



Arizona Leafy Greens Technical Subcommittee

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Sonia Salas
Western Growers
15525 Sand Canyon
Irvine, CA 92618

RE: Leafy Greens Guidance Comments

Greetings Ms. Salas,

The Arizona LGMA appreciates the efforts of Western Growers in revitalizing the metrics review process and provide this opportunity to give input for the continuous improvement of the Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens. The attached document represents a review of the CA LGMA strawman as posted on the Leafy Green Guidance website. We concur with the CA LGMA on many points. Where we differ, the AZ LGMA Technical Subcommittee's comments are noted and we have included some additional suggestions with regards to the following:

Physical Disinfection- We support inclusion of language that allows for other forms of disinfection other than chemical.

Post-Harvest Direct Product Contact and Harvest Food-Contact Surfaces – On Farm Practices Only – The CA LGMA proposed language makes reference to following other sections of the metrics. We suggest moving all of the language into Table 2G ease of use. Example (1) attached.

Chemical Compatibility – AZ LGMA Technical Subcommittee members note that issues with chemical compatibility have arisen. The water treatment approach selected by LGMA relies heavily on residual and microbial monitoring rather than on probabilities of real risk. Agronomic considerations should include crop inputs and the need for fertilizer and other crop protection chemicals. The AZ Technical Subcommittee offers Example (2) for review.

We look forward to the open discussion by all.

Sincerely,

Teresa Lopez
Administrator
Arizona Leafy Greens Marketing Agreement

AZ LGMA Technical Subcommittee Comments

Point#	Line or Section of Matrics	Issue addressed	Previous Language	Rationale	New Proposed Language	Comments
1	474-476	Clarification of sample process	Collect three (3) 100 mL samples no closer than 20 minutes apart. Acceptance Criteria and Data Monitoring Criteria as outlined in Table 2D - Routine Monitoring of Microbial Water Quality must be met.	Previous Language is too prescriptive	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.	At least one sample from the farthest or last sprinkler head. End of the system not necessarily indicative in each case.
2	495	Best Practice Language	No previous language	To add clarity and awareness to emphasize caution with Type B water	Efforts should always be made, when using Type B water, to avoid contact with the edible portion of the crop within 21 days of a scheduled harvest.	
	497-505		No previous language		Furrow Irrigation Best Management Practices:	
3		Best Practice Language	No previous language	To add clarity and awareness to emphasize caution with Type B water	1. Agricultural practices, such as irrigation methods, bed configuration, etc., should be implemented in a manner to avoid water from breaching the top of the bed.	
4		Best Practice Language	No previous language	To add clarity and awareness to emphasize caution with Type B water	2. Agricultural practices, such as equipment movement, irrigation practices, etc., should be monitored at headland and tail ditch locations for damaged beds which may allow water to contact the edible portion of the crop.	
5		Best Practice Language	No previous language	To add clarity and awareness to emphasize caution with Type B water	3. 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 (i.e. knives, gloves etc.) , and harvest equipment (i.e. machines, belts, trailers etc.) .	
	507-511		No previous language		Drip Tape Irrigation:	
6		Best Practice Language	No previous language	To add clarity and awareness to emphasize caution with Type B water	1. Drip tape should be handled, stored, used, and re-used in a manner that prevents damage and contamination to the drip tape. Consider flushing drip tape with sanitizer prior to use after storage.	Flush drip tape, use sanitizer prior to use after storage.
7		Best Practice Language	No previous language	To add clarity and awareness to emphasize caution with Type B water	2. 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.	
8	Table 2A	Clarification of 35 day sampling requirement	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.	To create sampling language based on system approach and allow more flexibility in sampling	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.	Includes allowance for sampling to be done at the irrigation event instead of a calendar date

	Table 2A	Sampling Frequency:		Sampling Frequency:	
9	Table 2A	Clarification of sampling requirement 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 during use no less than 18 hrs. apart and at least monthly during use from points within the delivery system.	To create sampling language based on system approach and allow more flexibility in sampling	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 during use no less than 18 hrs. apart and at least monthly (or at the next irrigation event if longer than monthly) during use from points within the delivery system.	Includes allowance for sampling to be done at the irrigation event instead of a calendar date
	Figure 1	Sampling Frequency:		Sampling frequency:	
10		Clarification of sampling requirement 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 during use.	To create sampling language based on system approach and allow more flexibility in sampling	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 and at least monthly (or at the next irrigation event if greater than monthly) during use.	Includes allowance for sampling to be done at the irrigation event
11	Figure 4	Clarification of sampling requirement Sample monthly during use and test for generic E. coli and total coliform using a FDA-allowed method.	To create sampling language based on system approach and allow more flexibility in sampling	Sample monthly (or at the next irrigation event if greater than monthly) during use and test for generic E. coli and total coliform using a FDA-allowed method.	Includes allowance for sampling to be done at the irrigation event
	Table 2E	Routine Verification of Microbial Water Quality :		Routine Verification of Microbial Water Quality:	
12	Right Column	Clarification of sampling requirement No less than one (1) sample per month per water distribution system is required under these metrics. If there are multiple potential point-of-use sampling points in a water distribution system, then samples shall be taken from different point-of-use locations each subsequent month (randomize or rotate sample locations).	To create sampling language based on system approach and allow more flexibility in sampling	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 in a water distribution system, then samples shall be taken from different point-of-use locations each subsequent sampling event (randomize or rotate sample locations).	Includes allowance for sampling to be done at the irrigation event
	Table 2E	Routine Verification Sampling Frequency:		Routine Verification Sampling Frequency:	
13	left column	Clarification of sampling requirement Additional samples shall be collected no less than 18 hrs. apart and at least monthly during use from points within the water distribution system.	To create sampling language based on system approach and allow more flexibility in sampling	Additional samples shall be collected during use no less than 18 hrs. apart and at least monthly (or at the next irrigation event if greater than monthly) during use from points within the water distribution system.	Includes allowance for sampling to be done at the irrigation event
14	Table 2G	Table Title is Confusing with Post Harvest off Farm Use Post-Harvest Direct Product Contact and Food-Contact Surfaces	Clarification that standard relates to on farm water use	Post-Harvest Direct Product Contact and Harvest Food-Contact Surfaces <i>Practices Only</i> <i>On Farm</i>	On farm and not for post-harvest. At time of harvest.

		Sampling procedure:		Sampling procedure:	
15	Left column of Table 2G	Clarification 100 mL sample collected aseptically at the point of use	To create sampling language based on system approach and allow more flexibility in sampling	Follow Type A Baseline Language and sampling requirements.	
		Sampling Frequency:		Sampling Frequency:	
16	Left column of Table 2G	Clarification One sample per water source shall be collected and tested prior to use if >60 days since last test of the water source.	To create sampling language based on system approach and allow more flexibility in sampling	Follow Type A Baseline Language and sampling requirements.	
	Left column of Table 2G	Physical/Chemical Testing :		Physical/Chemical Testing :	
17	Left column of Table 2G	Complicated Testing procedures, ORP no longer in use Target Variable: Water disinfectant (e.g., chlorine or other disinfectant compound, ORP). Multi Pass Water Acceptance Criteria: Chlorine > 1 ppm free chlorine after application and pH 5.5 – 7.5 OR ORP > 650 mV and pH 5.5 – 7.5 Other approved treatments per product EPA label for human pathogen reduction in water.	Simplify and create consistency in language and procedures	Follow B to A irrigation water treatment monitoring requirements.	The committee suggests that the previous language be removed and that new monitoring language be similar to B to A monitoring language. ORP no longer listed.
	Right column of Table 2G	Single Pass vs. Multiple Pass Systems		Single Pass vs. Multiple Pass Systems	
18	right hand column	Either/or option of testing Multi-pass use – Water must have non-detectable levels of E. coli and/or sufficient disinfectant to ensure returned water has no detectable E. coli (minimally 1 ppm chlorine).	Both E.coli and breakpoint disinfectant need to be monitored	Multi-pass use – Water must have non-detectable levels of <i>E. coli</i> or sufficient disinfection ant to ensure returned water has no detectable <i>E. coli</i>	Does not have to be a chemical sanitizer. Disinfection.
	Right hand Column 2G	Remedial Actions:		Remedial Actions:	
19	Remedial Actions Requirements	No previous language	Provide language to cover out of compliance water	Develop an SOP that determines what corrective actions will be required when post harvest water does not meet acceptance criteria.	Develop an SOP per company policy. Post harvest sampling if hydration /cooling water being used before transported to cooler.

20	Figure 6	Clarification	Acceptance Criteria Negative or below DL / 100 mL generic E. coli or >1 PPM free chlorine (pH 5.5 - 7.5) or >650 mV ORP (pH 5.5-7.5) after contact. REMOVE--change to no detect for generic E. coli/100 ml	Language Simplification	Acceptance Criteria Non-detect for generic E. coli / 100 mL	
21		Clarification	Action Level If water exceeding the acceptance criteria has been used postharvest, 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.		Action Level If water exceeding the acceptance criteria has been used postharvest, notify the handler of the water issue and determine an appropriate sampling and testing strategy for STEC (including E. coli O157:H7) and Salmonella as described in Appendix C or discard the affected product affected .	
	New		No previous language		Water used for aerial chemical applications within 21 days of a scheduled harvest	
22		Water requirements for overhead chemical applications		Best Practices for overhead chemical applications, clarify requirements	Develop a SOP for all of the overhead chemical application components. The SOP must address items such as: <ul style="list-style-type: none"> •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 •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. •Water treatment chemistry shall be compatible with the agricultural chemicals being applied. •Procedures to control pest access to the equipment (examples may include: avian deterrents, fencing, and rodent monitoring) must be in place. (validation can include: PCA records, label requirements, letter of guarantee) •Procedures to ensure storage of equipment does not pose a contamination risk must be in place. •Establish corrective action procedures for non-compliance scenarios, including: a) treatment failure; b) contaminated source water; c) Pest concerns; d) Chemical incompatibility; e) Equipment sanitation concerns • Document all corrective measures, cleaning activities, and maintenance 	Technical committee discussed lack of science with water treatment chemistry compatibility.
23		Record Keeping clarification		Clarify need for records	Type A Water: Have records that demonstrate the water used for chemical applications meets Type A source water requirements. See Tables 2B and 2C for historical and/or baseline water quality requirements for source water that will be used for overhead applications.	

24	Clarification		Clarify need for records	<p>Type B to A Agricultural Water Treatment</p> <p>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:</p> <ul style="list-style-type: none"> o Turbidity o Total suspended solids o pH o Antimicrobial dose o Historical microbial monitoring data <p>Refer to Appendix A for additional guidance.</p>	Reference Appendix A Flow rates.
25 & 26	Clarification		Clarify need for records	<p>Develop a written Standard Operating Procedure (SOP) for each unique application process to treat water that will be used within 21 days of a scheduled harvest. Prior to 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. Incorporate this assessment's findings into your water treatment SOP.</p> <p>A water treatment SOP should include :</p> <ul style="list-style-type: none"> • Step-by-step instructions to ensure the water treatment is correctly implemented • Location of water sources • Name, and suggested supplies needed • Sanitizer used and quantity used • Critical limits and operational limits • Water sampling location • Corrective actions if critical limits are not met • Required records 	
No #	Header			Develop a Baseline for Water Treatment	
27	Clarification		The intent is to show treatment is effective over multiple treatment events and all three (3) samples are not from the same treatment batch.	<p>Sample Size:</p> <p>A minimum of three (3), 100 mL, samples must be taken for each overhead application process (distinct water source, different sanitizer, different size water holding tank, etc.) The three (3) samples must be taken from different treated water batches.</p>	Water source like a canal. Not ranch but system. Can be confusing - how many water sources are you going to identify. Risks?
28	Clarification		clarification	<p>Acceptance criteria (generic E. coli):</p> <p>All three (3) samples must be non-detect for generic E. coli</p>	

				Ongoing Monitoring:	
29	Clarification		Clarification	Between microbiological routine testing events records must be kept that verifies that each application event is conducted following the parameters established during the initial setup.	
				Routine Testing :	
30	Clarification		Clarification	A minimum of ONE (1) microbiological sample must be taken each month or at the next application event if no applications occur within the monthly time period.	
				Acceptance Criteria :	
31	Clarification		Clarification	Non-detect for generic E. coli / 100 mL sample	
				Corrective Actions:	
				Acceptance Criteria	
32	New	No previous language	New language for corrective actions when chemical application water does not meet requirements.	If microbiological testing shows that the water did not meet generic E. coli acceptance criteria, within 21 days of a scheduled harvest, perform a root cause analysis and correct the concern. The product must be tested for pathogens before harvest if this water was used in aerial application. Follow the product testing requirements outlined in Table 2F	Guidance language needs to be developed to assist applicators with meeting this requirement.
				Monitoring Event	
33	New	No previous language	New language for corrective actions when chemical application water does not meet requirements.	<p>If monitoring shows that the water treatment parameters are not being met, do not use the water .</p> <ul style="list-style-type: none"> •Perform a corrective action to assure the water treatment is effective before using the water. •Take a microbiological sample to verify that the treatment was effective and have that result as part of the corrective action documentation. •If the verification microbiological sample does not meet acceptance criteria perform a root cause analysis and correct the treatment process. Product must be tested for pathogens before harvesting. •Follow Table 2F for product testing requirements. 	Guidance language needs to be developed to assist applicators with meeting this requirement.
				If water exceeding the acceptance criteria has been used within 21 days of harvest, notify the handler/shipper of the water issue and determine an appropriate sampling and testing strategy for STEC (including E. coli O157:H7) and Salmonella as described in Appendix C or discard the affected product.	

Line item 14 - Table 2G

The Table is a bit confusing as it implies Post harvest water use when it is about water used during harvest.

Post-harvest (i.e. at a plant/cooler) is outside the scope of the LGMA.

Water used during harvest in within the scope of the LGMA.

Recommended modification for consideration to clarify this section

Metric (left) side

This testing description is for irrigation water. Water used for harvest operations should not be the same water as that used for irrigation as it implies canal and reservoir water (treated) could be used. This should be clarified that only well water and municipal water is acceptable and must meet the acceptance criterial for Generic E. coli.

Additionally, as the point of use nurse tank that was most like filled the day of use, testing that water prior to use is not practical if you are to wait for results to be received before use. Recommend that this be changes to source water is tested and determined acceptable prior to use in the nurse tank of a harvest operation.

Suggestion

Microbial Testing

Water Type: Well or Municipal Water

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 hrs. and at least monthly during use.

Municipal & Well Exemption:

If generic *E. coli* are below detection limits for five consecutive monthly 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.

Test Method:

Any FDA allowed method ²²

Acceptance Criteria:

Negative or below DL for all samples

Physical/Chemical Testing Target Variable:

Water disinfectant (e.g., chlorine or other disinfectant compound).

Water Acceptance Criteria during use:

Chlorine

≥ 1 ppm free chlorine

Other approved treatments per product EPA label for human pathogen reduction in water.

Testing Procedure:

- Chemical reaction-based colorimetric test (i.e. test strips), or
- Ion-specific probe or
- 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 determined by historical data showing typical degree of variation.

Rationale (right side)

Water that is used during harvest operations that directly contacts the 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 *E. coli* 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.

Single Pass vs. Multiple Pass Systems

- Single pass use - Water must have non-detectable levels of *E. coli* or breakpoint disinfectant present at point of use
- Multi-pass use - Water must have non-detectable levels of *E. coli* and/or sufficient disinfection to ensure returned water has no detectable *E. coli* (minimally 1 ppm chlorine).

Remedial Actions:

If any single sample exceeds the acceptance criteria, then the water use shall be discontinued until remedial actions have been completed and generic *E. coli* or disinfectant levels are within acceptance criteria:

- Conduct a water system assessment of harvest equipment water tank(s) and distribution system to determine if a contamination is evident and can be eliminated. Eliminate identified contamination source(s) and/or treat with appropriate disinfectants.
- Retest the water at the same sampling point after conducting the harvest water system assessment and/or taking remedial actions to determine if it meets the outlined microbial acceptance criteria for this use.

For example, if a water sample for water used to clean food-contact surfaces has detectable *E. coli*, STOP using that water system, 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 verified, continue testing throughout the harvest date at the point(s) closest to use, to ensure the water system consistently delivers water that is safe, sanitary, and of appropriate microbial quality (i.e., negative result) for the intended use.

EXAMPLE 2

D3. Crop Nutrition and Crop Protection applications within 21 DTSH

Crop Nutrition and Crop Protection is necessary within the 21 DTSH window. These chemicals may be incompatible with water treatment chemicals and therefore may require nontreated water for their application. The timing of applications should be carefully considered using historical data and risk assessments. When making decisions consider chemical compatibility, label restrictions, manufacturers recommendations, chemical concentration, timing of irrigation to harvest, etc. When it is necessary to apply crop nutrition/protection materials aerially within 21 DTSH, the following restrictions apply:

1. Application should not exceed 3-4 hours or 1/3 of the total irrigation time.
2. Should be applied at the beginning of the irrigation event.
3. Should meet the following acceptance criteria for the DTSH timeframe or product testing is required. (see table)

Target Organism: Generic E coli

Sampling procedure: collect one sample pre- treatment from the source.

Sampling Frequency: Sampling is conducted during the irrigation event when crop nutrition/protection chemicals are being applied

Proposed Acceptance Criteria:

DTSH	Pre-treatment water test result	Action
0-7	0-10	No action required
	11-125	Raw product sampling required
	126+	Raw product sampling required
	235+	Raw product sampling required
8-14	0-10	No action required
	11-125	No action required
	126-234	Die-off must be met
	235+	Raw product sampling required
15-21	0-10	No action required
	11-125	No action required
	126-235	No action required
	235+	Raw product sampling required
>21	Follow metrics for B water	

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1. Historical data on quantified Total Coliform bacteria and generic *E. coli* for a water source and system is both acceptable and recommended as the microbiological benchmark against which post-treatment performance requirements should be planned and the treatment system design selected, together with other water constituent traits. As a general guiding principle,
 - 1.1 - Historical evidence for anticipating a treatment system can deliver, at least, a scientifically valid 2-log reduction in waters not exceeding 3 log of Total Coliform bacteria and a 3-log reduction of Total Coliform in water sources periodically exceeding log 3 but not log 4 Total Coliform populations. The system design would be selected to qualify and conform to treated-Type A water sources as described in the standard.
 - 1.2 - Historical generic *E. coli* data is a secondary verification value for Type B to Type A water treatment, to allow for those events when a non-conforming Total Coliform result is observed, where at least a 4-log reduction of *E. coli* from a relevant and comparable source water would be anticipated by following a scientifically valid treatment. As a guiding principle, scientifically valid treatment parameters would typically be drawn from published laboratory studies, public agency water treatment studies, and multi-year performance records from irrigation water treatment assessments reported by an accredited third-party laboratory.
 - 1.3 - Additional guidance should be provided in an Appendix of how to assess and optimize to meet this standard.
2. From both a practical compromise perspective and our consensus knowledge of reasoned acceptable risk, the standard of non-detect outcomes following treatment of a Type B water source is overly restrictive. The text providing a metric to accommodate periodic failure to observe a non-detect result is also unclear in its current form. As written, it appears that the standard is requiring 80% compliance in 3 samples... this does not seem the intent of the standard and should be clarified to a broader timeframe of experience with the system, for example a 30-day period. An alternative recommended approach is provided in #4 below.
3. Following our discussion of the quantitative Total Coliform post-treatment goal, it is recommended to revise the non-conforming value from 70 to 99 as these are not statistically different, especially given the considerable and routine use of MPN based methods for ag-water testing. A key rationale of this recommendation is in support of a simplified metric and to allow communication and training around a log-step system 999, 99, 0.99, and etc. Process definition and control around the currently aspirational goal of non-detection per 100ml would be the Detection Limit of 0.99 in a single 100 ml sample.
4. It is our consensus opinion, based on best available science and experience, that an acceptable option for adoption is based on the requirement for a paired pre and post-treatment microbiological sampling of irrigation sets during initial system design verification. During the initial implementation period of the adopted standards, these tests could be conducted at any time, including within the adopted preharvest interval (14 or 21-day period), with a goal to meet a 2-log reduction from a pre-treatment of peak historical log 3 Total Coliform bacteria in source water (described in #1.1).

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Similarly, a 3-log reduction would be required from a pre-treatment of peak historical log 4 Total Coliform bacteria (described in 1.1). These target numbers are based on the reported upper range of Total Coliform numbers in different surface waters in western states used for ag-water sources in overhead irrigation. It is important to note that sample analysis of the pre-treatment water source will require a 1:10 and 1:100 dilution to allow the operator, under commonly observed variability in Total Coliform numbers in surface waters, to demonstrate process control verification. In addition, the treatment system should result in non-detection of generic *E. coli* /100mL in the last four of five samples [an alternative to this is preferred by C. Rock citing AZ State Code as four of the last seven samples AZOS, 2016]; detection of 13 MPN/100mL (based on 12.6 MPN as explained below) is set as the single sample maximum result post-treatment. This performance expectation is based largely on the co-reduction of *E. coli* achievable within the specified Total Coliform log-reduction requirements and current water testing data outcomes among growers with mature on-farm water treatment systems using different antimicrobials. This is our best assessment of what water treatment should achieve to meet expectations for public health protection. Implementation would require a set of qualifying samples be collected before treatment and a set of samples collected post-treatment, taken at a specified interval window, according to the final definition of a stabilized system. A single sample maximum (SSM) of 12.6 MPN/100ml meets the standard as being a log greater reduction in risk to the current target standard of 126 MPN/100 ml of generic *E. coli*. Cited risk assessment for sprinkler irrigation (Rock et.al. 2019) was between 10 CFU and 13 CFU per 100ml for a risk of one in 10,000 (drinking water risk). Environmental die-off, different than drinking water acceptable risk standards for direct ingestion, is currently allowed, under the Produce Safety Rule, to be 0.5 log/day for up to four days. Under typical overhead irrigation scenarios for last irrigation event pre-harvest the acceptable risk migrates, due to environmental die-off to at least an additional two-log steps or one in 1,000,000. Exceedance of this SSM would default to one of the required actions including verification that the enumerated colonies are not generic *E. coli*, implement the required series of repeat water tests (if preharvest intervals allow subsequent irrigations), or conducting pre-harvest pathogen testing of the field per the specified sampling scheme.

- It is our consensus opinion that the best program and standards would require the documentation of a minimal key set of process parameters and performance data collection for every irrigation event. In-use monitoring and documentation of Total Suspended Solids, turbidity, pH, flow rates, and antimicrobial dose at specified approximate timepoints during treatment. This minimal routine monitoring serves as the practical basis for review of system design assumptions and critical correlation assessments of microbial standards to explain and predict non-conformities in a self-established treatment process. In conjunction with this data capture for each irrigation event, monthly verification samples for analysis of Total Coliform bacteria before and after treatment should be required to provide broader condition-specific performance data for future review of the standards and guidance. These data are essential for

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strategic planning of future standards and requirements as well as to defend the program

5. At this time, it is our opinion that 21 days is the most defensible planned pre-harvest date for a requirement to use Type A water quality for direct contact with the edible portion of the crop based on the most recent open environment trials with qualified pathogen surrogates.
 - Current research projects are developing models which will likely be useful to reduce this protective mitigation to less than 21 days, with appropriate, site-specific measurements.
 - This 21-day time interval is necessary, at this time, to give time to develop confidence in systems performance under broader, than current, in-use experience with multiple systems and local water source variability. In part, this conservative approach reflects the uncertainties and imperfect root-cause explanations for the consecutive outbreaks and relationship between the findings of case-matched *E. coli* O157:H7 in water conveyance systems.