● Develop appropriate means of reducing and controlling the possible transfer of human
797 pathogens to soil and water that may directly contact edible lettuce/leafy green tissues
798 through use of equipment.

- 799
- Maintain appropriate records related to equipment cleaning and possible cross-
- 800 contamination issues for a period of two years.

801

802 **12. ISSUE: FLOODING**

803 Flooding for purposes of this document is defined as the flowing or overflowing of a field with water
804 outside of a grower’s control, that is reasonably likely to contain microorganisms of significant
805 public health concern and is reasonably likely to cause adulteration of the edible portions of fresh
806 produce in that field. Pooled water (e.g., rainfall) that is not reasonably likely to contain
807 microorganisms of significant public health concern and is not reasonably likely to cause adulteration
808 of the edible portion of fresh produce should not be considered flooding.

809

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

813

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

823

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

829

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

834

835 **12.1. The Best Practices For Product That Has Come Into Contact With Flood**
836 **Water Are:**

- 837
- See Table 4 for numerical criteria for lettuce and leafy greens production fields that have
838 possibly come into contact with flood waters. The “Technical Basis Document”
839 (Appendix B) describes the process used to develop these metrics.

- 840
- FDA considers any crop that has come into contact with floodwater to be an
841 “adulterated” commodity that cannot be sold for human consumption.

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845

- To reduce the potential for cross contamination do not drive harvest equipment through flooded areas reasonably likely to contain microorganisms of public health significance (see previous section).

846
847

TABLE 4. FLOODING

When evidence of flooding in a production block occurs.

Practice	Metric/Rationale
Flooding Defined	The flowing or overflowing of a field with water outside a grower’s control that is reasonably likely to contain microorganisms of significant public health concern and is reasonably likely to cause adulteration of edible portions of fresh produce in that field. Additional discussion of this definition and implications for production is provided in the text portion of this document.
Allowable Harvest Distance from Flooding	<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 turnaround distance for production equipment to prevent cross-contamination of non-flooded ground or produce.

848
849

850 **12.2. The Best Practices for Product in Proximity to a Flooded Area But Not Contacted**
851 **By Flood Water Are:**

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

860

861 **12.3. The Best Practices For Formerly Flooded Production Ground Are:**

- 862 • Prior to replanting or soil testing, the designated food safety professional for the grower shall
863 perform a detailed food safety assessment of the production field. This designated professional
864 will be responsible for assessing the relative merits of testing versus observing the appropriate
865 time interval for planting, and also will coordinate any soil testing plan with appropriate third-
866 party consultants and/or laboratories that have experience in this type of testing.
- 867 • Evaluate the source of flood waters (e.g., drainage canal, river, irrigation canal, etc.) for
868 potential significant upstream contributors of human pathogens at levels that pose a significant
869 threat to human health.
- 870 • Allow soils to dry sufficiently and be reworked prior to planting subsequent crops on formerly
871 flooded production ground.
- 872 • Do not replant formerly flooded production ground for at least 60 days following the receding
873 of floodwaters. This period or longer and active tillage of the soil provide additional protection
874 against the survival of pathogenic organisms.
- 875 • If flooding has occurred in the past on the property, soil clearance testing may be conducted
876 prior to planting leafy greens. Soil testing may be used to shorten the clearance period to 30
877 days. If performed, testing must indicate soil levels of microorganisms lower than the standards
878 for processed compost. Suitable representative samples should be collected for the entire area
879 suspected to have been exposed to flooding.
- 880 • Sample previously flooded soil for the presence of microorganisms of significant public health
881 concern or appropriate indicator microorganisms. Microbial soil sampling can provide valuable
882 information regarding relative risks; however, sampling by itself does not guarantee that crops
883 grown within the formerly flooded production area will be free of the presence of human
884 pathogens.
- 885
- 886 • Evaluate the field history and crop selection on formerly flooded production ground.
- 887 • Assess the time interval between the flooding event, crop planting, and crop harvest.
888 Comparative soil samples may be utilized to assess relative risk if significant reductions in
889 indicator microorganisms have occurred within this time interval.

- 890
- Prevent cross-contamination by cleaning or sanitizing any equipment that may have contacted
- 891 previously flooded soil (also see the section on Equipment Facilitated Cross Contamination
- 892 above).

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

894 Lettuce/leafy greens are grown in varying regions but generally in moderate weather conditions. Cool,

895 humid conditions favor human pathogen persistence (Takeuchi and Frank 2000; Takeuchi *et al.* 2000)

896 while drier climates may present other problems such as requirements for additional water that may

897 increase the potential for introduction of human pathogens. Heavy rains in certain areas may also cause

898 lettuce/leafy greens to be exposed to contaminated soil due to rain splashing. It is important to tailor

899 practices and procedures designed to promote food safety to the unique environment in which each crop

900 may be produced

901

902 **13.1. The Best Practices Are:**

- Consider harvest practices such as removing soiled leaves, not harvesting soiled heads, etc., when
- 904 excessive soil or mud builds up on lettuce/leafy greens.
- Take care to reduce the potential for windborne soil, including soil from roads adjacent to fields,
- 906 water, or other media that may be a source of contamination to come into direct contact with the
- 907 edible portions of lettuce and leafy greens. Do not allow runoff from adjacent properties to come
- 908 into contact with produce.
- Evaluate and implement practices to reduce the potential for the introduction of pathogens into
- 910 production blocks by wind or runoff. Such practices may include but are not limited to berms,
- 911 windbreaks, diversions ditches and vegetated filter strips.
- When soil has accumulated on plants, remove soil during the harvest or further processing.
- 912
- 913

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

915 Lettuce/leafy greens are generally grown in rural areas that may have adjacent wetlands, wildlands, parks

916 and/or other areas where animals may be present. Some animal species are known to be potential carriers

917 of various human pathogens (Fenlon 1985; [Gorski et al. 2011](#); [Jay et al. 2007](#); [Keene et al. 1997](#);

918 [LeJeune et al. 2008](#); [Perz et al. 2001](#)). In addition, extensive development in certain farming communities

919 has also created situations with urban encroachment and unintentional access by domestic animals and/or

920 livestock which may also pose varying degrees of risk. Finally, it is possible that some land uses may be of

921 greater concern than others when located near production fields. Table 6 provides a list of these uses and

922 recommended buffer distances.

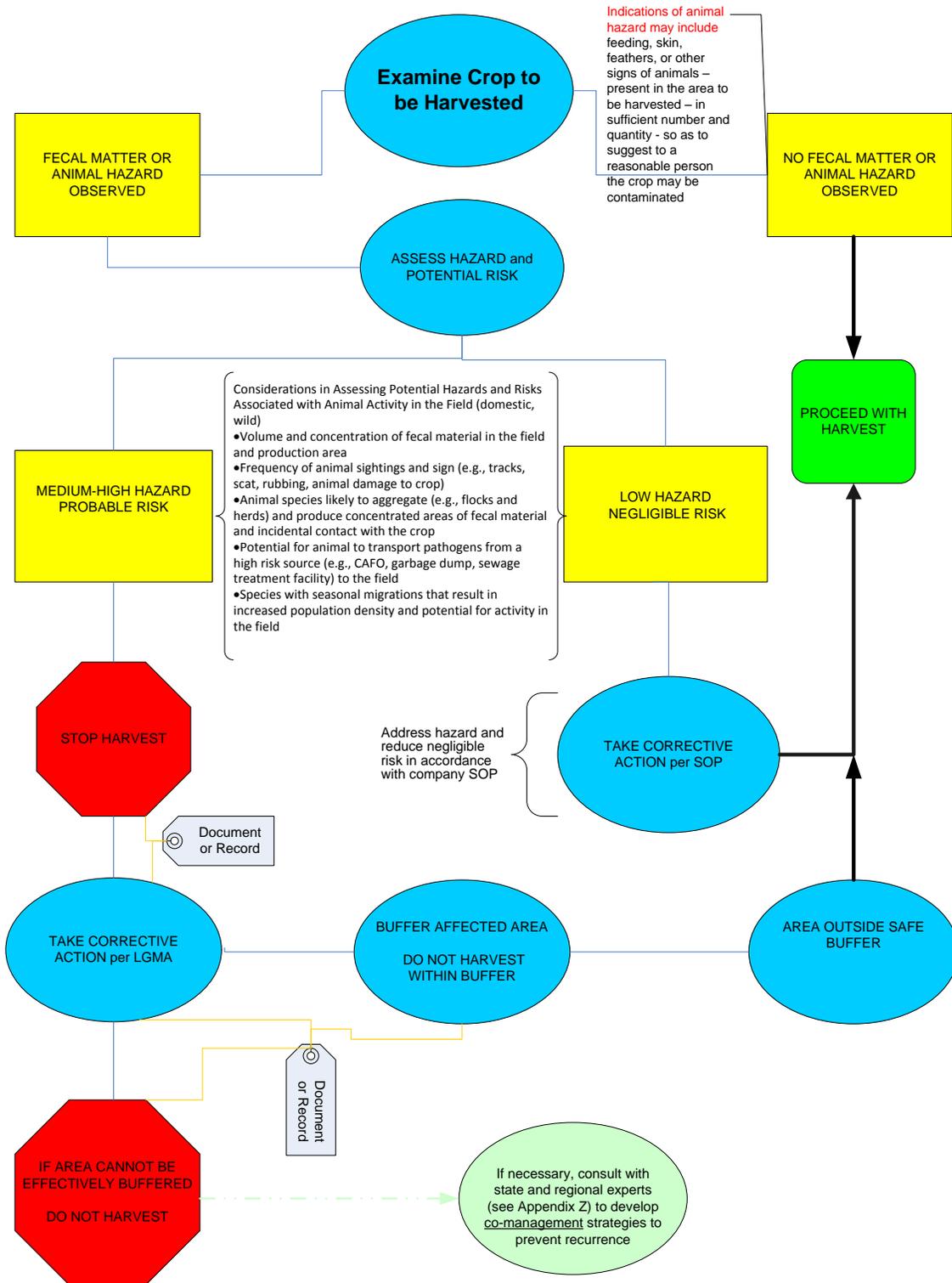
923

924 **14.1. The Best Practices Are:**

- See Tables 5 and 6 and Decision Tree (Figure 5) for numerical criteria and guidance applicable
- 926 to animal encroachment and adjacent land uses. The “Technical Basis Document” (Appendix
- 927 B) describes the process used to develop these metrics.
- During the Environmental Assessments discussed in Section 2, the location of any adjacent land
- 929 uses that are likely to present a food safety risk should be documented. In addition, as specified
- 930 in Table 6, any deviations from the recommended buffer distances due to mitigation factors or
- 931 increased risk should be documented.

- 932 • Evaluate and monitor animal activity in and proximate to lettuce/leafy greens fields and
933 production environments. Conduct and document periodic monitoring and pre-season, pre-
934 harvest, and harvest assessments. If animals present a probable risk (medium/high hazard),
935 make particular efforts to reduce their access to lettuce and leafy green produce.
- 936 • Fencing, vegetation removal, and destruction of habitat may result in adverse impacts to the
937 environment. Potential adverse impacts include loss of habitat to beneficial insects and
938 pollinators; wildlife loss; increased discharges of sediment and other pollutants resulting from
939 the loss of vegetative filtering; and increased air quality impacts if bare soil is exposed to wind.
940 It is recommended that producers check for local, state, and federal laws and regulations that
941 protect riparian habitat and wetland areas, restrict removal of vegetation or habitat, or regulate
942 wildlife deterrence measures, including hazing, harassment, lethal and non-lethal removal, etc.
- 943 • Evaluate the risk to subsequent crop production or production acreage that has experienced
944 recent postharvest grazing with or by domesticated animals that used field culls as a source of
945 animal feed.
- 946 • Document any probable risk (medium/high hazard) during production and/or harvest periods
947 and take appropriate corrective action per Table 5 in LGMA metrics.
- 948 • Locate production blocks to minimize potential access by animals and maximize distances to
949 possible sources of microbial contamination. For example, consider the proximity to water (i.e.,
950 riparian areas), animal harborage, open range lands, non-contiguous blocks, urban centers, etc.
951 Periodically monitor these factors and assess during preseason and preharvest assessments as
952 outlined in Tables 5 and 6. If the designated food safety professional deems that there is the
953 potential for microbial contamination from adjacent areas, a risk assessment shall be performed
954 to determine the risk level as well as to evaluate potential strategies to control or reduce the
955 introduction of human pathogens.
- 956 • DO NOT harvest areas of fields where unusually heavy activity by animals has occurred. If
957 animal intrusions are common on a particular production field, consider fencing, barriers,
958 noisemakers, and other practices that may reduce intrusions.
- 959 • Train harvest employees to recognize and report evidence (e.g., feces) of animal activity.
- 960 • Pooled water (e.g., a seasonal lake) from rainfall may attract animals and should be considered
961 as part of any land use evaluation.
- 962 • Consider controlling risks associated with encroachment by urban development. Risks may
963 include, but are not limited to, domestic animal fecal contamination of production fields and
964 harvest equipment and septic tank leaching.
- 965 • Growers are encouraged to contact the relevant agencies (e.g., the Regional Water Quality
966 Control Board and state and federal fish and wildlife agencies) to confirm the details of these
967 requirements. In addition, growers may wish to consult with local NRCS to evaluate the food
968 safety risks associated with wildlife, livestock, domestic animals and other adjacent land uses
969 and to develop and document strategies to control or reduce the introduction of human
970 pathogens for each production block.

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

When evidence of animal intrusion in a production block occurs.

Issue	Metric	Remedial Actions
<p>Evidence of Intrusion</p>	<p><u>Frequency</u></p> <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 <p><u>Variables</u></p> <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. <u>An example of a low hazard might be a sign of animal intrusion into the leafy green production area by a single small rodent/rabbit , carnivore (raccoon, skunk, stray dog), or solitary birds with minimal to no fecal deposition.</u> • 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, growers should check local, state and federal laws and regulations that protect riparian habitat and wetland areas, restrict removal of vegetation or habitat, or regulate wildlife deterrence measures, including hazing, harassment, lethal and non-lethal removal, etc. • Food safety assessments and corrective actions shall be documented and available for verification for a period of two years.

<p>Allowable Harvest Distance from Evidence of Intrusion</p>	<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 to high hazard (probable risk) intrusion should include a three foot buffer radius around a do not-harvest area where the impacted crop has been isolated. <p><u>Daily Harvest Assessment ONLY</u> 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.
<p>Verification</p>	<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.
<p>Rationale</p>	<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)	Due to the lack of science at this time, an interim guidance distance of 400 ft from the edge of crop is proposed. This number is subject to change as science becomes available. The proximate safe distance depends on the risk/mitigation factors listed to the right. Evaluate risk and document consideration of these factors. Research is being proposed to study appropriate distance.	Distance from active compost operation	--	--
		Topography: Uphill from crop	√	
		Topography: Downhill from crop		√
		Opportunity for water run off through or from composting operations	√	
		Opportunity for soil leaching	√	
		Presence of physical barriers such as windbreaks, diversion ditches, vegetative strips		√
Concentrated Animal Feeding Operations (as defined in 40 CFR 122.23)	Due to the lack of science at this time, an interim guidance distance of 400 ft from the edge of crop is proposed. This number is subject to change as science becomes available. The proximate safe distance depends on the risk/mitigation factors listed to the right. Evaluate risk and document consideration of these factors. Research is being proposed to study appropriate distance.	Fencing and other physical barriers such as berms, diversion ditches and vegetated strips can be employed to prevent intrusion of domestic animals, control runoff, etc.		√
		Topography: Uphill from crop	√	
		Topography: Downhill from crop		√
		Opportunity for water run off through or from CAFOs	√	
		Opportunity for soil leaching	√	
		Manure Management Program utilized		√
Non-synthetic Soil Amendment Pile (containing manure or animal products)	Due to the lack of science at this time, an interim guidance distance of 400 ft from the edge of crop is proposed. This number is subject to change as science becomes available. The proximate safe distance depends on the risk/mitigation factors listed to the right. Evaluate risk and document	Access and review COA for materials in question.		√
		Topography: Uphill from crop	√	
		Topography: Downhill from crop		√
		Opportunity for water run off through or from	√	

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
	consideration of these factors. Research is being proposed to study appropriate 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	non-synthetic soil amendment storage areas		
		Opportunity for soil leaching	√	
		Covering on pile to prevent wind dispersion		√
Grazing Lands/Domestic Animals (includes homes with hobby farms, and non commercial livestock)	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		√

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
Surface Water Distance from Untreated Manure	At least 100 feet separation for sandy soil and 200 feet separation for loamy or clay soil (slope less than 6%; increase distance to 300 feet if slope greater than 6%) is recommended.	Topography: Uphill from manure		√
		Topography: Downhill from manure	√	
		Opportunity for water runoff from or through untreated manure to surface waters.	√	
		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. 			

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

992 Detailed Background Guidance Information
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994 **14.2. Required Reference Documents**
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- 996 1. FDA Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables
997 (www.foodsafety.gov/~dms/prodguid.html)
- 998 2. UFFVA Food Safety Auditing Guidelines: Core Elements of Good Agricultural Practices for Fresh
999 Fruits and Vegetables
- 1000 3. UFFVA Food Safety Questionnaire for Fresh Fruits and Vegetables
- 1001 4. National GAPs Program Cornell University: Food Safety Begins on the Farm: A Grower Self
1002 Assessment of Food Safety Risks
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1004 **14.3. References**
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