

COMMODITY SPECIFIC FOOD SAFETY GUIDELINES

FOR THE PRODUCTION AND HARVEST OF LETTUCE AND LEAFY GREENS



SEPTEMBER 20, 2023 This document supersedes all previously published versions of the Commodity Specific Food Safety Guidelines for the Production and Harvest of Leafy Greens including those dated on or before March 30, 2023.

2 6. ISSUE: WATER

33

34

35

36

37

38

39

3 The safety of whole fresh and fresh-cut (e.g., bagged salad) leafy greens is a longstanding issue. Leafy greens are mostly 4 consumed raw without cooking or processing steps to eliminate microbial hazards. Therefore, the way they are grown, 5 harvested, packed, held, processed, and distributed is crucial to ensuring that the risk of human pathogen 6 contamination is minimized. LGMA recognizes that different crop characteristics may impact susceptibility to adhesion 7 and internalization of hazards. These metrics are intended to prioritize risk by classifying agricultural water systems for 8 specific uses within leafy greens operations. Remedial actions follow a "find and fix" structure to identify and correct 9 both system nonconformities and more serious failures. These metrics should be considered the minimum controls 10 necessary to assess agricultural water systems for fitness of use.

¹¹ General Agricultural Water Management - The Best Practices Are:

- Agricultural water systems are a function of the source, storage, and conveyance. Each component of an agricultural water system that is within your control must be evaluated to ensure that the quality of agricultural water used in leafy green operations is known (i.e., the required parameters are measured and conform to the prescribed standards) and adequate for its intended use.
- It's prudent to evaluate and make a good faith effort to address the food safety hazards proximate to your agricultural water systems that may not be under your control.
- NEVER use water from any water system that has not been microbially characterized and assessed as
 described below.
- Prior to annual use of the water in agricultural operations perform a written agricultural water assessment, as
 described in Appendix A, prior to use of water in agricultural operations. An agricultural water system
 description shall be prepared. The water assessment must identify conditions that are reasonably likely to
 introduce known or reasonably foreseeable hazards into or onto the leafy greens. The assessment must address
 the following elements:
- 25 • This A description (including the location and nature) of the agricultural water source and the type of 26 distribution system shall be created. Information in the description shall include permanent fixtures 27 such as wells, gates, reservoirs, valves, returns and other permanent above ground fixtures and could 28 also include non-permanent features such as tanks, drip stations, gas power pumps, pipes, water 29 treatment systems, etc. that make up a complete irrigation system. This could be achieved by using 30 maps, photographs, drawings or other means to communicate the location of permanent fixtures and the flow of the water system (including any water captured for re-use or other natural or managed 31 32 features which prevent environmental runoff from entering the water system).
 - ↔ Water sources and the production blocks they may serve should be documented.
 - The degree of protection from possible sources of contamination, including by other water users; animal impacts; and adjacent and nearby land uses related to animal activity (for example, grazing or commercial animal feeding operations of any size), application of biological soil amendment(s) of animal origin, or presence of untreated or improperly treated human waste.
 - Documented agricultural water practices for each agricultural water system, including the application methods as described in Table 1, water sources and the production blocks they may serve.
- Manage and maintain all components of your agricultural water system that are within your control including
 the water source and the on-ranch (farm) distribution /conveyance system(s) must be managed and
 maintained in a manner that minimizes human pathogen contamination.
- Testing water at the end of the delivery system (e.g., the last sprinkler head) or the point-of-use is essential for
 ensuring water that contacts the crop is of adequate microbial quality.

- For surface water sources, consider the impact of storm events on irrigation practices. Bacterial loads in surface
 water are generally much higher after a storm than normal, and caution shall be exercised when using these
 waters for irrigation.
- Water systems that convey untreated human or animal waste are never suitable for use in leafy greens
 operations in any manner and must be separated from conveyances utilized to deliver agricultural water.
- Water records must be reviewed, dated, and signed, within a week after the records are made, by a
 supervisor or responsible party.

52 Hazard Analysis – Step 1: Assessment of Agricultural Water Systems

Evaluating food safety hazards from agricultural water applications in leafy green operations must take into account
the quality of the agricultural water system, how the agricultural water will be applied, and when it will be applied.
Prior to using water in any leafy green operation, conduct an agricultural water system assessment (including source,
storage, and conveyance as described in Appendix A) and determine the agricultural water system type.

- 57 There are two types of agricultural water systems used in leafy green operations:
- Type A: Agricultural water that is unlikely to contain indicators of fecal contamination either due to natural
 hydrogeologic filtration or through controlled USEPA and state regulated treatment regime as demonstrated
 by an agricultural water system assessment as outlined in Appendix A, microbial testing, and when applicable,
 treatment verification.
- **Type B:** All other agricultural water systems.

65

66 67

68

69

70

71

72

73

74

75

76

77

- 63 1) Source: Evaluate each agricultural water source used in your leafy green operations and determine its
 64 type.
 - Some agricultural water sources are supplied by a third-party provider that certifies the water is of adequate microbial quality (i.e., unlikely to contain indicators of fecal contamination). Example of these sources are:
 - Public (e.g., municipal) or private providers that deliver certified potable water achieved through treatment or some other process
 - b) Some agricultural water sources deliver water of appropriate microbial quality due to natural physical, chemical, and biological processes that filter water as it passes through the soil. Examples of these sources for Type A agricultural water systems are:
 - Wells constructed in a manner such that contamination from outside sources (e.g., surface water or other surface chemical or biological influences / effects) is unlikely (e.g., well heads are protected, maintained, and monitored; see Appendix A for additional guidance), and water is tested to conform to standards.
 - Regulated recycled water (e.g., tertiary treated, purple pipe, etc.) providers that treat, test, and deliver water that is suitable for use in agricultural applications.¹
- 79 c) Some agricultural water sources are part of a Type A system due to on-ranch treatment that, when

¹ State regulations vary for recycled water. In some states recycled water for produce production allows a certain level of generic *E. coli*, total coliforms, and/or fecal coliforms.

80 81	operating under validated and verifiable parameters, turns Type B water into Type A. An example of a water source used in a Type B \rightarrow A agricultural water system is:
82	Treated surface water (verified to conform to standards)
83 84 85 86	d) Some agricultural water sources are considered part of a Type B system because they are vulnerable to contamination and have not been treated to achieve adequate microbial reduction and shall be used in a manner that minimizes contamination of the crop. Examples of water sources in a Type B agriculture water system are:
87 88	 Wells that may be vulnerable to contamination by outside sources including surface waters or by other surface chemical or biological influences / effects)
89	Untreated surface water
90 91 92 93 94 95 96	2) Storage and conveyance: Agricultural water source is only one component of an agricultural water system. An agriculture water system that starts out with water of appropriate microbial quality at the source may change quality as it progresses through the delivery system. Microbial water quality depends on the properties of the agricultural water system's components and how they are maintained (for more on system maintenance, see the section below on Best Practice for Managing Storage and Conveyance Systems). Agricultural water systems are typically opened or closed. For the purposes of this document, these systems are defined as follows:
97 98 99 100 101	 <u>Closed delivery systems</u> store or convey agricultural water in a manner that does not expose it to the outside environment and where water maintains the initial source type. Water from closed delivery systems must be tested at the end of the system to verify water quality is unchanged as it moves through the system. Additional details about testing requirements for a closed delivery system are provided in Tables 2B and 2C, and guidance is provided in Appendix A.
102 103 104 105 106 107 108	 <u>Open delivery systems</u>, at some point in the system, store or convey agricultural water in a manner that exposes it to the outside environment (i.e., a reservoir / pond, canal, lateral, uncovered water tank, etc.). Water in open delivery systems (e.g., reservoirs and ponds) may be used in overhead applications within 21 days to the scheduled harvest if it is treated (as described in Table 2D) at the time it is applied to crops. Additional details about testing requirements for an open delivery system are provided in Table 2F pertaining to Type B agricultural water systems, and guidance is provided in Appendix A.
109 110 111 112	3) System: Each component of an agricultural water system must be evaluated to ensure that the quality of agricultural water used in leafy green operations is known (i.e., the required parameters are measured and conform to the prescribed standards) and adequate for its intended use. Agricultural water use will vary depending on the type of system.
113 114	 When determining whether a system is Type A or B, each component (source, storage, conveyance, etc.) must be individually evaluated in typing an entire system.
115	• When Type A and B waters are combined, categorize water as Type B.
116	Hazard Analysis – Step 2: How Is Your Agricultural Water System Being Used?
117 118 119	Use/Application method : Risk of leafy green contamination is closely related to how water is used in the production and harvest environment as well as in post-harvest applications (Rock et al., 2019). For this reason, agricultural water requirements vary depending on how it is applied. In leafy green operations, agricultural water is 4

- typically used in aerial (e.g., sprayers, overhead sprinklers, aircraft), ground (e.g., furrow and drip irrigation), and
- 121 post-harvest applications. Agricultural water is also used for cleaning and, when appropriate, sanitizing equipment
- used during production, harvest, and post-harvest activities. Type A, Type B water that is treated to become Type A
- 123 (B \rightarrow A), and Type B agricultural water systems are suitable for specific uses as described in Table 1.
- 124
- 125 Timing of use: Risk of leafy green contamination is closely related to when agricultural water is applied in the 126 production environment. For this reason, requirements for agriculture water that is aerially applied to leafy green 127 crops vary depending on when the water is applied (Fonseca et al., 2010; Gutierrez-Rodriquez et al., 2012, 2019; 128 Koike et al., 2009; 2010; Moyne et al., 2011; Suslow et al., 2010; Wood et al., 2010).
- A number of environmental factors, including location of the operation, and the climatic conditions of UV, relative humidity, precipitation, and temperature, may alter the appropriateness of these time-based requirements. Based on the most appropriate, currently available research addressing the risks related to the timing of aerial agricultural water application in leafy green operations, time-based requirements are generally divided as follows:
- Within (<) 21 days of the scheduled harvest date
- Greater than (>) 21 days until the scheduled harvest date
- Agricultural water from a Type A agricultural water system used in overhead irrigation within (<)21 days of
 the scheduled harvest must meet the performance requirements for Type A agricultural water systems as
 outlined in Tables 2B and 2C.
- Untreated agricultural water that meets Type A requirements for irrigation water or Type B system that
 meets the performance requirements outlined in Table 2E may be used in aerial applications prior (>) 21 days
 before the scheduled harvest.
- To use agricultural water from a Type B agricultural water system in overhead irrigation within (<)21 days of
 the scheduled harvest date, the water must be treated to become Type A water (B→A) and demonstrated to
 meet the performance requirements as outlined in Table 2D.

 TABLE 1. Agricultural Water System Uses by Application Method – See TABLE 2A—2G

Application	Agricultural water systems (possible sources)	Treatment methods for use in direct contact with crop	Microbial indicator
 Overhead irrigation and chemical application priorto (>) 21 days before scheduled harvest date Germination Ground chemigation Drip irrigation Furrow irrigation Dust abatement Non-food-contact farm equipment cleaning 	Type A and B agricultural water systems	No treatment necessary if it can be demonstrated t o meet the microbial standards.	generic <i>E. coli</i>
 Overhead applications (including irrigation, pesticide spray, aerial chemigation) applied within (<) 21 days of scheduled harvest date 	Type A agricultural water systems (closed systems including water from wells, municipalities, tertiary treated and disinfected recycled water e.g., purple valve)	No treatment necessary if it can be demonstrated to meet the microbial standards.	generic <i>E. coli</i>
	Treated Type B→A agricultural water systems with open components such as reservoirs, ponds, canals, laterals, ditches, etc.	Must be treated and tested to demonstrate treatment efficacy and compliance with microbial standards.	generic <i>E. coli</i> and total coliforms
Application			
 Food-contact (harvest) equipment cleaning & sanitizing Hand wash water 	 Water that directly contacts of food-contact surfaces such as Maximum Contaminant Leve contain an approved antimic prevent cross-contamination performed, as appropriate to acceptance criteria have bee 	s equipment or utensils, mus I Goal for <i>E. coli</i> as specified robial treatment at a concen . Microbial or physical/chem o the specific operation, to de	t meet the by U.S. EPA or tration sufficientto ical testing shall be

150	Irrigation Water Sampling Plans and Remedial Actions
151 152 153 154	Testing agricultural water systems is one method of gathering evidence that your system is of adequate quality for its intended use. Along with visual monitoring of agricultural water systems, a water quality testing program is a vital best practice for protecting leafy green crops from contamination. To be most effective as a food safety tool, water samples must reflect, to the extent possible, the water at the point of use.
155	 As irrigation system equipment may change locations throughout the season, but water sources are
156	generally at a fixed location, a robust overhead irrigation water quality testing program must include
157	assessments of both the irrigation water source and the irrigation system. Assessing water quality at the
158	end of the delivery system ensures source water quality does not degrade as it moves through the system.
159	 For the purposes of this document, sampling of agricultural water systems occurs for the following three
160	reasons and Tables 2B-2C follow this framework providing specific details for each assessment's
161	requirements:
162 163	 Baseline microbial assessments: To "type" your agriculture water <u>source</u> and establish its "known" quality.
164	 Initial microbial water quality assessment: To test your agricultural water <u>system</u> prior to use to
165	ensure water is not degraded as it moves through the system.
166	 Routine system assessments: To monitor the microbial quality of your agricultural water system
167	throughout the season to ensure it continues to meet the microbial water quality standards.
168	 If you are applying water from a Type A agricultural water system greater than (>) 21 days
169	to the scheduled harvest date, you may choose to sample and test your water according to
170	Type B criteria rather than according to Type A criteria; however, Type A baseline (when
171	required) and initial microbial water quality assessments must be conducted before the 21
172	days-before-harvest window closes and routine verification / monitoring begins (per
173	requirements outlined in Tables 2B and 2C).
174	 Routine sampling is a part of building a dataset useful for evaluating individual data points
175	and evaluating trends to gain a better understanding of your agricultural water system.
176	 Non-routine sampling when food safety risks are deemed higher due to specific
177	circumstances (i.e., weather, animal and human activities, discharge, etc.) should also be
178	part of a robust food safety program. In the event that additional risk factors that could
179	affect water quality are observed or measured such as weather, manure application in a
180	nearby field, or animal-related activity, consider conducting additional water testing.
181	 If you are irrigating with Type B→A agricultural water systems, collecting and analyzing
182	water system data is essential for understanding how the treatment functions in your
183	irrigation system and can optimize its effectiveness.
184 185	• All agricultural water systems used in overhead irrigation prior to (>) 21 days before the scheduled harvest date must meet the water quality requirements outlined in Table 2E for Type B agricultural water systems.
186	 If a Type A or B agricultural water system fails the respective acceptance criteria, follow remedial action
187	steps as outlined in Table 2F (also included in Figures 2B, 3A and 3C). Consider performing root cause
188	analysis to determine if additional preventive measures can be incorporated into the agricultural water

system operation.

Retain documentation of all test results and/or Certificates of Analysis/Quality Assurance for a period of at least two (2) years.

192	² Best Practice for Managing Storage and Conveyance Systems	
193 194		op a SOP for the maintenance of ancillary equipment and water storage and conveyance components of gricultural water system used in your operations. The SOP must address:
195 196 197	0	Regularly scheduled visual inspections, including ancillary equipment connected to your storage and conveyance system, to ensure it is in good working order and does not pose a contamination risk to your system.
198 199	0	Measures to maintain water quality by removing debris and controlling the presence of weeds, algae, tule, trash, and when appropriate, sediment within the grower's control.
200 201	0	Procedures to control pest access to the storage and conveyance systems (examples may include: avian deterrents, fencing, and rodent monitoring).
202 203	0	Corrective actions to ensure irrigation pipes and drip tape are microbiologically safe to use if a pest infestation does occur.
204 205	0	Berms, slopes and diversion ditches for prevention of run-off (i.e., from irrigation or rain) into water storage and conveyance systems.
206	0	Procedures to ensure standing and/or stagnant water does not pose a contamination risk.
207 208	0	Management of agricultural water system components used to prepare crop amendments to ensure these activities and equipment are not a contamination source.
209 210	0	Water used in aerial applications (e.g., pesticide and fertilizer, etc.) within the 21-days-to-harvest window must be from Type A or $B \rightarrow A$ agricultural water systems. Implement practices to ensure:
211 212		 Holding tanks and equipment-mounted application tanks, manifold and boom lines, and nozzles are to be properly maintained and cleaned.
213 214		 Water treatment chemistry or approach is compatible with the agricultural chemicals being applied.
215	0	Establish corrective action procedures for non-compliance scenarios, including:
216		 Contaminated source water
217		 Animal intrusion
218		 Contaminating run-off
219		 Uncontrolled flooding [reference page, line and table]
220	• Docum	nent all corrective measures, cleaning activities, and maintenance.
221	Best Pract	ice for Furrow Irrigation Systems Management
222 223	-	Itural practices, such as irrigation methods, bed configuration, etc., should be implemented in a er to avoid water from breaching the top of the bed.
224 225	-	ltural practices, such as equipment movement, irrigation practices, etc., should be monitored at and and tail ditch locations for damaged beds which may allow water to contact the edible portion

226 of the crop.

241

242

Coordinate irrigation events with harvest, to the degree possible, to avoid saturation of the field soil to prevent excessive dirt and mud from getting on the edible portion of the crop, harvest tools (e.g., knives, gloves, etc.), and harvest equipment (e.g., machines, belts, trailers, etc.).

230 Best Practice for Drip Tape Irrigation Systems Management

- Drip tape should be handled, stored, used, and re-used in a manner that prevents damage and contamination to the drip tape.
- While in use, repairs to drip tape should be completed in a timely manner to prevent water contact with
 the edible portion of the crop.

²³⁵ Best Practice for Managing Irrigation Water Treatment Systems

- The minimum best practices for managing irrigation water treatment are outlined below and must be
 completed. For greater detail refer to Appendix A.
- Prior to 21 days-to-scheduled harvest conduct an initial irrigation water treatment assessment to establish treatment process parameters that will be monitored to ensure consistent treatment delivery and to demonstrate its effectiveness as described in Appendix A.
 - Repeat this assessment if a material change (e.g., change in equipment or type of water treatment) to your system occurs.
- Before using treated water to irrigate crops within the ≤ 21 days-to-scheduled harvest timeframe growers
 must first establish SOP's outlining irrigation treatment and process parameters for all irrigation treatment
 systems unless duplicated systems are in use.
- Confirm that water microbial quality is not being degraded as it passes through each of your water treatment systems (i.e., due to equipment conditions) by performing a microbial water quality assessment during an irrigation event before entering the ≤ 21 days-to-scheduled harvest timeframe.
- Collect three (3)-100 mL samples from 3 different sprinkler heads with at least one sample from the
 farthest/last sprinkler head. Acceptance Criteria and Data Monitoring Criteria as outlined in Table 2D Routine Monitoring of Microbial Water Quality must be met.

Best Practice Water Used for Overheard Chemical Applications within 21 Days of Scheduled Harvest (This section does NOT apply to chemical applications made through the distribution system i.e., sprinkler)

Type B water used for overhead applications within 21 days of scheduled harvest must be treated. With the start-up of any new treatment process it is important to evaluate all conditions that may affect water treatment efficacy and performance. Examples of parameters that provide valuable information about treatment efficacy in relationship to water quality are: Turbidity, pH, antimicrobial dose, historical microbial monitoring data, etc. (See Appendix A for additional guidance).

- Develop a SOP for all of the parts of the ag water system used in overhead chemical application. The SOP
 must address:
- Water used in overhead applications (e.g., pesticide and fertilizer, etc.) within the 21-days-to-harvest
 window must meet Type A and/or B→A water quality requirements.

263 264 265		 Holding tanks and equipment-mounted application tanks, manifold and boom lines, and nozzles MUST be regularly inspected and properly maintained and cleaned so they do not pose a contamination risk.
266 267		 Water treatment chemistry or approach shall be compatible with the agricultural chemicals being applied.
268 269 270		 Procedures to control pest access to the equipment during storage and staging (examples may include avian deterrents, fencing, and rodent monitoring) must be in place (validation can include: Pest control applicator (PCA) records, label requirements, letter of guarantee).
271 272 273		 Establish corrective action procedures for non-compliance scenarios including: treatment failure contaminated source water
274		 pest concerns
275		 chemical incompatibility
276		 equipment sanitation concerns.
277		 Document all corrective measures, cleaning activities, and maintenance.
278 279 280 281 282 283	•	Develop a SOP for each unique application process to treat water that will be used in an overhead application within 21 days of a scheduled harvest. Prior to the 21-days-to-scheduled-harvest conduct an initial water treatment assessment to establish treatment process parameters that will be monitored to ensure consistent treatment delivery and to demonstrate effectiveness. Repeat this assessment if a material change to your system occurs and incorporate this assessment's findings into your water treatment SOP. The SOP must address:
284		 Step-by-step instructions to ensure the water treatment is correctly implemented.
285		 Location of water sources
286		 Name and suggested supplies needed.
287		 Sanitizer used and quantity used.
288		 Critical limits and operational limits
289		 Water sampling location
290		 Corrective actions if critical limits are not met.
291		 Required records
292	٠	Develop a baseline for water treatment:
293 294 295 296		 Prior to the 21 days-to-scheduled harvest, a minimum of three (3)-100 mL samples must be taken for each overhead application process (distinct water quality source, different sanitizer, different size water holding tank, etc.). The three (3) samples must be taken from different treated water batches.
297		• All three (3) samples must be non-detect for generic <i>E. coli</i> .
298	•	Routine testing:
299 300		 A minimum of one (1) microbiological sample must be taken each month from a representative agricultural water system or at the next application event.
301		• This 100 mL sample should have no detectable generic <i>E. coli</i> .

302	Corrective action:
303	 If microbiological testing shows that the water did not meet generic <i>E. coli</i> acceptance criteria
304	within 21 days of a scheduled harvest, perform a root cause analysis and correct the concern.
305	Notify the grower/producer.
306	 The product must be tested for pathogens before harvest if this water was used in overhead
307	application. Follow the product testing requirements outlined in Table 2F.
308	Ongoing monitoring:
309	 Between microbiological routine testing events, records must be kept that verify that each
310	application event is conducted following the parameters established during the initial setup.
311	 If monitoring shows that the water treatment parameters are not being met, do not use the
312	water.
313	 Perform a corrective action to assure the water treatment is effective before using the
314	water.
315	 Take a microbiological sample to verify that the treatment was effective and have that
316	result as part of the corrective action documentation.
317	 If the verification microbiological sample does not meet acceptance criteria, perform a root
318	cause analysis and correct the treatment process. Product must be tested for pathogens
319	before harvesting. Follow Table 2F for product testing requirements.
320	 Maintain records that demonstrate the water used for chemical applications meets Type A source water
321	requirements. See Tables 2B and 2C for historical and/or baseline water quality requirements for source
322	water that will be used for overhead applications.
323	Other Considerations for Water
324 325	• Treat water only with antimicrobial treatments approved by the USEPA for use in agricultural applications in accordance with label specifications, guidelines for use, and consideration of environmental impacts.
326	 Antimicrobial treatments must be used and managed in a manner that meets all federal, state, and local
327	regulations.
328	 Do not store raw manure or any type of compost near irrigation water sources or conveyance systems (see
329	Table 0).
330	Best Practice for Irrigation Water from Type B Agricultural Water
331	The following table (2A) outlines the metrics for agricultural water conveyance systems whereby edible portions of the

crop are not likely to be contacted (e.g., germination, ground chemigation, furrow, drip irrigation, dust abatement 332 333 water); if water is used in the vicinity of produce, then testing is necessary. For any of these uses, the agricultural water 334 system must be assessed and monitored to demonstrate that the water meets the microbial standards for water that 335 is likely to contain indicators of fecal contamination. Routine monitoring of microbial quality is required for all water 336 types and remedial actions are required if water testing shows a conveyance system has failed to deliver water that meets the microbial standard. Efforts should always be made, when using Type B water, to avoid contact with the 337 338 edible portion of the crop within 21 days of a scheduled harvest. When performing remedial actions, it is the intent 339 that all remedial steps outlined in the tables below are followed and that they are followed in the order of sequence 340 as written.

341TABLE 2A. Irrigation Water from Type B Agricultural Water – See FIGURE 1

Metric	Rationale /Remedial Actions
Metric Examples of water from Type B agricultural water systems: • Ground chemigation • Drip irrigation • Furrow irrigation • Dust abatement	Rationale /Remedial ActionsWater for Type B use throughout the production of the crop shall meet or exceed microbial standards 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 depend on the number of samples taken. If only one sample has been taken, it must be below 126 MPN/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 rolling 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 (or at the next irrigation event if longer than monthly) at points of use within the distribution system.Ideally, irrigation water should not contain generic <i>E. coli</i> , but low levels do
Target Organisms: Generic <i>E. coli</i>	not necessarily indicate that the water is unsafe. Investigation and/or remedial action SHOULD be taken when test results are higher than normal or indicate an upward trend. Investigation and remedial action SHALL be taken when acceptance criteria are exceeded.
Sampling Procedure: 100 mL sample collected aseptically as close as practical to the point of use. Sampling Frequency: One sample per agricultural water source shall be collected and tested prior to use if >60 days since last test of the water source. Additional samples shall be collected no less than 18 hours apart and at least monthly (or at the next irrigation event ifgreater than monthly) during use from points within the delivery system.	 If the rolling geometric mean (n=5) or any one sample exceeds the acceptance criteria, then the water shall not be used until remedial actions have been completed and generic <i>E. coli</i> levels are within acceptancecriteria: Conduct an agricultural water assessment (Appendix A) of water source and conveyance system to determine if a contamination source is evident and can be eliminated. Eliminate identified contamination sources. Retest the agricultural water after taking remedial actions to determine if it meets the outlined microbial water quality acceptance criteria for this use. This sample should represent the conditions of the original water system, if feasible this test should be as close as practical to the original sampling point. A more aggressive sampling program (i.e., sampling once per week instead of once per month) shall be instituted if an explanation for the exceedance is not readily apparent. This type of sampling program should also be instituted if an upward trend is noted in normal sampling results. If follow-up agricultural water testing indicates that a crop has been

Metric	Rationale /Remedial Actions
Acceptance Criteria: ≤ 126 MPN/100 mL (rolling geometric mean n=5) and ≤ 576 MPN/100 mL for any single sample	shall be sampled and tested for STEC (including <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 the fresh market.
Test Method: Any FDA-allowed method ² Records: Each water sample and analysis shall record the type of water source, date, time, and location of the	

sample, the method of analysis, and, if quantitative, the detection limit. All test results and remedial actions shall be documented and available for verification from the producer/shipper who is the responsible party for a period of two years.

342

² Equivalent testing methodology for agricultural water https://www.fda.gov/food/foodscienceresearch/laboratorymethods/ucm575251.htm

344 FIGURE 1. Irrigation Water from Type B Agricultural Water – See TABLE 2A

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

Sampling Frequency: For Type B water, one sample per water source shall be collected and tested prior to use if >60 days since last test of the water source. Additional samples shall be collected during use no less than 18 hours apart andat least monthly (or at the next irrigation event if greater than monthly) during use.

- Sample sources as close to the point-of-use as practical using sampling methods as prescribed in Table 2A.
- Analyze samples for generic *E. coli* using a MPN methodology. Other EPA-, FDA- or AOAC International accredited method may be used.
- Geometric means, including rolling geometric means shall be calculated using the five most recent samples.

ACCEPTANCE CRITERIA

345

≤ 126 MPN/100ml (Geometric mean of 5 samples) <u>AND</u>

<576 MPN/100ml (all single samples)</p>

No further action necessary. Water maybe used in leafy green operations as outlinedin Table 2A.

ACTION LEVEL

>126 MPN/100ml (geometric mean over five samples)

OR

>576 MPN/100ml (any single sample)

REMEDIAL ACTIONS:

- Discontinue any agricultural production use until it returns to compliance.
- Examine the water source and distribution system to determine if a contaminationsource is evident and can be eliminated.
- After remedial actions have been taken, retest the water at the same sampling point.
- Continue testing daily for five days at the point closest to use.
- If any of the next five samples is >576 MPN/100mL, repeat sanitary survey and/orremedial action.
- Do not use this water system until the water can meet the outlined acceptance criteriafor this use.

CROP TESTING:

- If water exceeding the acceptance criteria has been used for crop production, sample and test product for STEC (including *E. coli* O157:H7) and *Salmonella* as described in Appendix C, prior to harvest.
- If crop testing indicates the presence of either pathogen, do NOT harvest for human consumption.

³⁴⁶ Best Practice for Irrigation Water from Type A Agricultural Water

The following tables (2B - 2F) refer to agricultural water distribution systems and not to specific ranches, lots, fields, 347 348 etc. The tables outline the metrics for overhead applications of agricultural water sourced from public/private supplies 349 (2B), regulated recycled water and private wells (2C), treated water supplies (2D), and untreated water that is likely to 350 contain indicators of fecal contamination (2E). Each type of agricultural water system must be assessed to demonstrate 351 that the water from the source and the distribution system meet the microbial standards. Treated water must be 352 assessed and monitored to demonstrate that the water treatment is working as intended and that the treated water 353 meets the microbial standard. Routine monitoring of microbial quality is required for all water system types, and remedial actions are required if water testing shows a system has failed to deliver water that meets the microbial 354 355 standard. When performing remedial actions, it is the intent that all remedial steps outlined in the tables below are 356 followed and that they are followed in the order of sequence as written.

358 TABLE 2B. Irrigation Water from Type A Agricultural Water Systems Sourced from Public or Private Providers –

359 See FIGURE 2A-2B

Metric	Rationale /Remedial Actions
Examples of these types of Type A	Irrigation water from Type A agricultural water systems sourced from
agricultural water systems: Water	regulated public or private providers would not be expected to contain
maycome from public and private	generic E. coli due to treatment or some other filtering-type process.
providersand are stored and	Water sourced from a public/private Type A agricultural water
conveyed in closed delivery	provider must be stored and conveyed in well-
systems.	maintained, closed systems and tested for generic E. coli.

B1. Baseline Microbial Assessment

A baseline microbial assessment of the water source is not necessary for a Type A system using source water from a public/private provider. In lieu of a baseline microbial assessment, acquire and maintain the supplier's most current COA on file.

Records: Records of the analysis of source water may be provided by municipalities, irrigation districts, or other water providers and must be available for verification from the grower/handler who is the responsible party for a period of two years

B2. Initial Microbial Water Quality Assessment

Target Organisms: Generic E. coli

Initial Assessment Sampling	;
Procedure:	

Aseptically collect at least three (3)-100mL samples during one irrigation eventwith at least one sample at the end of the delivery system (e.g., last sprinkler head).

Initial Assessment Sampling Frequency:

This is a one-time seasonal sampling event for each system with samples collected during one irrigation event occurring before the 21-days-to-scheduled-harvest period begins. (Also conduct this assessment after any material modifications to Type A overhead irrigation systems.)

Initial Assessment Acceptance Criterion:

Non-detectable in two (2) of three (3)-100 mL samples and 10 MPN as the single sample maximum for

The purpose of this assessment is to confirm that the water's microbial quality is not being degraded as it passes through your system (i.e., due to equipment conditions). The assessment is performed to verify that your irrigation water delivery system is able to maintain and deliver water of the same microbial quality (e.g., Type A) as the source water. Unless there is a material change to your system (e.g., change in equipment or type of watertreatment), this is a one-time assessment for each irrigation system, and it is not necessary to repeat system evaluations for each irrigation event.

To test your water delivery systems, sample and test irrigation water during an irrigation event. All discrete systems are to be tested before entering the 21-days-to-scheduled-harvest time frame. To assess the water delivery system, water samples are taken throughout the system with at least one sample at the endof the line where water contacts the crop.

Initial Assessment Testing

If at least two (2) in three (3) samples do not have detectable levels of generic *E. coli*, and the level in the one remaining sample is no greater than (\leq) 10 MPN, then the water system maintains its Type A status.

If water samples do not meet the acceptance criteria (i.e., if two (2)or more of the samples have detectable levels of generic *E. coli* <u>or</u> the level in at least one sample is greater than (>) 10 MPN), then conduct the following follow-up testing:

Metric	Rationale /Remedial Actions	
one (1) sample.	Follow-up Testing	
Follow-up Testing Acceptance Criterion: Non-detectable in four (4) of five (5)-100 mL samples and 10 MPN as the single sample maximum for one (1) sample. Note: For the purposes of water testing, MPN and CFU are considered equivalent.	Prior to the next irrigation event perform a root cause analysisand an agricultural water system assessment as described in Appendix A to identify and correct the failure. After assessing the system, retest the system for generic <i>E. coli</i> in five (5)-100 mL samples collected during the next irrigation event using the sampling procedure and frequency (described in the left column). Water samples can be pulled from the endof any system nodes/branches in the irrigation system of concern. Of the five (5) follow-up samples, four (4) must have no detectable generic <i>E. coli</i> and the one (1) remaining samplemust have levels no greater than (<) 10 MPN generic <i>E. coli</i> / 100mL.	
	If test results meet the acceptance criterion for generic <i>E. coli</i> , the water system can be used as a Type A system.	
	<u>Testing Failure</u> : When one sample has more than (>) 10 MPN generic <i>E coli</i> / 100 mL or more than one sample have detectable generic <i>E. coli</i> , the agricultural water system is disqualified for TypeA usage. Perform a root cause analysis to identify and correct the failure (see Appendix A for mitigation measures). In the interim, the water can be used as a Type B agricultural water system.	
Test Method: Any FDA-allowed metho	• • • •	
Records: Each water sample and analysis shall record the type of water source, date, time, and location of the sample, the method of analysis, and, if quantitative, the detection limit. All test results and remedial actions shall be documented and available for verification from the grower/handler who is the responsible party for a period of two years.		
B3. Routine Verification of Microbial	Water Quality	
Routine Verification SamplingProcedure: Aseptically collect at least three (3)- 100mL samples during one irrigation eventwith at least one sample taken at the end of the delivery system (e.g., last sprinkler head). Routine Verification	To verify irrigation water continues to meet the acceptance criterion throughout the season, design your sampling plan so eachdistinct irrigation system that is in use is sampled and tested at least once during the season. If two (2) or more of the samples have detectable levels of generic <i>E. coli</i> <u>or</u> the level in at least one sample is greater than (>) 10MPN, prior to the next irrigation event perform a Level 1 Assessment as outlined in <u>Table 2F</u> .	

Routine Verification SamplingFrequency:

Sample and test each distinct irrigationsystem for generic *E. coli* at least once during the season.

Routine Verification AcceptanceCriterion:

Non-detectable generic *E. coli* in 100

Metric	Rationale /Remedial Actions	
mLwater samples and < 10 MPN as the single sample maximum for one (1) in three (3) samples		
Note : For the purposes of water testing, MPN and CFU are considered equivalent.		
Test Method: Any FDA-allowed method ²		
Records: Each water sample and analysis shall record the type of water source, date, time, and location of the sample, the method of analysis, and, if quantitative, the detection limit. All test results and remedial actions shall be documented and available for verification from the grower/handler who is the responsible party for a		

period of two years.

362 FIGURE 2A. Irrigation Water from Type A Agricultural Water Systems Sourced from Public / Private

Providers – See TABLE 2B

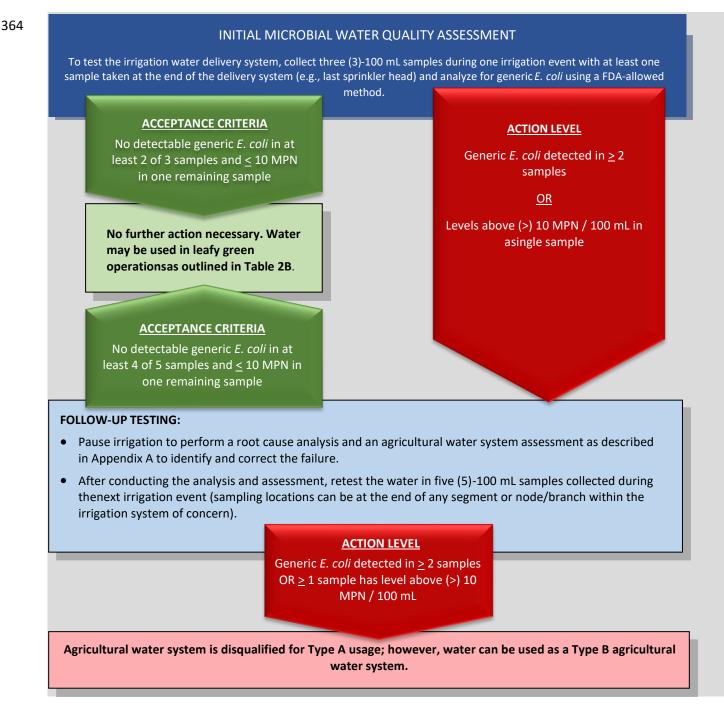


FIGURE 2B. Irrigation Water from Type A Agricultural Water Systems Sourced from Public / Private Providers – See TABLE 2B

367

ROUTINE MONITORING of MICROBIAL WATER QUALITY

- For Type A agricultural water from public/private sources for overhead applications when used within (<) 21 days of thescheduled harvest date. (When using Type A agricultural water from these sources for overhead applications up to (>) 21days of the scheduled harvest date follow water metrics in Table 2E/Figure 5 for Type B agricultural water systems.)
- Aseptically collect three (3) samples during one irrigation event with at least one sample taken at the end of the deliverysystem (e.g., last sprinkler head); each distinct irrigation system must be tested at least once during the season.
- Test for generic *E. coli* using a FDA-allowed method and assess microbial quality using the three (3) collected samples.

ACCEPTANCE CRITERIA

No detectable generic *E. coli* in at least 2 of 3 consecutive samples and < 10 MPN in one remaining sample

No further action necessary. Water may be used in leafy green operationsas outlined in Table 2B.

ACTION LEVEL

Generic E. coli detected in > 2 samples or one samplehas levels above (>) 10 MPN / 100 mL

CONDUCT A LEVEL 1 ASSESSMENT:

- If generic *E. coli* levels in your water exceed the acceptance criterion, prior to the next irrigation event conduct an agricultural water system assessment as described in Appendix A and retest water (as described in step #2 below) until it is shown to be back in compliance with the acceptance criterion.
- During the next irrigation event, collect 5 100 mL samples from the irrigation system and test for generic *E. coli*. Water can be pulled from the end of any system nodes/branches in the irrigation system of concern. If these water samples also fail to meet the acceptance criterion, discontinue use of this water for overhead applications while continuing to evaluate your water system to identify and correct any failures and continuing to testas described in this step until the water is back in compliance (see AppendixA for guidance on troubleshooting irrigation system failures).
- If this water (i.e., the water from the initial sampling to the last of the follow-up sampling) has been applied to leafy greens, either consider the crop unsuitable for the fresh market or test the crop from all affected lots (i.e., lots that have been irrigated with this water within the <21 days-to- scheduled-harvest window) for STEC (including *E. coli* O157:H7) and *Salmonella*. Product needs to be tested prior to harvesting and after your last irrigation event. Sample crop per the protocol described in Appendix C.If any individual sample tests positive for any of these human pathogens, the crop within that lot shall NOT be harvested for the fresh market and human consumption.

TABLE 2C. Irrigation Water from Type A Agricultural Water Systems Sourced from Private Wells or Regulated Tertiary Treated Recycled Water Supplies – See FIGURE 3A-3C

Metric	Rationale /Remedial Actions
 Examples of water from Type A agricultural water systems: Regulated recycled wastewater Water sourced from a well – well water is conveyed to the field in a closed delivery system and applied to the crop via overhead sprinklers. 	Irrigation water from Type A agricultural water systems with well source water would not be expected to contain generic <i>E.</i> <i>coli</i> due to natural filtration as the water passes through the soil. Water from regulated tertiary treated recycled water supplies may have low levels of generic <i>E. coli</i> due to regulatory allowable limits. Type A agricultural water systems must be stored and conveyed in well-maintained, closed systems and tested for generic <i>E. coli</i> . Remedial actions vary depending on when the water is being used in relation to harvest.
C1. Baseline Microbial Assessment	
Target Organisms: Generic E. coli	
 Baseline Assessment Sampling Procedure: If historical water test data is not available, aseptically collect at least three (3)-100 mL sample at the source. Baseline Assessment Sampling Frequency: Sample and test the water two times (with sampling events separated by no less than 7 days) before using the water within the 21-days-to-scheduled-harvest-window. Baseline Assessment Acceptance Criteria: Non-detectable generic <i>E. coli</i> in five (5) of six (6) 100 mL samples and ≤ 10 MPN as the single sample maximum for one (1) sample. Note: For the purposes of water testing, MPN and CFU are considered equivalent. 	The purpose of a baseline assessment is to ensure your water source (e.g., a well or regulated tertiary treated recycled water) meets the microbial standards for generic <i>E. coli</i> . This baseline microbial assessment must be conducted before these Type A water sources can be used for overhead irrigation within 21-days to-scheduled-harvest. For agricultural water systems with multiple wells, each well must be tested prior to use in order to validate the integrity of the agricultural water system. Self-certification with historical water test data: If at least four (4) of the last five (5) consecutive historical water tests (80%) have no detectable generic <i>E. coli</i> , the remaining one (1) sample does not exceed (\leq) 10 MPN in 100 mL, and one (1) of those tests was taken within the last 6 months, then the well/regulated tertiary treated recycled water supply is self-certified as a Type A agricultural water source. Self-certification process when no historical data is available: If historical data is unavailable, test each well or regulated recycled water twice (separated by no less than seven days) prior to use as the source water for a Type A agricultural water system. If at least five (5) of the six (6) total samples have no detectable generic <i>E. coli</i> and the remaining sample has \leq 10 MPN in 100 mL, then the water/well is self-certified as a Type A agricultural water source.
	<u>Testing Failure</u> : If test results do not meet the acceptance criteria, then the water/well cannot be considered a Type A agricultural water source. Perform a root cause analysis and an agricultural water system assessment as described in Appendix A to identify and correct the failure. In the interim, the water car be treated or used as a source for a Type B agricultural water

Metric	Rationale /Remedial Actions	
	system.	
Test Method: Any FDA-allowed method ²		
sample, the method of analysis, and, if quanti	record the type of water source, date, time, and location of the tative, the detection limit. All test results and remedial actions shall from the grower/handler who is the responsible party for aperiod	
C2. Initial Microbial Water Quality Assessme	nt	
Target Organism: Generic E. coli		
Initial Assessment Sampling Procedure: Aseptically collect at least three (3)-100 mL during one irrigation event at the end of thedelivery system (e.g., last sprinkler head).	The purpose of this assessment is to confirm that the water's microbial quality is not being degraded as it passes through your system (i.e., due to equipment conditions). The assessment is performed to verify that your irrigation water delivery system is able to maintain and deliver water of the	
Initial Assessment Sampling Frequency: This is a one-time seasonal sampling event for each system with samples collected during one irrigation event occurring beforethe 21-day-to-scheduled- harvest-period begins. (Also conduct this assessment after any material modifications to Type A overhead irrigation systems.)	same microbial quality (e.g., Type A) as the water source. Unless there is a material change to your system (e.g., changein equipment or type of water treatment), this is a one-time assessment for each irrigation system, and it is not necessary to repeat system evaluations for each irrigation event. To test your water delivery systems, sample and test irrigation water during an irrigation event. All discrete systems are to be tested before entering the 21-days-to-scheduled-harvest timeframe. To assess the water delivery system, water samples are taken at the end of the line where water contactsthe crop.	
Initial Assessment Acceptance Criteria: Non-detectable generic <i>E. coli</i> in two (2) ofthree (3)-100 mL samples and \leq 10 MPN asthe single sample maximum for one (1) sample.	Initial Assessment Testing If at least two (2) in three (3) samples do not have detectable levels of generic <i>E. coli</i> , and the level in the one remaining sample is no greater than (\leq) 10 MPN, then the water system maintains its Type A status.	
Follow-up Testing Acceptance Criteria: Non-detectable in four (4) of five (5)-100 mLsamples and ≤ 10 MPN as the single sample maximum for one (1) sample.	If water samples do not meet the acceptance criteria (i.e., iftwo (2) or more of the samples have detectable levels of generic <i>E. coli</i> <u>or</u> the level in at least one sample is greater than (>) 10 MPN), then conduct the following follow-up testing:	
Note : For the purposes of water testing, MPNand CFU are considered equivalent.	 Follow-up Testing Prior to the next irrigation event perform a root cause analysis and an agricultural water system assessment as described in Appendix A to identify and correct the failure. After assessing the system, retest the system for generic <i>E. coli</i> in five (5)-100 mL samples collected during the next irrigation event using the sampling procedure and frequency (described in the left column). Water samples can be pulled from the end of any system nodes/branches 	

Metric	Rationale /Remedial Actions
	in the irrigation system of concern. Of the five (5) follow- up samples, four (4) must have no detectable generic <i>E.</i> <i>coli</i> and the one (1) remaining sample must have levels no greater than (<u><)</u> 10 MPN / 100 mL.
	3) If test results meet the acceptance criterion for generic <i>E. coli</i> , the water system can be used as a Type A system.
	<u>Testing Failure</u> : When one sample has more than (>) 10 MPN / 100 mL or more than one sample have detectable generic <i>E.coli</i> , the agricultural water system is disqualified for Type A usage. Perform a root cause analysis to identify and correct the failure (see Appendix A for mitigation measures). In the interim, the water can be used as a Type B agricultural water system.
Test Method: Any FDA-allowed method ²	
sample, the method of analysis, and, if quantit	record the type of water source, date, time, and location of the tative, the detection limit. All test results and remedial actions tion from the grower/handler who is the responsible party for a
C3. Routine Verification of Microbial Water Q	uality
Target Organisms: Generic E. coli	
Sampling Procedure Three (3)-100 mL samples aseptically collected at the end of the delivery system (e.g., the last sprinkler head).	To verify irrigation water continues to meet the acceptance criterion throughout the season, design your sampling plan so each distinct irrigation system that is in use is sampled and tested at least once during the season.
Sampling Frequency	If two (2) or more of the samples have detectable levels of generic <i>E. coli</i> or the level in at least one sample is greater than
Sample and test each distinct irrigation system for generic <i>E. coli</i> at least once during the season.	 (>) 10 MPN, prior to the next irrigation event perform a Level 1 Assessment as outlined in Table 2F.
Acceptance Criterion	
Non-detectable generic <i>E. coli</i> in 100 mL water samples and \leq 10 MPN as the single sample maximum for one (1) in three (3) samples	
Note : For the purposes of water testing, MPN and CFU are considered equivalent.	
Test Method: Any FDA-allowed method ²	
sample, the method of analysis, and, if quantit	record the type of water source, date, time, and location of the cative, the detection limit. All test results and remedial actions tion from the grower/handler who is the responsible party for a

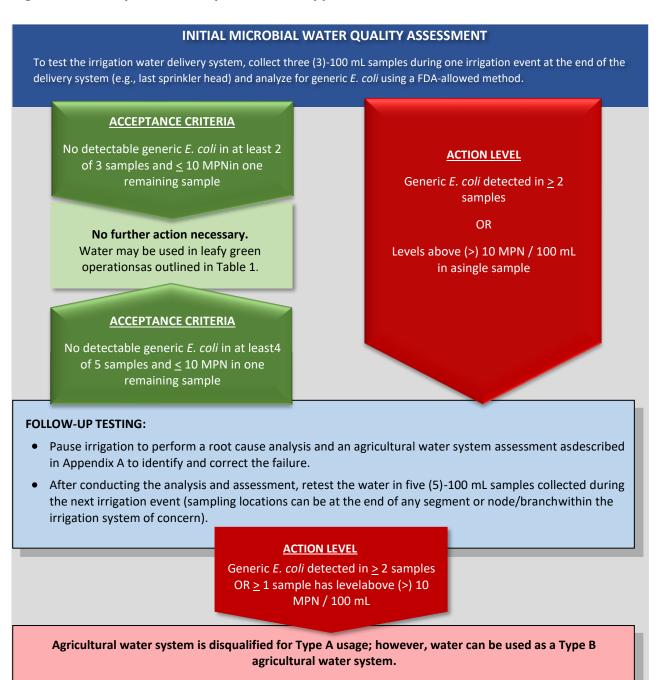
- 370 FIGURE 3A. Irrigation Water from Type A Agricultural Water Systems Sourced from Private Wells or
- 371 Regulated Tertiary Treated Recycled Water Supplies See TABLE 2C
- 372 **BASELINE MICROBIAL ASSESSMENT** Self-certification with historical water If historical data is unavailable: test data: To self-certify, take three (3)-100 mLsamples Assessment conducted using historical at the water source on two sampling occasions water test records consisting of 5 separated by \geq 7 days. consecutive water test results - one of which occurred in the last 6 months. ACTION LEVEL Generic *E. coli* detected in > 2 samples **ACCEPTANCE CRITERIA** or one sample has levels above (>) 10 MPN /100 mL No detectable generic *E. coli* in all but one sample and no greater than 10 MPN in that one sample Water source cannot be considered part of a Type A agricultural water system. Water source is self-certified; no further action necessary until the initial microbial water quality assessment. **REMEDIAL ACTION** • Perform a root cause analysis and an agricultural water system assessment as described in Appendix A to identify and correct the failure. • In the interim, the water can be treated or used as a source for a Type B agricultural water system. If you choose to treat the water, follow Type $B \rightarrow A$ water system requirements. • See Appendix A for guidance on mitigation

measures such as shock treatment for

contaminated wells.

373 FIGURE 3B. Irrigation Water from Type A Agricultural Water Systems Sourced from Private Wells or

- 374 Regulated Tertiary Treated Recycled Water Supplies See TABLE 2C
- 375



376 FIGURE 3C. Irrigation Water from Type A Agricultural Water Systems Sourced from Private Wells or

- 377 Regulated Tertiary Treated Recycled Water Supplies See TABLE 2C
- 378

ROUTINE MONITORING of MICROBIAL WATER QUALITY

- For Type A agricultural water from regulated recycle water / private well sources for overhead applications when used within (<) 21 days of the scheduled harvest date. (When using Type A agricultural water from these sources for overhead applications up to (>) 21 days of the scheduled harvest date follow water metrics in Table 2E/Figure 5 for Type B agricultural water systems.)
- Collect three (3) samples at the end of the delivery system (e.g., last sprinkler head); test each distinctirrigation system in use at least once during the season.
- Test for generic *E. coli* using a FDA-allowed method.
- Assess microbial quality using the three (3) collected samples.

ACCEPTANCE CRITERIA

No detectable generic *E. coli* in at least 2 of 3 consecutive samples and \leq 10 MPN in one remaining sample

No further action necessary. Water may be used in leafy green operationsas outlined in Table 2C.

ACTION LEVEL

Generic *E. coli* detected in ≥ 2 samples or one samplehas levels above (>) 10 MPN / 100 mL

CONDUCT A LEVEL 1 ASSESSMENT:

- If generic *E. coli* levels in your water exceed the acceptance criterion, prior to the next irrigation event, conduct an agricultural water systemassessment as described in Appendix A.
- Retest the water for generic *E. coli* during the next irrigation event in five (5) 100 mL samples. Water can
 be pulled from the end of any system nodes/branches in the irrigation system of concern. If these water
 samples also fail to meet the acceptance criterion, discontinue use of this water for overhead applications
 while continuing to evaluate your water system to identify and correct any failures and continuing to test
 as described in this step until the water is back in compliance (see Appendix A for guidance on
 troubleshooting irrigationsystem failures).
- If this water (the water from the initial sampling to the last of the follow-up sampling) has been applied to leafy greens, either consider the crop unsuitable for the fresh market or test the crop from all affected lots (i.e., lots that have been irrigated with this water within the <21 days-to-scheduled-harvest window) for STEC (including *E. coli*O157:H7) and *Salmonella*. Product needs to be tested prior to harvesting and after your last irrigation event. Sample crop per the protocol described in Appendix C. If any individual sample tests positive for any of these human pathogens, the crop within that lot shall NOT be harvested for the fresh market and human consumption.

379 **TABLE 2D:** Irrigation Water from Treated Type B → A Agricultural Water Systems – See FIGURE 4.

 Example of treated water from a Type B→A agricultural water system: Water may arrive at the production area in an irrigation district canal or lateral from which it is pumped and treated before being used in overhead sprinkler irrigation. When water from a Type B agricultural water system is used in an overhead application within (≤) 21 days to thescheduled harvest date, it must be treated to move it from a Type B agricultural water system to a Type A system (B→A) by a scientifically valid antimicrobial watertreatment - i.e., contain an approved antimicrobial watertreatment at sufficient concentration to prevent potential contamination risk during overhead applications. Microbial and/or physical/chemical testing of the source and system must be performed, as appropriate to the specific operation, to demonstrate that performance criteria have been met before use within (≤) 21 days to the scheduled harvest date and continues to be met throughout its use. Water in open delivery systems (e.g., reservoirs and ponds) may be used in overhead applications within 21 days to the scheduled harvest if it is treated at the sametime it is applied to crops. 	Metric	Rationale /Remedial Actions
	agricultural water system: Water may arrive at the production area in an irrigation district canal or lateral from which it is pumped and treated before	used in an overhead application within (\leq) 21 days to thescheduled harvest date, it must be treated to move it from a Type B agricultural water system to a Type A system (B \rightarrow A) by a scientifically valid antimicrobial watertreatment - i.e., contain an approved antimicrobial watertreatment at sufficient concentration to prevent potential contamination risk during overhead applications. Microbial and/or physical/chemical testing of the source and system must be performed, as appropriate to the specific operation, to demonstrate that performance criteria have been met before use within (\leq) 21 days to the scheduled harvest date and continues to be met throughout its use. Water in open delivery systems (e.g., reservoirs and ponds) may be used in overhead applications within 21 days to the scheduled harvest if it is treated at the

D1. Routine Verification of Microbial Water Quality

Target Organisms:

- Total coliforms (TC)
- Generic E. coli

Routine Verification Sampling Procedure:

Aseptically collect at least three (3)-100 mL samples during one irrigation event with at least one sample at the end of the delivery system (e.g., last sprinkler head).

Routine Verification Sampling Frequency:

Sampling is conducted monthly.

If the irrigation treatment system is being used prior to the 21-days-to-harvest-window, sample and test each distinct irrigation treatment system on at least one occasion.

If the irrigation treatment system is being used within the 21-days-to-harvest-window, sample each distinct irrigation treatment system on at least two occasions separated by at least three (3) days. Routine water sampling is performed to verify irrigation water continues to meet the microbial quality acceptance criteria throughout the season. Routine verification of treated irrigation water systems is focusedon the function of the system. Sampling needs to occur at a frequency that allows operators to verify they have control of their treatment system. An essential component of this verification process is building a dataset so microbial quality can be analyzed to best inform you how to effectively run your water treatment system.

Sample and test the system for total coliforms and generic *E. coli* in three (3)-100 mL samples. To maintainits Type A status, water samples must have:

 no detectable generic *E. coli* in at least two (2) of thethree (3) samples with a maximum level no greater than (<) 10 MPN in the remaining sample, and

Metric	Rationale /Remedial Actions
 Routine Verification Acceptance Criteria: <u>Generic E. coli</u>: No detection in two (2) of the last three (3) water samples with a maximum level of (<) 10 MPN allowed in one (1) sample [consecutive values] Routine Verification Data Monitoring Criteria: <u>Total coliforms</u>: A maximum level of ≤ 99 MPN in 100 mL in all water samples or an adequate log reduction based on the untreated water's baseline total coliforms levels* Note: For the purposes of water testing, MPN and CFU are considered equivalent. 	 data monitoring for total coliforms at a level nogreater than (≤) 99 MPN in 100 mL * * As an alternative to the threshold approach for total coliforms (≤ 99 MPN / 100 mL), operators can verify their irrigation treatment system by conducting paired pre- and post-treatment microbial testing of water distribution system (see Appendix A for additional guidance on conducting a log reduction assessment). If two (2) or more of the three (3)-100 mL samples do not meet the acceptance criteria for generic <i>E. coli</i> and at least one sample is greater than (>) 10 MPN and one (1) or more of the total coliforms results do not meet the monitoring criteria, prior to the next irrigation event perform a Level1 Assessment as outlined in Table 2F.
Test Method: Any FDA-allowed method ²	
	the type of water source, date, time, and location of the the detection limit. All test results and remedial actions

sample, the method of analysis, and, if quantitative, the detection limit. All test results and remedial actions shall be documented and available for verification from the grower/handler who is the responsible party for a period of two years.

D2. Routine Water Treatment Monitoring

Antimicrobial water treatments - USEPA-approved for use in agricultural water.

Target variable: Antimicrobial irrigation water treatment or manufacturer's operational specifications (e.g., per manufacturer's recommendations, chemical concentration, etc.).

 Testing Procedure: Chemical reaction-based colorimetric test, or Ion-specific probe, or Other as recommended by antimicrobial watertreatment supplier or manufacturer's specifications. Testing Frequency: Monitoring must be conducted whenever the irrigation treatment system is in use. Continuousmonitoring with periodic verification by titrationOR routine monitoring if the system can be shown to have a low degree of variation. 	 Monitor the efficacy of the water treatment method perthe manufacturer's label or operational instructions. To demonstrate the irrigation system is performing as intended <u>during each water treatment irrigation event</u>, document: Flow rates Treatment-related parameters such as residual antimicrobial levels, pH, dose settings, UVT, etc. If water quality falls outside the acceptable monitoring parameters, conduct microbial testing per section D1. Routine Verification of Microbial Water Quality.
---	--

Test Method: Per label instructions

Metric

Rationale / Remedial Actions

Records: During every irrigation event, treatment-related parameter values such as residual antimicrobial levels, pH, dose settings, UVT, etc. must be documented to demonstrate the system is working as intended. Each water sample and analysis shall record the type of water source, date, time, and location of the sample, the method of analysis, and, if quantitative, the detection limit. All test results and remedial actions shall be documented and available for verification from the grower/handler who is the responsible party for a period of two years.

380

382 FIGURE 4. Irrigation Water from Type B→A (Treated) Agricultural Water Systems – See TABLE 2D

383

384

ROUTINE MONITORING of MICROBIAL WATER QUALITY

- Collect three (3) 100 mL samples during one irrigation event with at least one sample taken at the end of the distribution irrigation system (e.g., last sprinkler head).
- Sample monthly during use and test for generic *E. coli* and total coliforms using a FDA-allowed method.
- If the irrigation system is being used up until 21 days to scheduled harvest, sample each distinct irrigation system on one occasion and follow microbial standards in Table 2E / Figure 5 for Type B agricultural water systems.
- If the irrigation system is being used within the 21-days-to-harvest-window, sample each distinct irrigation system on two occasions separated by at least three (3) days.

Generic *E. coli* detected in \geq 2 samples or level above (>) 10 MPN / 100 mL in a single sample

ACTION LEVEL

ACCEPTANCE CRITERIA

No detectable generic *E. coli* in at least 2 of 3 samples and \leq 10 MPN in one sample

DATA MONITORING CRITERIA

<u>< 99 MPN in 100 mL or an</u>
adequate log reduction based on
the untreated water's baseline
total coliform levels

No further action necessary.

Water may be used in leafy green operations as outlined in Table 2D.

CONDUCT A LEVEL 1 ASSESSMENT:

When using Type B \rightarrow A agricultural water for overhead applications within (<) 21 days of the scheduled harvest date:

- If generic *E. coli* or total coliform levels in your water exceed the acceptance and/or monitoring criteria, pause irrigation and conduct an agricultural water system assessment as described in Appendix A to determine why the treatment was not effective.
- Retest the water for generic *E. coli* and total coliforms during the next irrigation event in five (5) - 100 mL samples. Water can be pulled from any point in the distribution systems in the irrigation treatment system of concern with at least one coming from the last sprinkler head. If these water samples also fail to meet the acceptance and/or monitoring criteria, discontinue use of this water for overhead applications while continuing to evaluate your water system to identify and correct any failures and continuing to test as described in this step until the water is back in compliance (see Appendix A for guidance on troubleshooting irrigation system failures).
- If this water (the water from the initial sampling applied to the crop within 21 days to harvest to the first and last of the follow-up sampling) with generic *E. coli* above the acceptance criteria has been applied to leafy greens, either consider the crop unsuitable for the fresh market or test the crop from all affected lots (i.e., lots that havebeen irrigated with this water within the <21 days-to-scheduled-harvest window) for STEC (including *E. coli* O157:H7) and *Salmonella*. Product needs to be tested prior to harvesting and after your last irrigation event. Sample crop per the protocol described in Appendix C. If any individual sample tests positive for any of these human pathogens, the crop within that lot shall NOT be harvested for the fresh market and human consumption.

385 TABLE 2E. Irrigation Water from Type B Agricultural Water Systems Intended for Overhead Irrigation

386 prior to 21 days – See FIGURE 5

Metric	Rationale /Remedial Actions
Example of water from a Type B agricultural water system - water may arrive at the field in an irrigation district canal from which it is then used to overhead irrigate crop prior to 21 days to the scheduled harvest	Water from Type B agricultural water systems is untreated and exposed to the environment (e.g., open sources and/or delivery systems) so that its quality may be inadequate for overhead irrigation within (\leq) 21 days to the scheduled harvest date. Water from these systems is restricted to use in overhead irrigation when applied prior to (>) 21 days to the scheduled harvest date.
date.	Also, water from Type A agricultural water systems can be sampled and tested under Type B agricultural water system requirements when it is used for overhead irrigation prior to 21 days before the scheduled harvest date.

E1. Routine Verification of Microbial Water Quality

Target Organisms: Generic E. coli

Routine Verification Sampling Procedure:

100 mL sample collected aseptically at the point-of-use, i.e., one sprinkler head per water source for irrigation, water tap for pesticides, etc. preseason irrigation water may be tested and utilized.

Routine Verification Sampling Frequency:

One sample per water source shall be collected and tested prior to use if > 60 days since last test of the water source. Additional samples shall be collected no less than 18 hours apart and at least monthly (or at the next irrigation event if greater than monthly) during use from points within the water distribution system.

Routine Verification Acceptance Criterion:

< **126 MPN / 100 mL** (geometric mean) and <u>< 235 MPN/100mL</u> for any single sample. **Note**: For the purposes of water testing, MPN and CFU are considered equivalent. When using water from Type B agricultural water distribution systems for overhead applications **prior to (>) 21 days** of the scheduled harvest date, samples for microbial testing shall be taken as close as practicable to the point-of-use (i.e., to be determined by the sampler, to ensure the integrity of the sample, using sampling methods as prescribed in Table 2D) so as to test both the water source and the water distribution system. In a closed water distribution system (meaning no connection to the outside) water samples may be collected from any point within the system but are still preferred at the point-of-use. No less than one (1) sample per month (or at the next irrigation event) per water distribution system is required under these metrics. If there are multiple potential point-of-use sampling points ina water distribution system, then samples shall be taken from different point-of-use locations each subsequent sampling event (randomize or rotate sample locations).

Water for pre-harvest, direct edible portion contact prior to (>)21 days before scheduled harvest shall meet or exceed antimicrobial standards for recreational water, based on a rolling geometric mean of the five (5) most recent samples. However, a rolling geometric mean of five samples is not necessarily required prior to irrigation or harvest. If less than five (5) samples are collected prior to irrigation, the acceptance criteria depend on the number of samples taken. For example:

- If only one (1) sample has been taken, it must be below (<)126 MPN / 100 mL.
- Once two (2) 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 five (5)-sample rolling geometric mean. The *rolling* geometric mean calculation starts after five (5) samples have

Metric	Rationale /Remedial Actions	
	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 water distribution system.	
	Ideally, pre-harvest water used prior to 21 days before harvest for overheadapplications should not contain generic <i>E. coli</i> , but low levels do not necessarily indicate that the water is unsafe. Investigation and/or remedial action SHOULD be taken when test results are higher than normal or indicate an upward trend. Investigation and remedial action SHALL be takenwhen acceptance criteria are exceeded.	
	Remedial Actions: If the rolling geometric mean (n=5) or any one sample exceeds the acceptance criteria, then the water shall not be used whereby edible portions of the crop are contacted by water until remedial actions have been completed and generic <i>E. coli</i> levels are within acceptance criteria:	
	 Conduct an agricultural water system assessment of water source and water distribution system to determine if a contamination source is evident and can be eliminated. Eliminate identified contamination source(s). 	
	 For wells, perform an agricultural water system assessment and/or treatas described in Appendix A. 	
	Or begin water treatment	
	Retest the water after conducting the agricultural water system assessment and/or taking remedial actions to determine if it meets the outlined microbial acceptance criteria for this use. Retest the water daily, take three samples, no less than 18 hours apart at the point closest to use. This sample should represent the conditions of the original water system, if feasible this test should be at the original sampling point. A more aggressive sampling program (i.e., sampling once per week instead of once per month) or water	
Test Method: Any FDA-allowed method	treatment shall be instituted if an explanation for the exceedance is not readily apparent. This type of sampling program should also be instituted if an upward trend is noted in normal sampling results.	

Test Method: Any FDA-allowed method²

Records: Each water sample and analysis shall record the type of water source, date, time, and location of the sample, the method of analysis, and, if quantitative, the detection limit. All test results and remedial actions shall be documented and available for verification from the grower/handler who is the responsible party for a period of two years.

FIGURE 5. Irrigation Water from Type B Agricultural Water Systems intended for Overhead Irrigation – See TABLE 2E



ROUTINE MONITORING of MICROBIAL WATER QUALITY

- If using > 21 days prior to the scheduled harvest date, collect one (1) 100 mL samples per irrigation water system at the point of use monthly.
- Analyze samples for generic *E. coli* using a FDA-allowable method.
- Calculate geometric means using the five most recent samples.

ACCEPTANCE CRITERIA

< 126 MPN / 100mL
(geometric mean)</pre>

AND

<u>< 235 MPN / 100 mL in a</u> single sample

No further action necessary.

Water from this source may be used for any use such as crop foliar applications and/or irrigation up until 21 days to scheduled harvest. However, when test results are higher than normal or indicate an upwardtrend, investigation and/or remedial action **SHOULD** be taken.



- If crop has been directly contacted with water exceeding acceptance criteria, sample and test product for STEC (including *E. coli* O157:H7) and *Salmonella* as described in Appendix C, prior to harvest.
- If crop testing indicates the presence of either pathogen, do NOT harvest for fresh market and human consumption.

ACTION LEVEL

> 126 MPN / 100mL (geometric mean)

<u>OR</u>

235 MPN / 100 mL in a single sample

REMEDIAL ACTIONS:

- Discontinue use for foliar and direct contact with the edible portion of the plant applications until it returnsto compliance.
- Examine the water source and distribution system to determine if a contamination source is evident and can be eliminated.
- For wells, perform an agricultural water system assessment and/or treat as described in Appendix A.
- After performing an agricultural water system assessment and/or remedial actions, retest the water atthe same sampling point.
- Take three samples, no less than 18 hours apart at the point closest to use. If any of these samples is >126 MPN/ 100mL, repeat agricultural water system assessment and/or remedial action.
- Do not use water from that water system, in a manner that directly contact edible portions of the crop, until the water can meet the outlined acceptance criteria forthis use or treat water to meet the acceptance criteria.

TABLE 2F. Level 1 Assessment - Remedial Actions for Type A and B→A Agricultural Water Systems – See FIGURE 4

	back in compliance (see Appendix A for guidance on troubleshooting irrigation treatment system failures).
	 Water can still be used as a Type A system and no pre-harvest pathogen testing is required as long as the generic <i>E. coli</i> acceptance criterion is met.
Test Method: Any FDA-allowed method ²	
Records : Each water sample and analysis shall record the type of water source, date, time, and location of the sample, the method of analysis, and, if quantitative, the detection limit. All test results and remedial actions shall be documented and available for verification from the grower/handler who is the responsible party for a period of two years.	

395 TABLE 2G. Harvest Direct Product Contact, Harvest Food-Contact Surfaces, and Hand Wash Water (On

396 Farm Practices Only) - See FIGURE 6

Metric	Rationale /Remedial Actions
 Water Type: Municipal Well (Type A) Reverse Osmosis Microbial Water Quality Testing	Water used during harvest operations that directly contacts edible portions of harvested crop, water used forhand washing, or is used on food-contact surfaces such asequipment or utensils, shall be sourced from municipal, well (Type A) or reverse osmosis water sources.
Target Organism: Generic E. coli	
Sampling Procedure: Prior to use in harvest equipment, a 100 mL sample collected aseptically at the water source. Sampling Frequency: One sample per water source shall be collected and tested prior to use if >60 days since last test of the water source. Additional samples shall be collected at intervals of no less than 18 hours and at least monthly during use. For wells and municipal water sources, if generic <i>E. coli</i> are below detection limits for five consecutive samples, the requirements for 60 days and monthly sampling are waived, and the sampling frequency may be decreased to no less than once every 180 days. This exemption is void if there is a significant water source or distribution system change. Reverse Osmosis Systems: No less than one (1) sample per month per system is required. Test Method: Any FDA allowed method ² Acceptance Criteria: Negative or below DL for all samples	 Testing must be conducted to demonstrate that this water meets the Maximum Contaminant Level Goal for generic <i>E. coli</i> as specified by U.S. EPA or contain an approved disinfection method at sufficient concentration or of sufficient wavelength to prevent cross-contamination. Microbial or physical/chemical testing shall be performed, a appropriate to the specific operation, to demonstrate that acceptance criteria have been met. Single-Pass vs. Multiple-Pass Systems Single-pass use – Water must have non-detectable levels of generic <i>E. coli</i> or breakpoint disinfectant present at point of entry. Multi-pass use – Water must have non-detectable levels of generic <i>E. coli</i> and/or sufficient disinfectant toensure multi-pass water has no detectable generic <i>E. coli</i>. Remedial Actions: Develop an SOP that determines what corrective actions will be required when harvest water does not meet acceptance criteria. If any single sample exceeds the acceptance criteria, then DO NOT USE THE WATER until remedial actions have been completed and generic <i>E. coli</i> or disinfectant levels arewithin acceptance criteria: Conduct an agricultural water system assessment of water source and distribution system to determine if

	Rationale /Remedial Actions
 Physical/Chemical Testing Target Variable: Water disinfectant (e.g., UV transmittance, chlorine or other disinfectant compound). Multi-Pass Water Acceptance Criteria: Chlorine 1 ppm free chlorine after application and pH 5.5 – 7.5 Other approved treatments per product EPA label for human pathogen reduction in water. Testing Procedure: Chemical reaction-based colorimetric test, or lon-specific probe, or UV transmittance Other as recommended by disinfectant supplier. Testing Frequency: Prior to first use on day of harvest. During harvest, samples shall be taken at routine intervals (i.e., hourly, breaks, lunch, etc.) as determine by historical data showingtypical degree of variation. 	 a contamination source is evident and can be eliminated.Eliminate identified contamination source(s) and/or treat with appropriate disinfectants. For wells, perform an agricultural water system assessment and/or treat as described in Appendix A. Retest the water at the same sampling point after conducting the agricultural water assessment for waterused for harvest and/or taking remedial actions to determine if it meets the outlined microbial acceptancecriteria for this use. For example, if the water intended for use on food-contact surfaces has detectable generic <i>E. coli</i>, DO NOT USE THE WATER. Examine the distribution line and source inlet as described in Appendix A and retest from the same point of use. After corrective actions have been implemented and verifiedthe water may be used for harvest operations and hand wash water.

FIGURE 6. Harvest Direct Product Contact, Harvest Food-Contact Surfaces, and Hand Wash Water (On Farm Practices Only) – See TABLE 2G

401

Water Type: Municipal, Wells (Type A), and Reverse Osmosis:

Water that directly contacts edible portions of harvested crop shall meet microbial standards set forth in U.S. EPA National Drinking Water Regulations and/or contain an approved disinfectant at sufficient concentration to prevent cross-contamination.

SAMPLING FREQUENCY:

One sample per water source shall be collected and tested prior to use if > 60 days since last test of the water source. Additional samples shall be collected no less than 18 hours apart and a least monthly during use.

- Sample sources using sampling methods as prescribed in Table 2G.
- Analyze samples for generic *E. coli* using any FDA allowed method.

ACCEPTANCE CRITERIA

Negative or below DL /100 mL generic *E. coli*

OR

MULTI-PASS WATER ACCEPTANCE CRITERIA

Chlorine ≥1 ppm free chlorine (pH 5.5 - 7.5) OR

Sufficient disinfectant; physical treatment - sufficient wavelength to prevent cross- contamination. Other approved treatments per product EPA label for human pathogen reduction in water.

No further action necessary. Water from this source may be used for anypurpose.

ACTION LEVEL

Positive generic E. coli

REMEDIAL ACTIONS:

- DO NOT USE THE WATER.
- Follow your SOP for corrective action to bring water backinto compliance with the acceptance criteria.
- For wells, perform an agricultural water system assessment and/or treat as described in Appendix A.
- After agricultural water system assessment on water usedfor harvest and/or remedial actions have been taken, retest the water at the same sampling point.
- After corrective actions have been implemented and verified the water may be used for harvest operations.
- If water exceeding the acceptance criteria has been used during harvest, it is NOT appropriate microbial quality for this use. Sample and test product for STEC including *E. coli* O157:H7 and *Salmonella* as described in Appendix C.