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<b>Aerosolized</b>	The dispersion or discharge of a substance under pressure that generates a suspension of fine particles in air or other gas.
<b>animal by-product</b>	Most parts of an animal that do not include muscle meat including organ meat, nervous tissue, cartilage, bone, blood and excrement.
<b>animals of significant risk</b>	Animals that have been determined by the Centers for Disease Control to have a higher risk of carrying E. coli O157:H7. These animals are cattle, sheep, goats, pigs (domestic and wild), and deer.
<b>adenosine tri-phosphate (ATP)</b>	A high energy phosphate molecule required to provide energy for cellular function.
<b>ATP test methods</b>	Exploits knowledge of the concentration of ATP as related to viable biomass or metabolic activity; provides an estimate of cleanliness.
<b>Biofertilizers</b>	Fertilizer materials/products that contain microorganisms such as bacteria, fungi, and cyanobacteria that shall promote soil biological activities.
<b>Biosolids</b>	Solid, semisolid, or liquid residues generated during primary, secondary, or advanced treatment of domestic sanitary sewage through one or more controlled processes.
<b>colony forming units (CFU)</b>	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.
<b>Concentrated Animal Feeding Operation (CAFO)</b>	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.

<b>coliforms</b>	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.
<b>cross contamination</b>	The transfer of microorganisms, such as bacteria and viruses, from one place to another.
<b>E. coli</b>	<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.
<b>fecal coliforms</b>	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.”
<b>Flooding</b>	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.
<b>food contact surface</b>	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.
<b>food safety assessment</b>	A standardized procedure that predicts the likelihood of harm resulting from exposure to chemical, microbial and physical agents in the diet.
<b>food safety professional</b>	Person entrusted with management level responsibility for conducting food safety assessments before food reaches consumers; requires formal training in scientific principles and a solid understanding of the principles of food safety as applied to agricultural production.
<b>geometric mean</b>	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.

<b>Hydroponic</b>	The growing of plants in nutrient solutions with or without an inert medium (as soil) to provide mechanical support.
<b>Indicator microorganisms</b>	An organism that when present suggests the possibility of contamination or under processing.
<b>leafy greens</b>	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.
<b>Monthly</b>	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.
<b>most probable number (MPN)</b>	Estimated values that are statistical in nature; a method for enumeration of microbes in a sample, particularly when present in small numbers.
<b>nonsynthetic crop treatments</b>	Any crop input that contains animal manure, an animal product, and/or an animal by-product that is reasonably likely to contain human pathogens.
<b>Ready to eat (RTE) food</b> <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;
<b>synthetic crop treatments (chemical fertilizers)</b>	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.).

<b>oxidation reduction potential (ORP)</b>	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.
<b>parts per million (ppm)</b>	Usually describes the concentration of something in water or soil; one particle of a given substance for every 999,999 other particles.
<b>Pathogen</b>	A disease causing agent such as a virus, parasite, or bacteria.
<b>pooled water</b>	An accumulation of standing water; not free-flowing.
<b>process authority</b>	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.
<b>risk mitigation</b>	actions to reduce the severity/impact of a risk
<b>soil amendment</b>	Elements added to the soil, such as compost, peat moss, or fertilizer, to improve its capacity to support plant life.
<b>ultraviolet index (UV index)</b>	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.
<b>Validated process</b>	A process that has been demonstrated to be effective through a statistically-based study, literature, or regulatory guidance.
<b>water distribution system</b>	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.

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

133 [Appendix A](#): Sanitary Survey

[Appendix B](#): Technical Basis Document

134 [Appendix C](#): Crop Sampling Protocol

[Appendix Z](#): Resource Agency Contacts

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

136

137 **INTRODUCTION**

138

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

153

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

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

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

179 In the last 10 years, the focus of food safety efforts has been on the farm, initial cooling and  
180 distribution points, and value-added processing operations. Fruit and vegetable processing  
181 operations have developed sophisticated food safety programs largely centered on current  
182 Good Manufacturing Practices (cGMPs) and the principles of Hazard Analysis Critical

183 Control Point (HACCP) programs. As we develop a greater understanding of food safety  
184 issues relative to the full spectrum of supply and distribution channels for fruits and  
185 vegetables, it has become clear that the next generation of food safety guidance needs to  
186 encompass the entire supply chain.

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

## 194 **SCOPE**

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

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

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

221  
222 Safe production, packing, processing, distribution and handling of lettuce/leafy greens  
223 depend upon a myriad of factors and the diligent efforts and food safety commitment of  
224 many parties throughout the distribution chain. No single resource document can anticipate  
225 every food safety issue or provide answers to all food safety questions. These guidelines  
226 focus on minimizing only the microbial food safety hazards by providing suggested actions  
227 to reduce, control or eliminate microbial contamination of lettuce/leafy greens in the field to  
228 fork distribution supply chain.

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

236  
237 These guidelines are intended only to convey the best practices associated with the industry.  
238 The Produce Marketing Association, the United Fresh Produce Association, Western  
239 Growers, and all other contributors and reviewers make no claims or warranties about any  
240 specific actions contained herein. It is the responsibility of any purveyor of food to maintain  
241 strict compliance with all local, state and federal laws, rules and regulations. These  
242 guidelines are designed to facilitate inquiries and developing information that must be  
243 independently evaluated by all parties with regard to compliance with legal and regulatory  
244 requirements. The providers of this document do not certify compliance with these guidelines  
245 and do not endorse companies or products based upon their use of these guidelines.

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

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

263  
264 Users are strongly urged to maintain regular contact with and utilize information available  
265 from their trade associations, the U.S. Food and Drug Administration, the U.S. Department of  
266 Agriculture, the U.S. Environmental Protection Agency, the Centers for Disease Control and  
267 Prevention, and state agricultural, environmental, academic, and public health authorities.

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

273  
274  
275

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

276 **1. PURPOSE**

277 The issues identified in this document are based on the core elements of Good Agricultural  
278 Practices. The specific recommendations contained herein are intended for lettuce and leafy  
279 greens only. If these specific recommendations are effectively implemented this would  
280 constitute the best practices for a GAP program for the production and harvest unit operations  
281 of lettuce and leafy greens.  
282

283 **2. ISSUE: GENERAL REQUIREMENTS**

284 In addition to the area-specific requirements discussed in latter sections, there are several  
285 general requirements that are part of an effective best practices program. These requirements  
286 are outlined below.  
287

288 **2.1. The Best Practices Are:**

- 289 • A written Leafy Greens Compliance Plan which specifically addresses the Best  
290 Practices of this document shall be prepared. This plan shall address at least the  
291 following areas: water, soil amendments, environmental factors, work practices,  
292 and field sanitation.
- 293 • Handlers shall have an up to date growers list with contact and location  
294 information on file.
- 295 • The handler shall comply with the requirements of The Public Health Security  
296 and Bioterrorism Preparedness and Response Act of 2002 (farms are exempt  
297 from the Act) including those requirements for recordkeeping (traceability) and  
298 registration.
- 299 • Each grower and handler shall designate an individual responsible for their  
300 operation's food safety program. Twenty-four hour contact information shall be  
301 available for this individual in case of food safety emergencies.

302

303 **3. ISSUE: ENVIRONMENTAL ASSESSMENTS**

304 This section addresses assessments that shall be completed prior to the first seasonal planting,  
305 within one week prior to harvesting and during harvest operations. These environmental  
306 assessments are intended to identify any issues related to the produce field, adjacent land  
307 uses, or intrusion by animal of significant risk (see Table 5) that might impact produce safety.  
308

309 **3.1. The Best Practices Are:**

- 310 • Prior to the first seasonal planting and within one week prior to harvest, perform  
311 an environmental assessment of the production field and surrounding area. Focus

312 these assessments on evaluating the production field for possible animal of  
313 significant risk intrusion or other sources of human pathogens of concern,  
314 assessing adjacent land uses for possible sources that might contaminate the  
315 production field, and evaluating nearby water sources for the potential of past or  
316 present flooding.

- 317 ○ Assessment of Produce Field
  - 318 ■ Evaluate all produce fields for evidence of animal of significant
  - 319 risk intrusion and/or feces. If any evidence is found, follow
  - 320 procedures identified in the “Production Locations -
  - 321 Encroachment by Animals and Urban Settings.”
- 322 ○ Assessment of Adjacent Land Use
  - 323 ■ Evaluate all land and waterways adjacent to all production fields
  - 324 for possible sources of human pathogen of concern. These
  - 325 sources include, but are not limited to, manure storage, compost
  - 326 storage, CAFO’s, grazing/open range areas, surface water,
  - 327 sanitary facilities, and composting operations (see Table 6 for
  - 328 further detail). If any possible uses that might result in produce
  - 329 contamination are present, follow management practices identified
  - 330 in the sections below related to environmental and land use
  - 331 concerns.
- 332 ○ Assessment of Historical Land Use
  - 333 ■ To the degree practical, determine and document the historical
  - 334 land uses for production fields and any potential issues from these
  - 335 uses that might impact food safety (i.e., hazardous waste sites,
  - 336 landfills, etc.).
- 337 ○ Assessment of Flooding
  - 338 ■ Evaluate all produce fields for evidence of flooding. If any
  - 339 evidence is found, follow procedures identified in the “Flooding”
  - 340 section below.
- 341

#### 342 4. ISSUE: WATER

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

349  
350 There are several different approaches and values that can be utilized to ensure that water is  
351 of appropriate quality for its intended use. The metrics applied in this edition of the  
352 Commodity Specific Guidance should be considered a starting point in industry efforts to  
353 continuously improve the quality of water used in production of these commodities.

354  
355 The current metrics are intended to provide standards associated with water uses; however, it  
356 is known that various water sources have different microbial qualities, and each source  
357 should be monitored accordingly. Typical microbial values associated with various sources

358 can be found in the Sanitary Survey document ([Appendix A](#)). During the sanitary survey that  
359 is performed prior to each growing season expected microbial values and historical  
360 monitoring data should be used to evaluate the quality of the water source.  
361

362 **4.1. The Best Practices Are:**

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

383 Other Considerations for water

- 384 ○ Evaluate irrigation methods (drip irrigation, overhead sprinkler, furrow, etc.)  
385 for their potential to introduce, support or promote the growth of human  
386 pathogens on lettuce and leafy greens. Consider such factors as the potential  
387 for depositing soil on the crop, presence of pooled or standing water that  
388 attracts animals, etc.
- 389 ○ When waters from various sources are combined, consider the potential for  
390 pathogen growth in the water.
- 391 ○ For surface water sources, consider the impact of storm events on irrigation  
392 practices. Bacterial loads in surface water are generally much higher after a  
393 storm than normal, and caution shall be exercised when using these waters for  
394 irrigation.
- 395 ○ Use procedures for storing irrigation pipes and drip tape that reduce or  
396 eliminate potential pest infestations. Develop procedures to provide for  
397 microbiologically safe use of irrigation pipes and drip tape if a pest  
398 infestation does occur.

399                   ○ Reclaimed water shall be subject to applicable state and federal regulations  
400                   and standards. Use of this water for agricultural purposes must meet the most  
401                   stringent standard as defined by the following: state and federal regulation or  
402                   Table 1 of this document.

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

404   Lettuce/leafy greens may be sprayed with small amounts of water during machine harvest or  
405   in the field container just after harvest to reduce water loss. Water used in harvest operations  
406   may contaminate lettuce and leafy greens if there is direct contact of water containing human  
407   pathogens with edible portions of lettuce/leafy greens.  
408

409   **5.1.        The Best Practices Are:**

- 410           • Due to the timing of application of water that directly contacts edible portions of  
411           lettuce/leafy greens, assure the water is of appropriate microbial quality (e.g.,  
412           meets U.S. EPA microbial standards for drinking water).
- 413           • Test the water source periodically to demonstrate it is of appropriate microbial  
414           quality for its intended purpose (e.g., meets U.S. EPA or WHO microbial  
415           standards for drinking water) or assure that it has appropriate disinfection  
416           potential as described in Table 1.

417

418 TABLE 1. WATER USE

Use	Metric	Rationale /Remedial Actions
<p><b>PREHARVEST Foliar Applications</b> Whereby Edible Portions of the Crop <b>ARE</b> Contacted by Water</p> <p>(e.g. overhead sprinkler irrigation, pesticides/fungicide application, etc.)</p>	<p><b>Target Organism:</b> generic <i>E. coli</i>.</p> <p><b>Sampling Procedure:</b> 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><b>Sampling Frequency:</b> One sample per water source shall be collected and tested prior to use if &gt;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><b>Municipal &amp; Well Exemption:</b> 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>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. No less than one sample per month per distribution system is required under these metrics. If there are multiple potential point-of-use sampling points in a distribution system, then samples shall be taken from different point-of-use locations each subsequent month (randomize or rotate sample locations).</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 <b>SHOULD</b> be taken when test results are higher than normal, or indicate an upward trend. Investigation and remedial action <b>SHALL</b> be taken when acceptance criteria are exceeded.</p> <p><b>Remedial Actions:</b> 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"> <li>• 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).</li> <li>• For wells, perform a sanitary survey and/or treat as described in Appendix A Sanitary Survey.</li> <li>• 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</li> </ul>

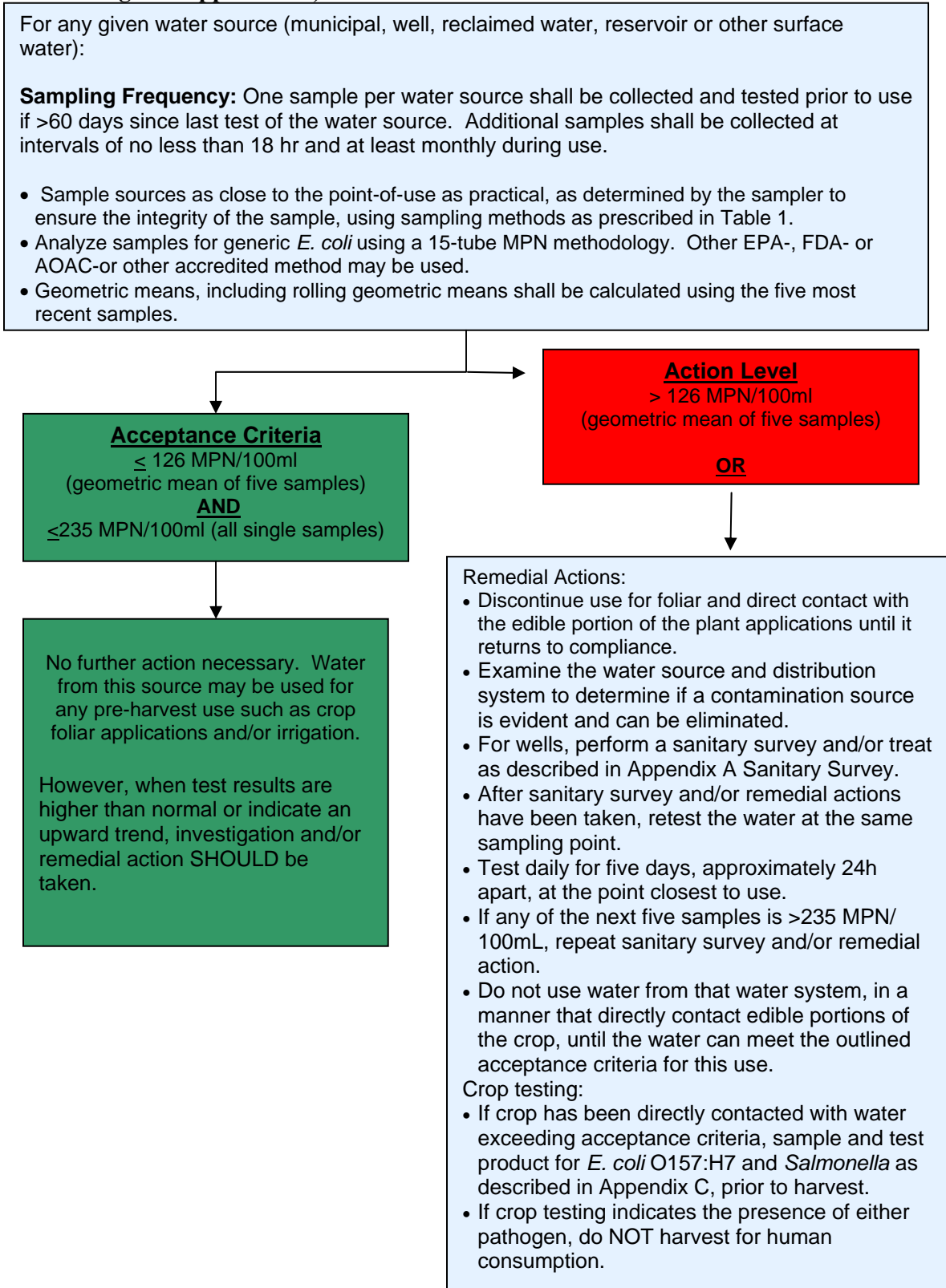
	<p><b>Test Method:</b> 15 tube MPN (FDA BAM) or other U.S. EPA, AOAC, or other method accredited for quantitative monitoring of water for generic <i>E. coli</i>. Presence/absence testing with a similar limit of detection may be used as well.</p> <p><b>Acceptance Criteria:</b> ≤126 MPN (or CFU*)/100 mL (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><b>Crop Testing:</b> 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><b>Records:</b> All test results and remedial actions shall be documented and available for verification from the grower who is the responsible party for a period of two years.</p>
<p><b>PREHARVEST Non-foliar Applications</b> Whereby Edible Portions of the Crop are <b>NOT</b> 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><b>Target Organism, Sampling Procedure, Sampling Frequency Test Method and Municipal Well Exemption:</b> as described for foliar application.</p> <p><b>Acceptance Criteria:</b> ≤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><b>POSTHARVEST Direct Product Contact or Food Contact Surfaces</b></p>	<p><b><u>Microbial Testing</u></b>  <b>Target Organism, Sampling Procedure, and Test Method:</b> as described for foliar application.</p> <p><b>Sampling Frequency:</b> One sample per water source shall be collected and tested prior to use if &gt;60 days since last test of the water source. Additional samples shall be collected at intervals of no less than 18 hr and at least monthly during use.</p> <p><b>Acceptance Criteria:</b>  <b>Negative or below DL for all samples</b></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><b>Single Pass vs. Multiple Pass Systems</b></p> <ul style="list-style-type: none"> <li>• Single pass use – Water must have non-detectable levels of <i>E. coli</i> or breakpoint disinfectant present at point of entry</li> <li>• 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)</li> </ul> <p><b>Remedial Actions:</b>  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"> <li>• 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).</li> <li>• For wells, perform a sanitary survey and/or treat as described in Appendix A Sanitary Survey.</li> <li>• 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.</li> </ul>
	<p><b><u>Physical/Chemical Testing</u></b>  <b>Target Variable:</b>  Water disinfectant (e.g. chlorine or other disinfectant compound, ORP).</p> <p><b>Multi Pass Water Acceptance Criteria:</b></p> <ul style="list-style-type: none"> <li>• <u>Chlorine</u>  ≥1 ppm free chlorine after application and pH 6.5 – 7.5 OR</li> <li>• ORP ≥ 650 mV, and pH 6.5 – 7.5</li> <li>• <u>Other approved treatments</u> per product EPA label for human pathogen reduction in water.</li> </ul> <p><b>Testing Procedure:</b></p> <ul style="list-style-type: none"> <li>• Chemical reaction based colorimetric test, or</li> <li>• Ion specific probe, or</li> <li>• ORP, or</li> <li>• Other as recommended by disinfectant supplier.</li> </ul>	<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><b>Records:</b> 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>

	<p><b>Testing Frequency:</b> 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>	
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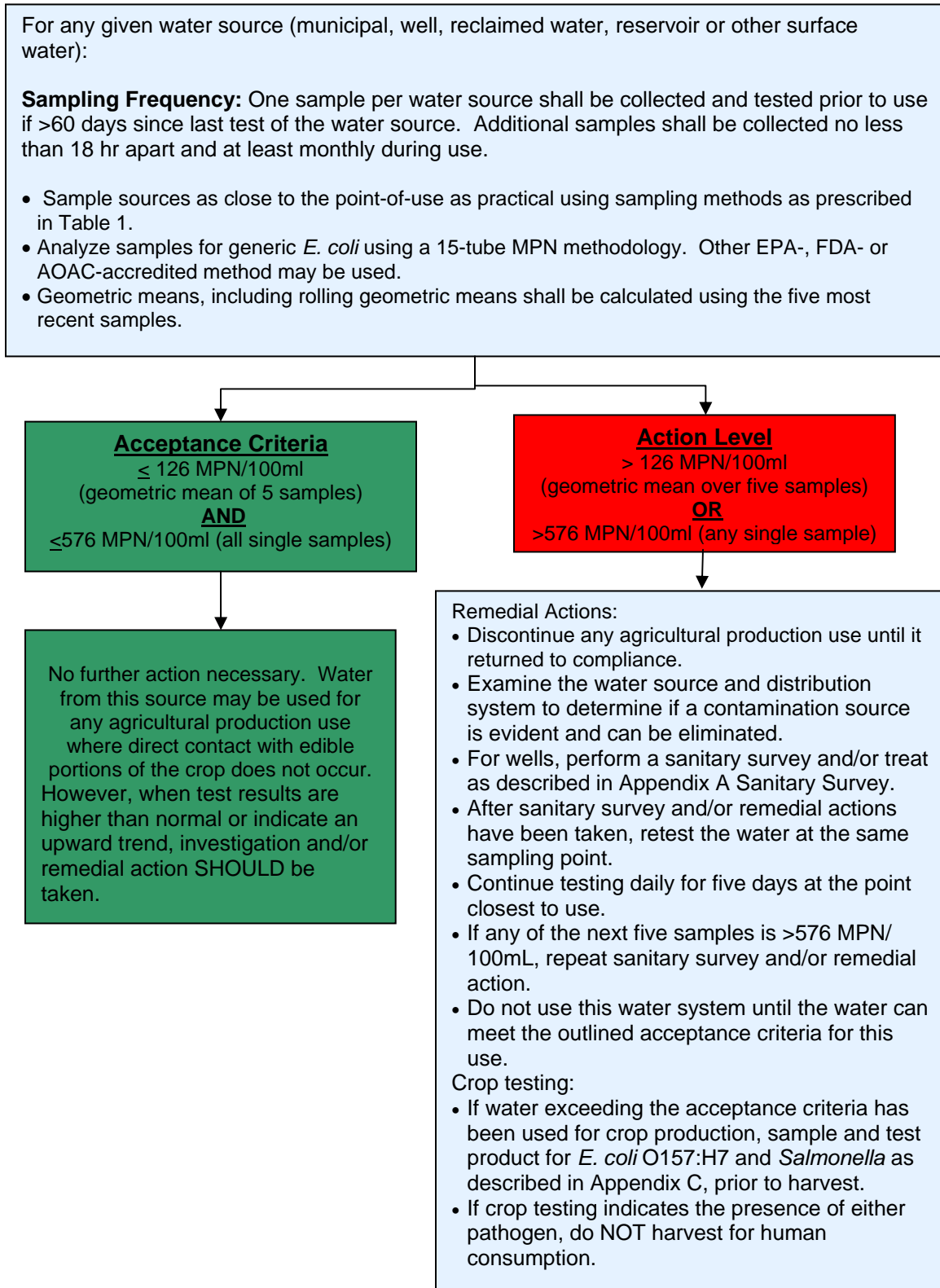
**Figure 1A. Decision Tree for PRE-HARVEST WATER USE – Foliar Applications whereby edible portions of the crop are contacted by water (e.g. overhead irrigation, pesticide/fungicide applications)**



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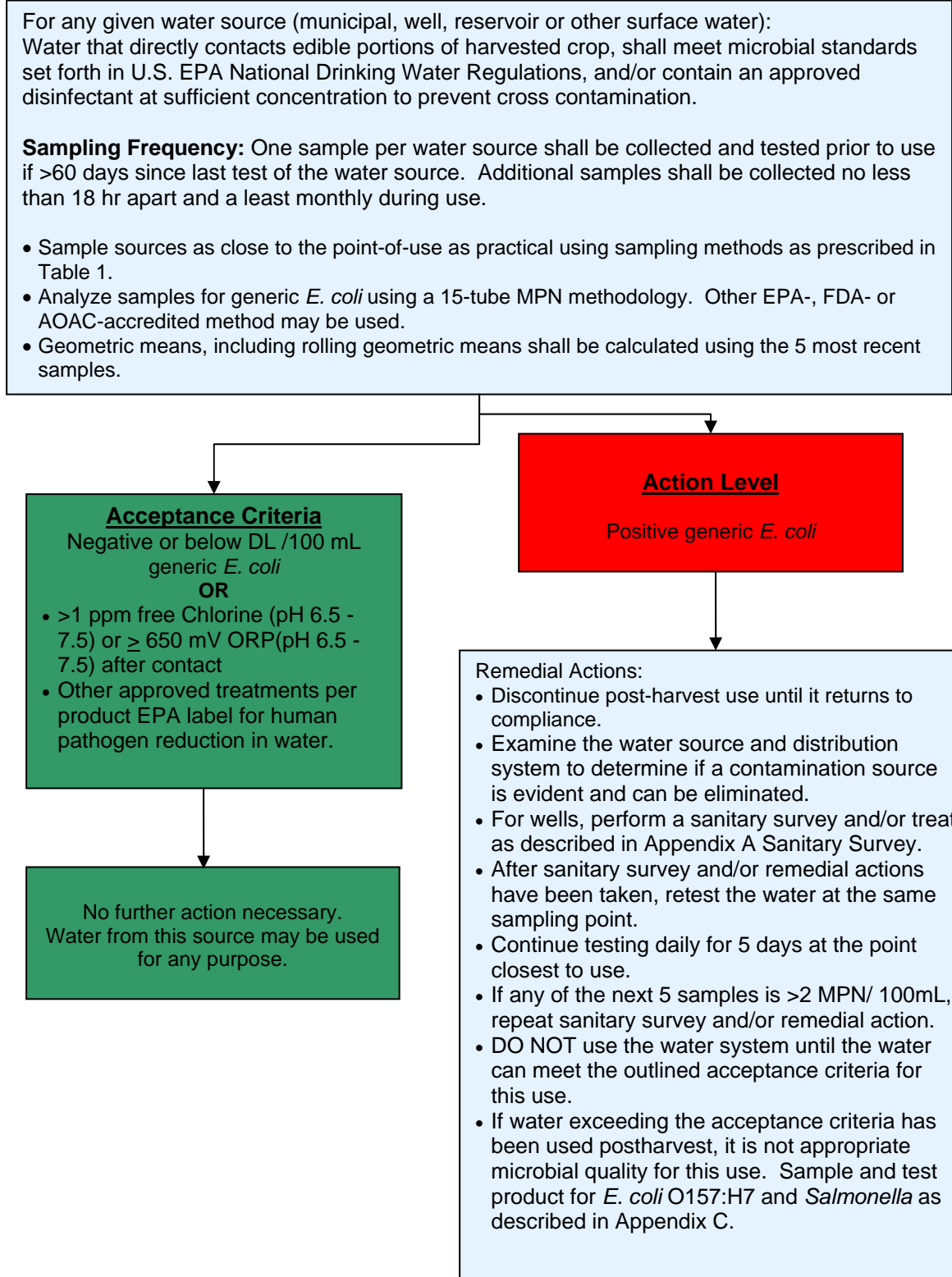
**Figure 1B. Decision Tree for PRE-HARVEST WATER USE – Non-Foliar Applications whereby edible portions of the crop are NOT contacted by water (e.g. furrow or drip irrigation, dust abatement water)**



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



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433 **6. ISSUE: SOIL AMENDMENTS**

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

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

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460 **6.1. The Best Practices Are:**

- 461 • DO NOT USE raw manure or soil amendment that contain un-composted,  
462 incompletely composted or non-thermally treated animal manure to fields which  
463 will be used for lettuce and leafy green production.
- 464 • See Table 2 and Decision Trees (Figures 2A and 2B) for numerical criteria and  
465 guidance for compost and soil amendments used in lettuce and leafy greens  
466 production fields. The “Technical Basis Document” (Appendix B) describes the  
467 process used to develop these metrics.
- 468 • Any soil amendment that does not contain animal manure must have a document  
469 (e.g., ingredient list, statement of identity, letter of guaranty, etc.) from the  
470 producer or seller demonstrating that it is manure free. This document must  
471 indicate in some way that manure is not an ingredient used in the production of  
472 the amendment or provide the ingredients of the product. A statement of identity  
473 or product is sufficient for single-chemical amendments (i.e., “calcium  
474 carbonate” or “gypsum”). If “inert ingredients” are listed as part of an  
475 amendment, then a document from the producer or seller is necessary indicating  
476 manure has not been added. The manure free document must be available for  
477 verification before harvest begins and it must be saved and available for

- 478 inspection for 2 years. A new document is required every two years and if there  
479 is a significant process or ingredient change.
- 480 • Implement management plans (e.g., timing of applications, storage location,  
481 source and quality, transport, etc.) that significantly reduce the likelihood that soil  
482 amendments being used contain human pathogens.
- 483 • Verify that the time and temperature process used during the composting process  
484 reduces, controls, or eliminates the potential for human pathogens being carried  
485 in the composted materials, as applicable to regulatory requirements.
- 486 • Maximize the time interval between soil amendment application and time to  
487 harvest.
- 488 • Implement practices that control, reduce or eliminate likely contamination of  
489 lettuce/leafy green fields in close proximity to on-farm stacking of manure.
- 490 • Use soil amendment application techniques that control, reduce or eliminate  
491 likely contamination of surface water and/or edible crops being grown in adjacent  
492 fields.
- 493 • Segregate equipment used for soil amendment handling, preparation, distribution,  
494 applications or use effective means of equipment sanitation before subsequent use  
495 that effectively reduce the potential for cross contamination.
- 496 • Minimize the proximity of wind-dispersed or aerosolized sources of  
497 contamination (e.g., water and manure piles) that may potentially contact growing  
498 lettuce/leafy greens or adjacent edible crops. Segregate equipment used for soil  
499 amendment applications or use effective means of equipment sanitation before  
500 subsequent use.
- 501 • Compost suppliers shall have written Standard Operating Procedures to prevent  
502 cross-contamination of finished compost with raw materials through equipment,  
503 runoff, or wind, and growers shall obtain proof that these documents exist.
- 504 • Compost operations supplying compost to leafy greens crops shall maintain  
505 temperature monitoring and turning records for at least two years, and growers  
506 shall obtain proof that this documentation exists. This applies to composting  
507 operations regulated under Title 14 CCR as well as smaller operations that do not  
508 fall under Title 14.
- 509 • Perform microbiological testing of soil amendments prior to application (Table  
510 2).
- 511 • Do not use biosolids as a soil amendment for production of lettuce or leafy  
512 greens.
- 513 • Retain documentation of all processes and test results by lot (at the supplier)  
514 and/or Certificates of Analysis available for inspection for a period of at least two  
515 years.
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TABLE 2. SOIL AMENDMENTS

Amendment	Metric/Rationale
<p><b>Raw Manure or Not Fully Composted Animal Manure Containing Soil Amendments (see composted manure process definition below)</b></p>	<p><b>DO NOT USE OR APPLY</b> 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><b>Composted Soil Amendments (containing animal manure or animal products)</b></p> <p>*Composted soil amendments should not be applied after emergence of plants.</p>	<p><b>Please see Figure 2A: Decision Tree for Use of Composted Soil Amendments.</b></p> <p><b>Composting Process Validation:</b></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 for 15 days, with a minimum of five turnings.</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><b>Target Organisms:</b></p> <ul style="list-style-type: none"> <li>• Fecal coliforms</li> <li>• <i>Salmonella</i> spp</li> <li>• <i>E. coli</i> O157:H7</li> </ul> <p><b>Acceptance Criteria:</b></p> <ul style="list-style-type: none"> <li>• Fecal coliforms &lt;1000 MPN/gram</li> <li>• <i>Salmonella</i>: Negative or &lt; DL (&lt;1/ 30 grams)</li> <li>• <i>E. coli</i> O157:H7: Negative or &lt; DL (&lt;1/ 30 grams)</li> </ul>

Amendment	Metric/Rationale
	<p><b>Recommended Test Methods:</b></p> <ul style="list-style-type: none"> <li>• Fecal coliforms: 9 tube MPN</li> <li>• <i>Salmonella spp.</i>: U.S. EPA Method 1682</li> <li>• <i>E. coli</i> O157:H7: Any laboratory validated method for compost sampling.</li> <li>• Other U.S. EPA, FDA, or AOAC-accredited methods may be used as appropriate.</li> </ul> <p><b>Sampling Plan:</b></p> <ul style="list-style-type: none"> <li>• 12 point sampling plan composite sample (divide each lot/pile into a 3 x 4 grid and extract 12 equivolume samples.)</li> <li>• Sample may be taken by the supplier if trained by the testing laboratory</li> <li>• Laboratory must be certified/accredited for microbial testing by an appropriate process authority</li> </ul> <p><b>Testing Frequency:</b></p> <ul style="list-style-type: none"> <li>• 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.</li> </ul> <p><b>Application Interval:</b></p> <ul style="list-style-type: none"> <li>• Must be applied &gt;45 days before harvest</li> </ul> <p><b>Documentation:</b></p> <ul style="list-style-type: none"> <li>• 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.</li> </ul> <p><b>Rationale:</b></p> <ul style="list-style-type: none"> <li>• 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 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.</li> </ul>

<p><b>Soil amendments containing animal manure that has been physically heat treated or processed by other equivalent methods.</b></p>	<p><b>Please see Figure 2B: Decision Tree for Use of Physically Heat Treated Soil Amendments.</b></p> <p><b>Physical Heat Process Validation</b></p> <ul style="list-style-type: none"> <li>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.</li> </ul> <p><b>Target Organism:</b></p> <ul style="list-style-type: none"> <li>Fecal coliforms</li> <li><i>Salmonella</i> spp</li> <li><i>E. coli</i> O157:H7</li> </ul> <p><b>Acceptance Criteria:</b></p> <ul style="list-style-type: none"> <li>Fecal coliforms Negative or &lt; DL per gram</li> <li><i>Salmonella</i>: Negative or &lt; DL (&lt;1/ 30 grams)</li> <li><i>E. coli</i> O157:H7: Negative or &lt; DL (&lt;1/ 30 grams)</li> </ul> <p><b>Recommended Test Methods:</b></p> <ul style="list-style-type: none"> <li>Fecal coliforms: 9 tube MPN</li> <li><i>Salmonella</i> spp: U.S. EPA Method 1682</li> <li><i>E. coli</i> O157:H7: Any laboratory validated method for testing soil amendments.</li> <li>U.S. EPA, FDA, AOAC-or other accredited methods may be used as appropriate</li> </ul> <p><b>Sampling Plan:</b></p> <ul style="list-style-type: none"> <li>12 point sampling plan composite sample (divide each lot/pile into a 3 x 4 grid and extract 12 equivolume samples)</li> <li>Sample may be taken by the supplier if trained by the testing laboratory</li> <li>Laboratory must be certified/accredited by annual review of laboratory protocols based on GLPs by recognized NGO.</li> </ul> <p><b>Testing Frequency:</b></p> <ul style="list-style-type: none"> <li>Each lot before application to production fields. <ul style="list-style-type: none"> <li>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</li> </ul> </li> </ul>
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of the standard process or microbial inactivation calculations of organisms of significant risk (included w/Certificate) as outlined in FDA CFSAN publication “**Kinetics of Microbial Inactivation for Alternative Food Processing Technologies. Overarching Principles: Kinetics and Pathogens of Concern for All Technologies**” (Incorporated for reference in Appendix E Thermal Process Overview)

**Application Interval:**

- If the physical heat treatment process used to inactivate human pathogens of significant public health concern that may be found in animal manure containing soil amendments, is validated and meets the microbial acceptance criteria outlined below, then no time interval is needed between application and harvest.
- If the physical heat treatment process used to inactivate human pathogens of significant public health concern that may be found in animal manure containing soil amendments is not validated but will likely significantly reduce microbial populations of human pathogens (minimum temperature: 300°F (150°C) for 60 minutes resulting in a moisture content <30% dry weight) and meets that microbial acceptance criteria outlined above, then a 45 day interval between application and harvest is required.

**Documentation:**

- All test results and/or Certificates of Analysis 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.

**Rationale:**

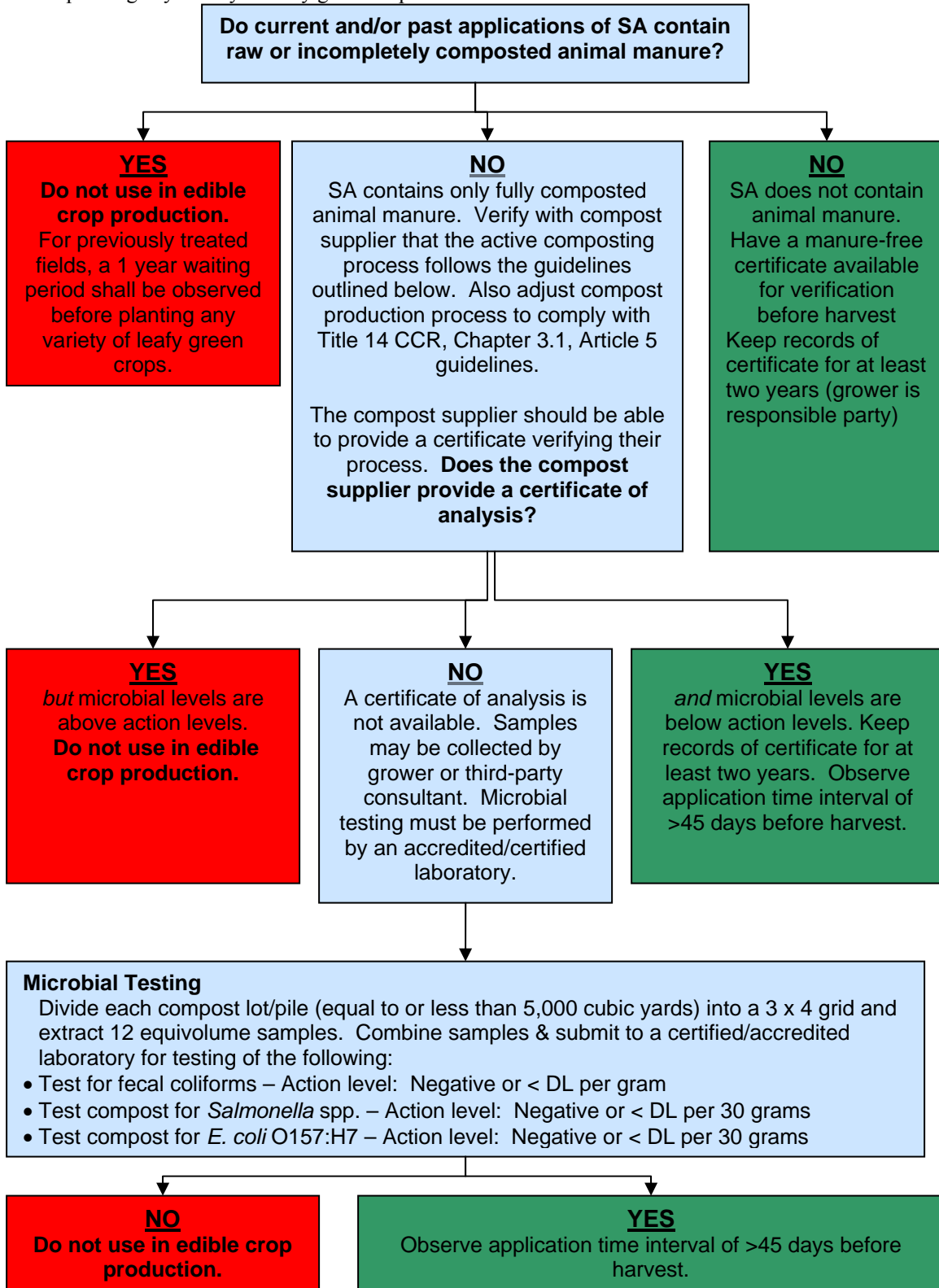
- The microbial metrics and validated processes for compost are based on allowable levels from California state regulations (CCR Title 14 - Chapter 3.1 - Article 5 2007), with the addition of testing for *E. coli* O157:H7 as the microbe of particular concern. A more stringent level of fecal coliform was also included to address the much more controlled nature of soil amendments produced in this manner. The above suggested application interval was deemed appropriate due to the specified multiple hurdle risk reduction approach outlined. Raw manure must be composted with an approved process and pass testing requirements before application.
- 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.

<b>Soil Amendments Not Containing Animal Manure</b>	<ul style="list-style-type: none"><li>• Any soil amendment that DOES NOT contain animal manure must have documentation that it is manure-free.</li><li>• The documentation must be available for verification before harvest begins.</li><li>• 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</li><li>• 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.</li></ul>
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### Figure 2A. Decision Tree for Composted Soil Amendments (SA)

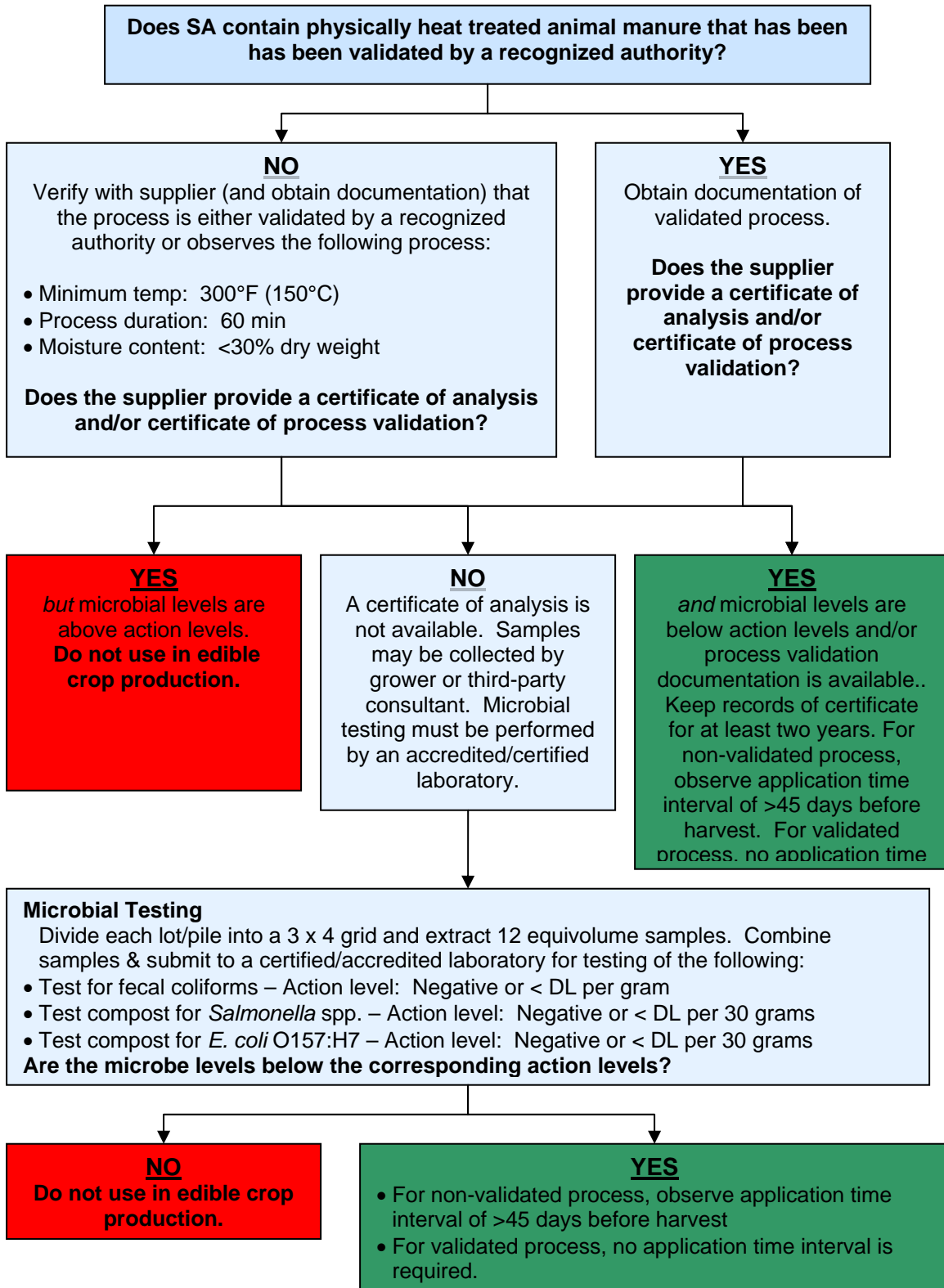
If raw manure has been directly applied to the field in the past, a 1 year waiting period shall be observed before planting any variety of leafy green crops.



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



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

530 Nonsynthetic crop treatments are commonly applied post-emergence for pest and disease  
531 control, greening, and to provide organic and inorganic nutrients to the plant during the  
532 growth cycle. For the purposes of this document, they are defined as any crop input that  
533 contains animal manure, an animal product, and/or an animal by-product that is reasonably  
534 likely to contain human pathogens. Due to the potential for human pathogen contamination,  
535 these treatments should only be used under conditions that minimize the risk for crop  
536 contamination.  
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538 **7.1. The Best Practices Are:**

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

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TABLE 3. NONSYNTHETIC CROP TREATMENTS

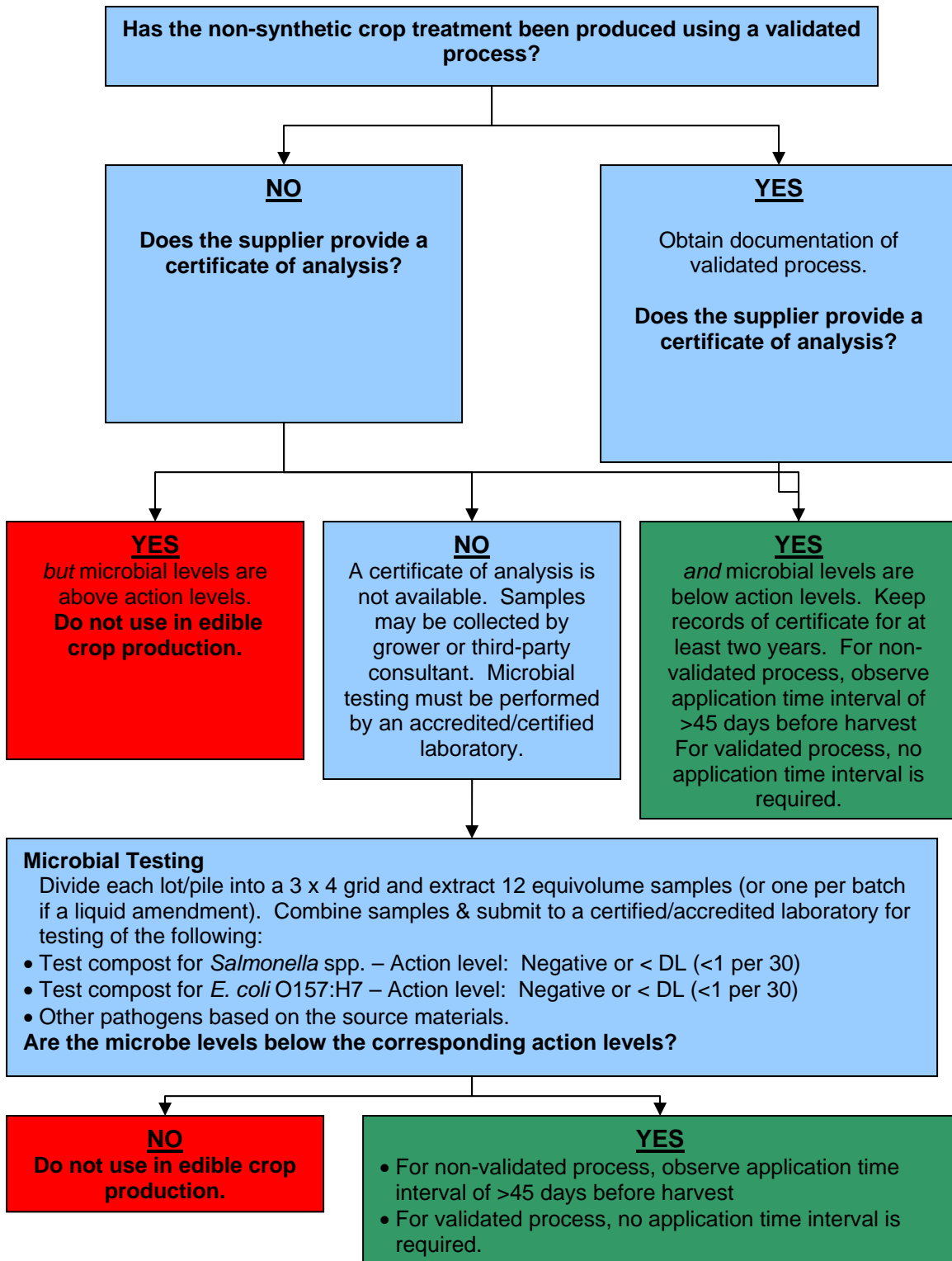
Treatment	Metric/Rationale
<p><i>Any crop input that contains animal manure, an animal product, and/or an animal by-product that is reasonably likely to contain human pathogens.</i></p> <p>Examples include but are not limited to:</p> <ul style="list-style-type: none"> <li>• Compost teas,</li> <li>• Fish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

Treatment	Metric/Rationale
	<p><b>Application Interval:</b></p> <ul style="list-style-type: none"> <li>• If the physical, chemical and/or biological treatment process used to render the crop input safe for application to edible crops is validated and meets that microbial acceptance criteria outlined above, no time interval is needed between application and harvest.</li> <li>• 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.</li> </ul> <p><b>Documentation:</b></p> <ul style="list-style-type: none"> <li>• 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.</li> </ul> <p><b>Rationale:</b></p> <ul style="list-style-type: none"> <li>• 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.</li> </ul>

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573

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



574  
575

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

577

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

581

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

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

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

595

596 **8.1. The Best Practices Are:**

- 597
- Prepare an SOP for harvest equipment that addresses the following:
    - 598 ○ Sanitation verification
    - 599 ○ Daily inspection
    - 600 ○ Periodic microbial swabs or other equivalent indicator
    - 601 ○ Proper cleaning, sanitation and storage of hand harvest equipment (knives,  
602 scythes, etc.)
    - 603 ○ Control procedures when equipment is not in use, including policy for  
604 removal of equipment from the work area or site and the use of scabbards,  
605 sheathes or other storage equipment.
  - 606 • Prepare an SOP for handling and storage of product containers that addresses the  
607 following:
    - 608 ○ Over night storage
    - 609 ○ Contact with the ground
    - 610 ○ Container assembly (RPC, fiber bin, plastic bin, etc)
    - 611 ○ Damaged containers
    - 612 ○ Use of containers only as intended
  - 613 • Prepare an SOP for sanitary operation of equipment which addresses:
    - 614 ○ Spills and leaks

- 615 ○ Inoperative water sprays
- 616 ○ Exclusion of foreign objects (including glass, plastic, metal and other
- 617 debris)
- 618 ○ Establish and implement cleaning and sanitation schedules for containers
- 619 and equipment that will be used in hydration.
- 620 ○ Maintain logs documenting cleaning and sanitation, and retain these
- 621 records for at least two years.
- 622 ○ Establish policies for the storage and control of water tanks and
- 623 equipment used for hydration operations when not in use.
- 624
- 625 ● Establish appropriate measures that reduce and control the potential introduction
- 626 of human pathogens at the cut surface during and after mechanical harvest
- 627 operations. Due to the cut surface being more vulnerable to microbial
- 628 contamination, this best practice is extremely important and all practical means
- 629 should be taken to reduce the possibility of introduction of contamination at this
- 630 process step.
- 631 ● If re-circulated rinse or antioxidant solutions are used on the cut surface, take all
- 632 practicable precautions to prevent them from becoming a source of
- 633 contamination.
- 634 ● Design equipment to facilitate cleaning by using materials and construction that
- 635 facilitate cleaning and sanitation of equipment food contact surfaces (e.g.,
- 636 transportation tarps, conveyor belts, etc.).
- 637 ● Establish the frequency of equipment cleaning and sanitation by developing
- 638 Sanitation Standard Operating Procedures (SSOPs) and a sanitation schedule for
- 639 machine harvest operations.
- 640 ● Evaluate the use of cleaning verification methods for harvesting equipment (e.g.,
- 641 ATP test methods).
- 642 ● Locate equipment cleaning and sanitizing operations away from product and other
- 643 equipment to reduce the potential for cross contamination.
- 644 ● Establish equipment storage and control procedures to minimize the potential for
- 645 contamination when not in use. Establish policies and sanitary design options that
- 646 facilitate frequent and thorough cleaning and sanitizing of food contact surfaces.
- 647 ● Develop and implement appropriate cleaning, sanitizing, storage and handling
- 648 procedures of all food contact surfaces to reduce and control the potential for
- 649 microbial cross contamination.
- 650 ● Allow adequate distance for the turning and manipulation of harvest equipment to
- 651 prevent cross contamination from areas of animal of significant risk intrusion or
- 652 adjacent land that may pose a risk.
- 653

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

656 After manual harvest of lettuce/leafy greens, placing or stacking product on soil before the  
657 product is placed into a container may expose the product to human pathogens if the soil is  
658 contaminated. Research has demonstrated that microbes, including human pathogens, can  
659 readily attach to cut lettuce/leafy green surfaces (Takeuchi *et al.* 2001).  
660

661 **9.1. The Best Practices Are:**

- 662 • Evaluate appropriate measures that reduce and control the potential introduction  
663 of human pathogens through soil contact at the cut surface after harvest (e.g.  
664 frequency of knife sanitation, no placement of cut surfaces of harvested product  
665 on the soil, container sanitation, single use container lining, etc.).
- 666 • Do not stack soiled bins on top of each other if the bottom of one bin has had  
667 direct contact with soil unless a protective barrier (*i.e.*, liner, cover, *etc.*) is used  
668 to separate the containers.

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

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

675 **10.1. The Best Practices Are:**

- 676 • Use appropriate preventive measures outlined in GAPs such as training in appropriate  
677 and effective hand washing, glove use and replacement, and mandatory use of  
678 sanitary field latrines to reduce and control potential contamination.
- 679 • Establish a written worker practices program (*i.e.*, an SOP) that can be used to verify  
680 employee compliance with company food safety policy. This program shall establish  
681 the following practices for field and harvest employees as well as visitors.
  - 682 ○ Prior to harvest, an individual should be designated as responsible for  
683 harvesting food safety
  - 684 ○ Use, storage, record keeping, and proper labeling of chemicals
  - 685 ○ Training on proper sanitation and hygiene practices
  - 686 ○ Requirements for workers to wash their hands before beginning or returning  
687 to work
  - 688 ○ Confinement of smoking, eating and drinking of beverages other than water  
689 to designated areas.
  - 690 ○ Personal item storage
- 691 • A written physical hazard prevention program should be developed for leafy green  
692 products that are intended for further processing. The program must address the  
693 following:

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

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

728 When farm equipment has had direct contact with raw untreated manure, untreated compost,  
729 waters of unknown quality, animals of significant risk, or other potential human pathogen  
730 reservoirs it may be a source of cross contamination. Such equipment should not be used in  
731 proximity to or in areas where it may contact edible portions of lettuce and or leafy greens.  
732

733 **11.1. The Best Practices Are:**

- 734 • Identify any field operations that may pose a risk for cross-contamination. These  
735 include management personnel in the fields, vehicles used to transport workers,  
736 as well as many other possibilities.
- 737 • Segregate equipment used in high-risk operations or potentially exposed to high  
738 levels of contamination.
- 739 • Use effective means of equipment cleaning and sanitation before subsequent  
740 equipment use in lettuce/leafy greens production, if it was previously used in a  
741 high-risk operation.
- 742 • Develop appropriate means of reducing and controlling the possible transfer of  
743 human pathogens to soil and water that may directly contact edible lettuce/leafy  
744 green tissues through use of equipment.
- 745 • Maintain appropriate records related to equipment cleaning and possible cross-  
746 contamination issues for a period of two years.

747

748 **12. ISSUE: FLOODING**

749 Flooding for purposes of this document is defined as the flowing or overflowing of a field  
750 with water outside of a grower's control, that is reasonably likely to contain microorganisms  
751 of significant public health concern and is reasonably likely to cause adulteration of the  
752 edible portions of fresh produce in that field. Pooled water (e.g., rainfall) that is not  
753 reasonably likely to contain microorganisms of significant public health concern and is not  
754 reasonably likely to cause adulteration of the edible portion of fresh produce should not be  
755 considered flooding.

756

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

761

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

771

772 "Adulterated food may be subject to seizure under the Federal Food, Drug, and Cosmetic  
773 Act, and those responsible for its introduction or delivery for introduction into interstate  
774 commerce may be enjoined from continuing to do so or prosecuted for having done so. Food  
775 produced under unsanitary conditions whereby it may be rendered injurious to health is

776 adulterated under § 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)  
777 (4); (US FDA 2004).

778

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

784

785 **12.1. The Best Practices For Product That Has Come Into Contact With**  
786 **Flood Water Are:**

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

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

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

795

796  
797

**TABLE 4. FLOODING**

When evidence of flooding in a production block occurs.

<b>Practice</b>	<b>Metric/Rationale</b>
<b>Flooding Defined</b>	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.
<b>Allowable Harvest Distance from Flooding</b>	<ul style="list-style-type: none"> <li>• Buffer and do not harvest any product within 30 ft of the flooding.</li> <li>• Required buffer distance may be greater than 30 ft based on risk analysis by food safety professional.</li> <li>• 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.</li> </ul>
<b>Verification</b>	<ul style="list-style-type: none"> <li>• 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.</li> </ul>
<b>Time Interval Before Planting Can Commence Following the Receding of Floodwaters</b>	<ul style="list-style-type: none"> <li>• 60 days prior to planting provided that the soil has sufficient time to dry out.</li> <li>• 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.</li> <li>• Appropriate mitigation and mitigation strategies are included in the text portion of the document.</li> </ul>
<b>Rationale</b>	<ul style="list-style-type: none"> <li>• <a href="#">The basis for the 30 foot distance is the turn around distance for production equipment to prevent cross-contamination of non-flooded ground or produce.</a></li> </ul>

798  
799

800 **12.2. The Best Practices for Product in Proximity to a Flooded Area But**  
801 **Not Contacted By Flood Water Are:**

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

812

813 **12.3. The Best Practices For Formerly Flooded Production Ground Are:**

- 814 • Allow soils to dry sufficiently and be reworked prior to planting subsequent crops  
815 on formerly flooded production ground.
- 816 • Do not replant formerly flooded production ground for at least 60 days following  
817 the receding of floodwaters. This period or longer and active tillage of the soil  
818 provide additional protection against the survival of pathogenic organisms.
- 819 • If flooding has occurred in the past on the property, soil clearance testing may be  
820 conducted prior to planting leafy greens. Soil testing may be used to shorten the  
821 clearance period to 30 days. If performed, testing must indicate soil levels of  
822 microorganisms lower than the standards for processed compost. Suitable  
823 representative samples should be collected for the entire area suspected to have  
824 been exposed to flooding.
- 825 • Sample previously flooded soil for the presence of microorganisms of significant  
826 public health concern or appropriate indicator microorganisms. Microbial soil  
827 sampling can provide valuable information regarding relative risks; however,  
828 sampling by itself does not guarantee that crops grown within the formerly  
829 flooded production area will be free of the presence of human pathogens.
- 830 • Prior to replanting or soil testing, the designated food safety professional for the  
831 grower shall perform a detailed food safety assessment of the production field.  
832 This designated professional will be responsible for assessing the relative merits  
833 of testing versus observing the appropriate time interval for planting, and also  
834 will coordinate any soil testing plan with appropriate third-party consultants  
835 and/or laboratories that have experience in this type of testing.
- 836 • Evaluate the field history and crop selection on formerly flooded production  
837 ground.
- 838 • Assess the time interval between the flooding event, crop planting, and crop  
839 harvest. Comparative soil samples may be utilized to assess relative risk if

- 840 significant reductions in indicator microorganisms have occurred within this time  
841 interval.
- 842 • Evaluate the source of flood waters (e.g., drainage canal, river, irrigation canal,  
843 etc.) for potential significant upstream contributors of human pathogens at levels  
844 that pose a significant threat to human health.
  - 845 • Prevent cross-contamination by cleaning or sanitizing any equipment that may  
846 have contacted previously flooded soil (also see the section on Equipment  
847 Facilitated Cross Contamination above).

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

849 Lettuce/leafy greens are grown in varying regions but generally in moderate weather  
850 conditions. Cool, humid conditions favor human pathogen persistence (Takeuchi and Frank  
851 2000; Takeuchi *et al.* 2000) while drier climates may present other problems such as  
852 requirements for additional water that may increase the potential for introduction of human  
853 pathogens. Heavy rains in certain areas may also cause lettuce/leafy greens to be exposed to  
854 contaminated soil due to rain splashing. It is important to tailor practices and procedures  
855 designed to promote food safety to the unique environment in which each crop may be  
856 produced  
857

858 **13.1. The Best Practices Are:**

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

870

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

873 Lettuce/leafy greens are generally grown in rural areas that may have adjacent wetlands,  
874 wildlands, and/or parks harboring wildlife. Some wildlife species are known to be potential  
875 carriers of various human pathogens (Fenlon 1985). Specific wildlife species that have been  
876 shown to pose the greatest risk are the focus of this section and are listed in Table 5. In  
877 addition, extensive development in certain farming communities has also created situations  
878 with urban encroachment and unintentional access by domestic animals and livestock which  
879 may also pose varying degrees of risk depending on the animal species. Finally, it is possible  
880 that some land uses may be of greater concern than others when located near production  
881 fields. Table 6 provides a list of these uses and recommended buffer distances.

882

883 **14.1. The Best Practices Are:**

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

- 925 • Train harvest employees to recognize and report evidence (e.g., feces) of animal  
926 of significant risk activity.
- 927 • Pooled water (e.g., a seasonal lake) from rainfall may attract animals of  
928 significant risk and should be considered as part of any land use evaluation.
- 929 • Consider controlling risks associated with encroachment by urban development.  
930 Risks may include, but are not limited to, domestic animal fecal contamination of  
931 production fields and harvest equipment and septic tank leaching.
- 932 • Growers are encouraged to contact the relevant agencies (e.g., the Regional  
933 Water Quality Control Board and state and federal fish and wildlife agencies) to  
934 confirm the details of these requirements. In addition, growers may wish to  
935 consult with local NRCS to evaluate the food safety risks associated with wildlife  
936 of significant risk, livestock, domestic animals and other adjacent land uses and  
937 to develop and document strategies to control or reduce the introduction of  
938 human pathogens through wildlife of significant risk for each production block.

939  
940

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

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

Issue	Metric	Remedial Actions
<p><b>Evidence of Intrusion</b></p>	<p><u>Frequency</u></p> <ul style="list-style-type: none"> <li>• There shall be a periodic monitoring plan in place for production fields.</li> <li>• There shall be Pre Season, Pre Harvest, and Harvest Assessments</li> </ul> <p><u>Variables</u></p> <ul style="list-style-type: none"> <li>• Physical observation of animals in the field</li> <li>• Downed fences</li> <li>• Animal tracks in production block</li> <li>• Animal feces or urine in production block</li> <li>• Eaten plants in production block</li> </ul> <p><u>Animals of Significant Risk</u></p> <ul style="list-style-type: none"> <li>• Deer</li> <li>• Pigs (wild and domestic)</li> <li>• Cattle</li> <li>• Goats and Sheep</li> </ul>	<ul style="list-style-type: none"> <li>• If there is evidence of intrusion by animals of significant risk, the production block must undergo a detailed food safety assessment by appropriately trained food safety personnel (see Glossary) prior to harvest, as defined in the text of this document.</li> <li>• In developing remedial and corrective actions, consider consulting with wildlife and/or domestic animal experts as appropriate.</li> <li>• If remedial actions cannot be formulated that control or eliminate the identified risk, destroy the block by disking under the crop.</li> <li>• Equipment used to destroy crop must be cleaned and sanitized upon exiting the field.</li> <li>• Investigate potential causes for intrusion by animals of significant risk and assess the extent of intrusion and impact on crop food risk.</li> <li>• Formulate effective corrective actions. Prior to taking action that may affect natural resources, growers should check local, state and federal laws and regulations that protect riparian habitat, restrict removal of vegetation or habitat, or restrict construction of wildlife deterrent fences in riparian areas or wildlife corridors.</li> <li>• Evidence of intrusion by animals of significant risk and corrective actions shall be documented and available for verification for a period of two years.</li> </ul>
<p><b>Allowable Harvest Distance from Evidence of Intrusion</b></p>	<p><b>Please see Figure 5. Decision Tree for Conducting Pre-Harvest and Harvest Assessments.</b></p> <p><u>Monitoring</u> Evaluate and monitor animal of significant risk activity in and proximate to lettuce/leafy greens fields and production environments. Conduct periodic monitoring, pre-season, pre-harvest, and harvest assessments.</p> <p><u>Pre Harvest Assessment:</u> Conduct the pre-harvest assessment not more than one week prior to harvest.</p> <p><b>Fecal Material</b></p> <ul style="list-style-type: none"> <li>• Do not harvest any produce that has come into direct contact with fecal material.</li> <li>• 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</li> </ul>	

Issue	Metric	Remedial Actions
	<p>adequately control the risk. The food safety professional can increase this buffer distance if deemed appropriate.</p> <ul style="list-style-type: none"> <li>Remove fecal material from the field and dispose of properly.</li> </ul> <p><b>Intrusion</b></p> <ul style="list-style-type: none"> <li>If evidence of animal of significant risk intrusion is found in a production field, conduct a visual food safety assessment to determine whether the areas of intrusion can be adequately controlled (e.g., solitary deer track with no evidence of feeding), or whether a three foot buffer radius non-harvest area should be applied (e.g., wide areas of wild pig rooting and tracks).</li> </ul> <p><u>Harvest Assessment</u></p> <p>If evidence of animal of significant risk intrusion into the production block is not discovered until harvest operations:</p> <ul style="list-style-type: none"> <li>Stop harvest operations.</li> <li>Initiate an intensified block assessment for evidence of further contamination and take appropriate actions per the aforementioned actions.</li> <li>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.</li> <li>Require all employees to wash and sanitize their hands/gloves before resuming harvest operations.</li> <li>If contamination is discovered in harvest containers such as bins/totes, discard the product, and clean and sanitize the container before reuse.</li> </ul>	
<b>Verification</b>	<ul style="list-style-type: none"> <li>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.</li> </ul>	
<b>Rationale</b>	<ul style="list-style-type: none"> <li>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.</li> </ul>	

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**TABLE 6. CROP LAND AND WATER SOURCE ADJACENT LAND USE**

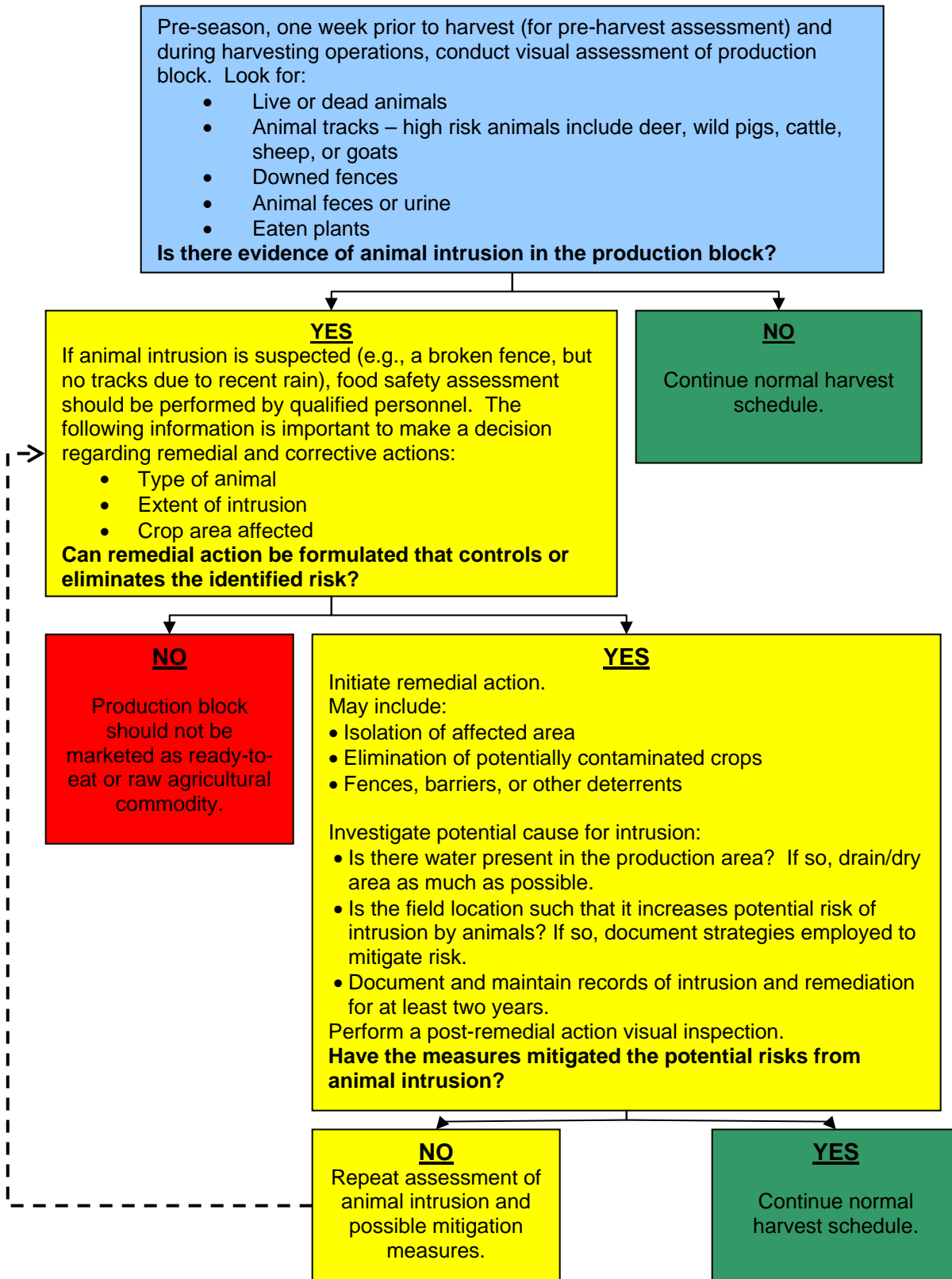
Land Use/Water Source	Metric (This distance may be either increased or decreased depending on risk and mitigation factors.)	Considerations for Risk Analysis*		
		Risk/Mitigation Factors	Increase Distance	Decrease Distance
Composting Operations (manure or animal products)	Due to the lack of science at 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 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	Access and review COA for materials in question.		√
		Topography: Uphill from crop	√	
		Topography: Downhill from crop		√
		Opportunity for water run off through or from non-synthetic soil amendment storage areas	√	
		Opportunity for soil leaching	√	
		Covering on pile to prevent wind dispersion		√

Land Use/Water Source	Metric (This distance may be either increased or decreased depending on risk and mitigation factors.)	Considerations for Risk Analysis*		
		Risk/Mitigation Factors	Increase Distance	Decrease Distance
	distance of 30 feet from the edge of the crop is proposed			
Grazing Lands/Domestic Animals (includes homes with hobby farms, and non commercial livestock)	30 ft from the edge of crop.	Fencing and other physical barriers such as berms, diversion ditches and vegetated strips can be employed to prevent intrusion of domestic animals, control runoff, etc.		√
		Topography: Uphill from crop	√	
		Topography: Downhill from crop		√
		Opportunity for water run off through or from grazing lands	√	
		Opportunity for soil leaching	√	
Homes or other building with a septic leach field.	30 ft from the edge of crop to the leach field.	Active leach field: < 10 yrs old		√
		Active leach field: > 25 yrs old	√	
		Inactive leach field		√
		Topography: Uphill from crop	√	
		Topography: Downhill from crop		√
		Physical barriers		√
Well Head Distance from Untreated Manure	200 ft separation of untreated manure from wells, although less distance may be sufficient.	Topography: Uphill from manure		√
		Topography: Downhill from manure	√	
		Opportunity for water run off from or through untreated manure to well head	√	
		Opportunity for soil leaching	√	
		Presence of physical barriers such as windbreaks, diversion ditches, vegetative strips		√
Surface Water Distance from Untreated Manure	At least 100 feet separation for sandy soil and 200 feet separation for loamy or clay soil (slope less than 6%; increase distance to 300 feet if slope greater than 6%) is	Topography: Uphill from manure		√
		Topography: Downhill from manure	√	

Land Use/Water Source	Metric (This distance may be either increased or decreased depending on risk and mitigation factors.)	Considerations for Risk Analysis*		
		Risk/Mitigation Factors	Increase Distance	Decrease Distance
	recommended.	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"> <li>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.</li> </ul>			

954 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  
955 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  
956 state and federal fish and wildlife agencies) to confirm the details of these requirements.

957 **Figure 5. Decision Tree for Conducting Pre-harvest and Harvest Assessment of Animal Activity in Field**  
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964 15. **DETAILED BACKGROUND GUIDANCE INFORMATION**

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966 15.1. **Required Reference Documents**

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- 968 1. FDA Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables  
969 (www.foodsafety.gov/~dms/prodguid.html)
- 970 2. UFFVA Food Safety Auditing Guidelines: Core Elements of Good Agricultural Practices for Fresh  
971 Fruits and Vegetables
- 972 3. UFFVA Food Safety Questionnaire for Fresh Fruits and Vegetables
- 973 4. National GAPs Program Cornell University: Food Safety Begins on the Farm: A Grower Self  
974 Assessment of Food Safety Risks  
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976 15.2. **References**

977

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