



**SUMMARY OF COMMENTS AND QUESTIONS
REGARDING PROPOSED CHANGES TO
THE CA LGMA-APPROVED GUIDELINES**

Topics Discussed:

Flooding

Romaine Testing and Data Analysis Program

Prepared by:

Western Growers

for the California Leafy Green Marketing Agreement

August 23, 2023



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BACKGROUND

Since the inception of the Leafy Green Handlers Marketing Agreement (LGMA), Western Growers (WG) has facilitated a systematic amendment process to update the LGMA-approved guidelines (also known as the LGMA metrics). On July 5, 2023, Western Growers opened a 30-day-comment period regarding best practices following flooding and a proposed preharvest romaine testing and data collection program for California (CA) LGMA members. Following the comment period, WG hosted a webinar on August 8, 2023, to share suggested changes and comments received and for stakeholders to discuss additional comments and questions regarding the proposed amendments.

WG received online proposals/comments from five parties (Arizona LGMA Technical Subcommittee, CALGMA Technical Committee, Gurmail Mudahar from Tamura & Antle, Channah Rock, University of Arizona in collaboration with Trevor Suslow, University of California, Davis, and Hilary Thesmar with Food Marketing Institute) via email and the www.leafygreenguidance.com website and several comments and questions during the August 8, 2023, webinar. The webinar was moderated by Sonia Salas, Western Growers and had 31 attendees, who are listed below in alphabetical order. This report was prepared with the assistance of iDecisionSciences, LLC.

Webinar Attendees:

Last Name	First Name	Company/Organization
Alfaro	Adriana	Food Marketing Institute
Besselman	Catherine	Aanika Biosciences, Inc.
Brooks	Amanda	Harrison Farms, Inc
Burr	Kate	Ocean Mist Farms
Callahan	Christopher	The University of Vermont
Carrillo	Jaime	Willoughby Farms, Inc
Clarke	Jennifer	California Leafy Greens Research Program
Cornejo	Henry	Western Growers Insurance Services
Davis	De Ann	Western Growers
Gilbert	Mandy	Creekside Organics, Inc
Gorny	Jim	U.S. Food and Drug Administration, Division of Produce Safety
Komar	Greg	LGMA California
Licata	Alyssa	LGMA California
Linares	Florencia	Talam Biotech
Lopez	Silvia	Fresh Del Monte
Lopez	Teressa	LGMA Arizona
Mehta	Vyom	Chipotle
Mudahar	Gurmail	Tanimura & Antle, Inc
Ortiz	Jose	D'Arrigo Bros Co of California
Padilla	Samuel	Pasquinelli Produce Company



Last Name	First Name	Company/Organization
Ramirez	Catalina	Beachside Produce, LLC
Reyes	Gustavo	University of Illinois
Reyes	Leticia	Fresh Express, Inc
Rios	German	Fresh Express, Inc
Rock	Channah	University of Arizona School of Plant Services
Smith	Michelle	U.S. Food and Drug Administration, Office of Food Safety
Stoeckel	Don	Cornell University Library
Thesmar	Hilary	Food Marketing Institute
Urbina	Mayra	Visionary Vegetables
Valdes	Francisco	Sabor Farms
Van Horn	Kami	Rousseau Farming Company
York	Tim	LGMA California

INTRODUCTION

The August 8th webinar offered background regarding the proposed changes and additions to the flooding section and the addition of a revised “test-and-learn” pre-harvest romaine data collection program for the CA LGMA members.

This report provides a summary of currently proposed amendments to assist the CA LGMA Technical Committee and the CA LGMA Board in finalizing their approval process. The full version of the original proposed changes is attached at the end of this report as Appendix I. Alternative versions with suggested edits are also included as Appendix II and III. Appendix IV contains a comment submitted by the Arizona LGMA Technical Subcommittee that affects a section not included in this round of amendments.

Please note that comments in quotes are written statements provided by the named individual(s) or entity that have been copied and pasted with only minor grammatical edits. Comments without quotes are summarized from recorded discussions during the webinar. Tracked changes (in blue) are included below to illustrate proposed amendments.

1.) PROPOSED REVISIONS to 12. ISSUE - FLOODING

Proposed revision #1 - Changes to “The Best Practices for Product That Has Come into Contact with Flood Water Are”:

Proponent: CA LGMA Staff

- See Table 5 for numerical criteria for lettuce and leafy greens production fields that have possibly come into contact with flood waters. ~~The Technical Basis Document (Appendix B) describes the process used to develop these metrics.~~

Rationale: This statement is unnecessary because it is applicable to the entire document and duplicates what is stated in the introduction.

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



Rationale: Not all equipment entering the field is harvesting equipment. "Field" equipment is more inclusive.

Comments:

Gurmail Mudahar: CPS research found very low likelihood of pathogens (<5%), so "reasonably likely to" is too strong wording and should be changed to "that may contain".

Proposed revision #2 – Bulleted items below are proposed changes made to Table 5:

Proponent: CA LGMA staff

- Allowable Harvest Distance from Flooding
 - Buffer and do not harvest any product within ~~30-100~~ ft. of the flooding.
 - Required buffer distance may be greater than ~~30-100~~ ft. based on risk analysis by foodsafety professional.
- Rationale – The basis for the ~~30-100~~ ft. distance is ~~due to the known potential for subsurface horizontal water movement and seepage that is not necessarily visible, is the turn-around distance for production equipment to prevent cross-contamination of non-flooded ground or produce.~~

Rationale: Based on lateral subsurface water movement in non-equilibrium conditions such as flooding and the known potential for seepage that is not necessarily visible.

Comments:

Channah Rock: "The 30 ft buffer distance to allow for turning of common field ground preparation, cultivation, and harvest equipment is not an adequate preventive and precautionary metric. One subject matter expert (SME) was in the field, "boots on the ground", taking head lettuce samples during the April 2006 flood when that practical decision was made. Several generations of such equipment have occurred since then. Despite suggestions to the contrary, subsurface lateral and preferential flow in cropland soils subject to flooding is a well-studied and documented discipline. The depth of an impeding clay layer strongly influences both lateral and vertical capillary flow under, particularly, extended flooding conditions. Additionally, from practical experience, it can be challenging to accurately define the leading edge of flood water across various ranch soil types and topographies. Clearly, site-specific conditions make this potential uncertain without extensive testing. Therefore, our simple suggestion is to extend this buffer area to a more protective distance." Additional verbal comment during webinar: She is concerned about how people determine the "leading edge" of a flooded area (i.e., it is difficult to determine) and how to buffer appropriately.

Trevor Suslow via Channah Rock: The setback of 30 ft was arbitrary and not protective enough - based on work in the field. 100 ft better reflects what is needed to avoid cross-contamination, but to address industry practical issues, the actual metric (x) could be $30 < x < 100$.

Gurmail Mudahar: "No evidence of water seepage upward against gravity. Buffer distance should stay 30 ft. Per hydrology science, due to gravitational force, water movement occurs downward. However, below soil surface at water table level (it is more than 100 ft deep in most flooded areas, it may travel horizontally at gradient level. Considering the non-flood area is higher than the flooded and is several hundred ft above water table, there is no chance that flooded water will contaminate surface soil further than flood line. Originally 30 ft buffer was implemented due to farm equipment movement, and there should not be any change from original 30 ft buffer." Additional verbal comment during webinar: This would affect fields where any kind of water (not just flooding) is running next to it. Also, this is only an issue for ground water (i.e., wells within 100 ft) and, because of contaminated water table, wells should be evaluated, but surface water should not be an issue (i.e., no interaction between surface and subsurface waters in flooding).



CA LGMA Technical Committee: Keep buffer at 30 ft. Additional comments during webinar provided by Greg Komar: What evidence/data was the increase from 30 to 100 ft based on?

Jose Ortiz (verbal comment provided during the webinar): Sampled (composite of 40 subsamples) a field that was flooded and got 2 positives at 30 days. Resampled for *E. coli* and *Salmonella* at the same locations in intervals of 1-5, 8-12, 12-18 inches from leading edge of flooding and got one positive at 1-5 inches. Did not find *E. coli* or any pathogens at locations greater than 5 inches from flooding leading edge, so does not understand the need for a 100 ft setback distance.

- Time Interval Before Planting Can Commence Following the Receding of Floodwaters:
- Appropriate soil testing can be used to shorten this period to ~~30-7~~ days prior to planting. This testing must be performed ~~a manner that accurately represents the production field and indicates soil levels of microorganisms lower than the recommended standards for processed compost in accordance with the sampling and testing requirements explained later in this section. Suitable representative samples should be collected for the entire area suspected to have been exposed to flooding. For additional guidance on appropriate soil sampling techniques, use the Soil Screening Guidance: Technical Background Document (US EPA 1996). Specifically, Part 4 provides guidance for site investigations. Reputable third-party environmental consultants or laboratories provide sampling services consistent with this guidance.~~
- ~~Appropriate mitigation and mitigation strategies are included in the text portion of the document.~~

Rationale: Changed to 7 days based on the die-off observed during 2023 post-flooding rapid response CPS project and to reflect the existence of the soil sampling and testing requirements as is being proposed. Last bullet deleted to reduce unnecessary language and simplify the text.

Comments:

Channah Rock: "The original wording provided as a recommendation to the guidance development process was a 7-day interval between chosen soil sampling dates if the initial test results failed to meet acceptance criteria. The intent of the 7 days waiting period was in relation to timing between successive sample collection events after flood waters had receded. We retain and reiterate the recommendation that samples should be collected no less than 7 days apart. An individual grower may choose to re-sample if multiple passes with ground-work equipment have been performed, but a seven-day waiting period is still prudent. As the proposed metric stands, it is recommended to modify the language to reflect current learnings from the CPS Rapid Response study that indicates a setback timing of 20 days once ground is sufficiently dry, and groundwork has commenced to initiate sampling."

Proposed revision #3 – The Best Practices for Product in Proximity to A Flooded Area, But Not Contacted by Flood Water Are:

Proponent: CA LGMA Staff

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

Rationale: In order to prevent cross-contamination, equipment must be sanitized as well as cleaned.

Comments: No comments were made regarding this change.

- To facilitate avoiding contaminated/adulterated produce, place markers identifying both the high-water line of the flooding and an interval ~~30-100~~ feet beyond this line. If ~~30-100~~ feet is not sufficient to prevent cross-contamination ~~while turning harvesting or other farm equipment in the field~~, use a greater appropriate



~~interval~~buffer distance. Take photographs of the area for documentation. Do not harvest product within the ~~30-100~~-foot buffer zone.

Rationale: Buffers are provided for protection from more than just turning equipment in the field. "Buffer distance" better describes what the 100 feet is used for and is consistent with the term "buffer zone" that is used in this bullet.

Comments: No comments were made regarding this change.

Proposed revision #4 – Bulleted items below are proposed changes to “The Best Practices for Formerly Flooded Production Ground Are:”

Proponent: CA LGMA Staff

- Evaluate the source of flood waters (e.g., drainage canal, river, irrigation canal, etc.) for potential significant upstream contributors of human pathogens at levels that pose a significant threat to human health. This may include testing of the flood water.

Rationale: Provides additional information to the directive to "evaluate the source of flood waters".

Comments: No comments were made regarding this change.

- Allow soils to dry sufficiently and be reworked prior to soil testing and/or planting subsequent crops on formerly flooded production ground.

Rationale: Reworking soil and allowing it to dry is important for both post-flood planting and soil testing.

Comments: No comments were made regarding this change.

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

Rationale: Unnecessary since the period is defined in the previous sentence as "at least 60 days".

Comments: No comments were made regarding this change.

- If flooding has occurred in the past on the property, soil clearance testing may be conducted prior to planting leafy greens. Soil testing may be used to shorten the clearance period to ~~30-7~~ days. If performed, testing must indicate negative for STEC and/or EHEC, E. coli O157:H7, and Salmonella and all samples must be ≤ 10 MPN/gram of soil for generic E. coli. soil levels of microorganisms lower than the standards for processed compost. Suitable representative samples should be collected for the entire area suspected to have been exposed to flooding

- Historical, baseline data from non-flooded soil testing may be used to support replanting in the event that generic E. coli acceptance criteria cannot be met.

- ~~• Sample previously flooded soil for the presence of microorganisms of significant public health concern or appropriate indicator microorganisms~~
- ~~• Evaluate the field history and crop selection on formerly flooded production ground.~~
- ~~• Assess the time interval between the flooding event, crop planting, and crop harvest. Comparative soil sample may be utilized to assess relative risk if significant reductions in indicator microorganisms have occurred within this time interval.~~
- ~~• Prevent cross-contamination by cleaning or sanitizing any equipment that may have contacted previously flooded soil (also see the section on Equipment-Facilitated Cross-Contamination above).~~



Rationale: Sub-bullet is recommended based on SME experience - some soil types have naturally higher E coli levels that may be above the 10 MPN requirement. Historical data can provide an alternative justification for high generic *E. coli* levels.

Comments:

Gurmail Mudahar: “*E. coli* O157:H7 should be removed as STEC/ EHEC are suggested as alternatives. Since soil is tested for STECs, and all pathogenic *E. coli* strains are tested, there is no need to test for indicator organisms including generic *E. coli*. It should be removed.”

CA LGMA Technical Committee: Use of “historical baseline data” is unnecessary since testing for generic *E. coli* is not required.

Proposed revision #5 – Addition of a new section, “The Best Practices for Soil Sampling and Testing Are:” (All blue-lettered language is part of this proposed change)

Proponent: CA LGMA Staff

Rationale: This soil sampling protocol and BPs are based on Channah Rock’s work conducting post-flooding soil sampling during the CPS-funded rapid response project. *E. coli* O157:H7 was added to the list of target organisms to provide greater flexibility for laboratory testing methods and practices.

[Microbial soil sampling can provide valuable information regarding relative risks; however, sampling by itself does not guarantee that crops grown within the formerly flooded production area will be free of the presence of human pathogens. The decision to plant, or replant ground that has been flooded, is a risk-based decision.](#)

[The soil sampling parameters below are considered reasonable acceptance criteria when testing previously flooded soil.](#)

- [Sample area: Samples shall be collected from the previously flooded area moving from most flooded to least flooded. If available, include at least 2 samples from a non-flood area within the contiguous ranch. See the sampling diagram \(Figure X\) below.](#)

Comments:

Gurmail Mudahar: “Describe difference between “most” and “least” flooded areas? It should be one language (i.e., flooded area) to avoid confusion.”

Channah Rock: “Samples should be focused with more samples collected from where flood waters entered or exited the field. Between the two sampling events (minimum 7 days), samples should be collected in different locations based on previous sampling data prioritizing areas where indicator organisms were elevated.”

- [Minimum number of samples per defined lot location: A minimum of 10 individual soil samples shall be collected from an individual lot.](#)

Comments:

Channah Rock: “It is recommended that a *minimum* of 20 samples for generic *E. coli*, and including a minimum of 10 of these samples, to be used in pathogen-targeting, be collected during each sampling event.”

- [Lot size: Lot size is determined by the grower based on field flooding, ability to work the ground, and future planting.](#)
- [Sample depth: Each soil sample shall be collected at a composite depth between 1 – 6 inches from the soil surface. It is important to maintain a consistent sampling depth across the defined lot.](#)

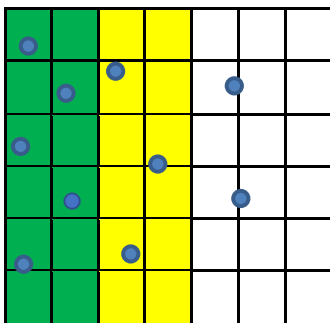
- [Sample weight: Sufficient soil weight shall be collected \(approximately 100 grams per sample\). Request the lab to analyze a minimum of 25 grams per target organism. Based on recent tests on flood-impacted soil, the surface-only nature of boot swab samples was shown to be less sensitive and, therefore, they are not acceptable for this purpose.](#)

Comments:

Channah Rock: "It is recommended that an approximate ≥ 100 -gram soil samples be collected from each unique sample location (taken from 2 to 6 inches below the soil surface). A sample location would consist of an approximate 9 ft sq area with 5 composited soil scoops/auger samples per location in an oversize bag/container to allow for mixing on-site. Reasonable effort should be made to hand mix the sample prior to sample submission. A total of 25 grams must be processed in the service laboratory for each of the 20 samples for generic *E. coli* and a separate 25 g may be removed from each of the 10 of the samples for pathogen-targets."

- [Sampling plan: Random sampling shall be conducted with more samples taken closer to the location where flood waters entered and exited the field and fewer samples from the buffer and non-flooded area.](#)

[Figure X. A sampling diagram outlining soil samples collected across a defined lot in a randomized pattern across vertical transects, with more samples collected closest to the flooded area \(green\) and fewer samples collected away from the flooded area \(white\).](#)



Green: Flooded area

Yellow: Buffer (100 ft from water mark)

White: Non-flooded area (>100 ft from water mark)

● = Approximate 100-gram sample

Comments:

Gurmail Mudahar: "Non flooded area sampling should be removed as there is no evidence that areas next to flood are contaminated. Fig X needs to be removed... Non flooded areas should not be included in sampling. There is no scientific evidence of flood water seepage upwards. See my hydrology comments in previous section."

Jose Ortiz (verbal comment provided during the webinar): Diagram recommends sampling up to 200 ft (100 ft buffer + 100 ft non-flooded area) away from flooded area; potentially implicates product up to 200 ft. from flooded area, esp. with composite sampling.

- [Testing frequency: Minimum one sampling event.](#)



- [Timing: The initial sampling event shall be conducted at least 7 days after flood waters have receded. It is important to note that because of flooded ground saturation, the use of tractors and other implements may take longer than 7 days post-water receding.](#)
- [Subsequent sampling events may be conducted until results indicate the acceptance criteria below have been achieved.](#)
- [Until these metrics are met, all equipment passing through the flood-impacted areas must be cleaned and sanitized before entering non-flooded areas.](#)

Comments:

Channah Rock: "It is recommended that a minimum of two sampling events within the identified flood-impacted area would be used to benchmark and more effectively screen for evidence of target foodborne pathogen contamination."

- [Target organisms:](#)
 - [Generic *E. coli*](#)
 - [Salmonella](#)
 - [E. coli O157:H7](#)
 - [STEC and/or EHEC](#)

Comments:

Gurmail Mudahar: "Since STECs are tested, there is no need of testing an indicator organism including Generic *E. coli*."

CA LGMA Technical Committee: "Remove generic *E. coli* to simplify testing requirements by removing fecal indicator testing and just test for pathogens." Additional comments during webinar provided by Greg Komar: What is the value of testing for both fecal indicator bacteria and pathogens? Seeking to simplify requirements.

AZ LGMA Technical Subcommittee (TSC): "After the California flooding events of 2022-2023 a thorough review of the current metrics was warranted. The TSC is supportive of data driven changes to this section. However, the TSC has not been provided with the research data that supports the changes presented and would like more information on how these recommendations were determined. Additional information will provide the TSC the information needed to determine whether the changes are appropriate for the Arizona growing regions. Additionally, we are unaware if research or data exists with regard to generic *E. coli* levels in Arizona soils and would like time to review what levels are appropriate for these soils."

Channah Rock: Regarding "the use of indicator organisms: Given the minimal samples that are being proposed, it is suggested that, at this time, generic *E. coli* prevalence and distribution be utilized as the less costly and viable option for evaluating flood-related fecal loading of cropland soil in comparison to direct pathogen testing alone. Though variable as compared to some pathogens, evidence of die-off of generic *E. coli* may be useful in decision-making in combination with results from pathogen testing within specific areas of flooded soils to guide future pathogen test samplings. The purpose of generic *E. coli* testing is not to draw correlations to specific expectations for pathogen die-off. Due to a more likely prevalence, it is suggested that standards be adopted in such a manner as to encourage industry to map broader lot-defined areas to prioritize pathogen testing and record quantitative evidence of die-off timing. The SME's recommend that acceptance criteria of a SSM of < 10 MPN/gram for generic *E. coli* for 20 independent soil samples and non-detect outcomes for all 10, or greater, independent soil samples for pathogen targets." Additional verbal comments during webinar: Fecal indicator bacteria (FIB) do not align 100% with pathogens; however, FIB capture the variability we see in soils across a specific area or lot. FIB can potentially help you to see a reduction in bacteria over time. Because FIB populations correlate with soil



moisture, population data can help highlight or point to areas of the field that require more work (i.e., increased mitigation efforts).

Jose Ortiz (verbal comment provided during the webinar): Test results take longer for STEC than for *Salmonella* and *E. coli* O157:H7; should be limited to *Salmonella* & O157.

Anonymous (written in Q&A during webinar): AZ needs info on generic *E. coli* levels in soil to support generic *E. coli* testing.

- Acceptance criteria for sample set (sampling event):

- Generic *E. coli*: All 10 samples <10 MPN or CFU/gram of soil*
- *Salmonella*: Negative or non-detect
- *E. coli* O157:H7: Negative or non-detect
- STEC or EHEC: Negative or non-detect

- Results:

- If you meet the acceptance criteria, planting can commence.
- If you do not meet the acceptance criteria:
 - Consider conducting additional groundwork with the use of tractors and implements to turn the soil to encourage drying out and aeration.
 - Repeat sampling and testing until the criteria have been met or you have reached 60 days from when the water has receded from the ranch.
 - Perform enhanced pre-harvest product testing per Western Growers' Appendix C: Sampling and Testing Protocol at the sample location of the failure when generic *E. coli* acceptability criteria is not met.

Comments:

Gurmail Mudahar: "This option should be removed as this is contradicting 60 days rule."

*_Historical baseline data from non-flooded soil testing may be used in lieu of pre-harvest product testing to support replanting in the event that generic *E. coli* acceptance criteria cannot be met.

Comments:

CA LGMA Technical Committee: "Simplifying testing requirements by removing testing for fecal indicators and just testing for pathogens."

Gurmail Mudahar: "Soil testing is not done on regular basis. This comment is not clear. This comment should be removed."



2.) PROPOSED REVISIONS: Addition of 17. ROMAINE TESTING AND DATA ANALYSIS PROGRAM

Proponent: CA LGMA Staff

17. ROMAINE TESTING AND DATA ANALYSIS PROGRAM

The purpose of a standardized romaine testing program is to enable the leafy greens industry to learn from personal and aggregated data, which contributes to industry knowledge and verifies that current food safety programs are adequate. The goal of this project is to collect and analyze data along with other potential key learnings from standardized romaine testing for a 2-year period.

LGMA handlers who test their romaine will report those test results using the approved database. Only romaine that is currently being tested, such as for customer and/or regulatory requirements, internal company policies, etc., must be submitted. No additional romaine is required to be tested if a handler member does not have a testing policy in place.

The Best Practices for Sampling and Testing Are:

Sampling and testing parameters are as follows:

- Data sources: Current romaine test results
- Timeline: 2 consecutive years from program start date
- Sampling timeline: <10 days for pre-harvest or <24 hours for post-harvest samples
- Test organisms: STEC and/or EHEC, *E. coli* O157:H7, *Salmonella*
- Sampling lot size: <10 acres for both a pre-harvested product and/or a company-defined post-harvest product lot for product sampled at any step prior to, but not including processing.
- Sample size: Minimum 375 g from n = 60 sub-samples *
- Sampling method: Randomized sampling within a designated lot

*The entire 375-gram sample must be analyzed by the laboratory.

The Best Practices for Data Reporting and Analysis Are:

California LGMA members will submit data on a quarterly basis in excel format including the following information:

- Acres sampled; cartons sampled
- Sampling stage (pre-harvest or post-harvest) **
- Commodity and field-packed description (romaine, romaine hearts, top and tail, etc.) †
- Sampling region (District 1-Salinas/Watsonville/San Joaquin Valley, Kern County, District 2-Oxnard/Santa Maria or District 3-Blythe/Imperial Valley)
- Sample date
- Organism tested (STEC and/or EHEC, *E. coli* O157:H7, *Salmonella*)
- Test result (molecular or cultural confirmed positive)

**Note: pre-harvest and post-harvest data will be analyzed separately

†Baby romaine is not included.



Rationale: The program is structured to move the industry to a standardized protocol and practice for submitting and analyzing aggregated industry data. The quarterly reporting time frame is practical for the industry in the pilot program.

Based on industry survey of preharvest product testing, approximately 90% of survey respondents are conducting testing as depicted in the proposed parameters.

Comments:

AZ LGMA Technical Subcommittee: "...while we feel data can inform decisions moving forward, we stand by our comments made previously (prefer a research approach based on environmental hazard and risk assessment) and as recent as February 14th, 2023. Arizona LGMA would like to ask that the CA LGMA metric changes include a pre-harvest testing policy as was revised in Version 15 of the Arizona LGMA metrics to help continue alignment between the two LGMA programs. This would require that a Standard Operating Procedure (SOP) be developed to address conducting any pre- or post-harvest testing."

- Pre-harvest product testing is required when environmental risk assessments deem it is necessary.
- Develop a pre-harvest testing SOP. When deciding on sampling plans, see Appendix C for sampling plan options and recommendations. The SOP must address the following minimum requirements:
 - All lettuce and leafy green commodities. If testing programs differ by commodity, outline in the SOP.
 - Sampling timeline. An interval closer to estimated harvest date is considered a best practice.
 - Target organisms. Test for E. coli O157:H7, STEC/EHEC, and Salmonella.
 - Sampling lot size. Sampling lot size may decrease when risk is elevated.
 - Sample size.
 - Number of grabs. More individual grabs per lot improves the probability of contamination detection.
 - Sampling method. Laboratories used for analytical parameters must be certified and/or accredited by recognized State, Federal, or international bodies (ISO) for the analytical methods being reported and the matrices being analyzed.
 - Risk considerations, including when a sampling plan should be more stringent based on the identified risk.
 - Develop a test and hold policy.
 - Corrective measures to be taken when positive samples are detected.
 - Records review and documentation
- Samples must be taken by a trained sampler. If utilizing in-house samplers, implement mandatory training on the sampling protocol for personnel conducting pre-harvest product testing.
 - If a positive test result is reported, do not harvest the sampling lot. Determine if further investigation and root cause analysis (RCA) is of value based on observations and elective follow-up sampling. Utilize industry guidance¹ on how to evaluate the value of and conduct RCA activities.

Last year the AZLGMA Technical Subcommittee and the Executive Committee approved adding additional training requirements around personnel conducting environmental assessments in the field. Comment has been provided in the interest of aligning AZ and CA LGMA requirements: "To further address alignment of the LGMA's we recommend that CA LGMA adopt training requirement for individuals conducting environmental hazard and risk assessments." The following language from AZLGMA's leafy green guidance document, *4. Personnel Qualifications and Training*, is provided for consideration.

- For personnel conducting environmental hazard and risk assessments, training must be completed, and the training program must address the following minimum requirements:



- When an environmental hazard or risk assessment should be completed.
- How to conduct an environmental hazard or risk assessment.
- Potential hazard and risk identification.
- Recognizing product that may be contaminated with known or reasonably foreseeable hazards.
- Mitigations and corrective actions.
- When an environmental hazard or risk assessment deems pre-harvest product testing is necessary.

General comment for all proposed revisions:

Hilary Thesmar - "Food Marketing Institute on behalf of our retail, wholesale and product supplier members support the changes made to the commodity specific food safety guidelines. This is an important step forward and we encourage Western Growers and LGMA to continue to advance the food safety guidelines as we learn more about preventing contamination during production, harvesting, processing, storage and distribution."

Poll Report

Q1). In addition to today's comments on the CA LGMA proposed changes related to flooding best practices, should other issues be considered? If yes, please send us a specific suggestion via the Q&A box.

A1). Yes = 4, No = 10

Q2). In general, do you agree with the CA LGMA proposal to add a new section on requirements to share existing product testing data? If no, please provide a clear explanation via the Q&A box

A2). Yes = 11, No = 4

The poll results suggest general support to add a new section on requirements to share existing product testing data as well as to include proposed changes to the flooding best practices section of the CA -LGMA approved metrics.



APPENDIX I: THE ORIGINAL REVISIONS PROPOSED by CALGMA STAFF

12. ISSUE: FLOODING

Flooding for purposes of this document is defined as the flowing or overflowing of a field with water outside of a grower's control, that is reasonably likely to contain microorganisms of significant public health concern and is reasonably likely to cause adulteration of the edible portions of fresh produce in that field. Pooled water (e.g., rainfall) that is not reasonably likely to contain microorganisms of significant public health concern and is not reasonably likely to cause adulteration of the edible portion of fresh produce should not be considered flooding. If flood waters contain microorganisms of significant public health concern, crops in close proximity to soil such as lettuce/leafy greens may be contaminated if there is direct contact between flood water or contaminated soil and the edible portions of lettuce/leafy greens (Wachtel et al. 2002a; 2002b).

In the November 4, 2005, FDA "Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce/leafy greens," the agency stated that it considers ready-to-eat crops (such as lettuce/leafy greens) that have been in contact with flood waters to be adulterated due to potential exposure to sewage, animal waste, heavy metals, pathogenic microorganisms, or other contaminants. The FDA is not aware of any method of reconditioning these crops that will provide a reasonable assurance of safety for human food use or otherwise bring them into compliance with the law. Therefore, the FDA recommends that such crops be excluded from the human food supply and disposed of in a manner that ensures they do not contaminate unaffected crops during harvesting, storage or distribution. "Adulterated food may be subject to seizure under the Federal Food, Drug, and Cosmetic Act, and those responsible for its introduction or delivery for introduction into interstate commerce may be enjoined from continuing to do so or prosecuted for having done so. Food produced under unsanitary conditions whereby it may be rendered injurious to health is adulterated under § 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a) (4)); (US FDA 2004).

Areas that have been flooded can be separated into three groups: 1) product that has come into contact with flood water, 2) product that is in proximity to a flooded field but has not been contacted by flood water, and 3) production ground that was partially or completely flooded in the past before a crop was planted. The considerations for each situation are described below and presented in Table 5.

The Best Practices for Product That Has Come into Contact with Flood Water Are:

- See Table 5 for numerical criteria for lettuce and leafy greens production fields that have possibly come into contact with flood waters. [The Technical Basis Document \(Appendix B\) describes the process used to develop these metrics.](#)
- FDA considers any crop that has come into contact with floodwater to be an "adulterated" commodity that cannot be sold for human consumption.
- To reduce the potential for cross-contamination do not drive [harvest-field](#) equipment through flooded areas reasonably likely to contain microorganisms of public health significance (see previous section).



TABLE 5. Flooding – When evidence of flooding in a production block occurs.

Practice	Metric/Rationale
Flooding Defined	The flowing or overflowing of a field with water outside a grower’s control that is reasonably likely to contain microorganisms of significant public health concern and is reasonably likely to cause adulteration of edible portions of fresh produce in that field. Additional discussion of this definition and implications for production is provided in the text portion of this document.
Allowable Harvest Distance from Flooding	<ul style="list-style-type: none"> • Buffer and do not harvest any product within 30-100 ft. of the flooding. • Required buffer distance may be greater than 30-100 ft. based on risk analysis by foodsafety professional. • If there is evidence of flooding, the production block must undergo a detailed food safety assessment by appropriately trained food safety personnel (see Glossary) prior to harvest, as defined in the text of this document.
Verification	<ul style="list-style-type: none"> • Documentation must be archived for a period of two years following the flooding event. Documentation may include photographs, sketched maps, or other means of delineating affected portions of production fields.
Time Interval Before Planting Can Commence Following the Receding of Floodwaters	<ul style="list-style-type: none"> • 60 days prior to planting provided that the soil has sufficient time to dry out. • Appropriate soil testing can be used to shorten this period to 30-7 days prior to planting. This testing must be performed a manner that accurately represents the production field and indicates soil levels of microorganisms lower than the recommended standards for processed compost in accordance to with the sampling and testing requirements explained later in this section. Suitable representative samples should be collected for the entire area suspected to have been exposed to flooding. For additional guidance on appropriate soil sampling techniques, use the Soil Screening Guidance: Technical Background Document (US EPA 1996). Specifically, Part 4 provides guidance for site investigations. Reputable third-party environmental consultants or laboratories provide sampling services consistent with this guidance. • Appropriate mitigation and mitigation strategies are included in the text portion of the document.
Rationale	<ul style="list-style-type: none"> • The basis for the 30-100 ft. distance is due to the known potential for subsurface horizontal water movement and seepage that is not necessarily visible, is the turn around distance for production equipment to prevent cross-contamination of non-flooded ground or produce.

The Best Practices for Product in Proximity to A Flooded Area, But Not Contacted by Flood Water Are:

- Prevent cross-contamination between flooded and non-flooded areas (e.g., cleaning ~~and sanitizing~~ equipment, eliminating contact of any farming or harvesting equipment or personnel with the flooded area during growth and harvest of non-flooded areas).
- To facilitate avoiding contaminated/adulterated produce, place markers identifying both the high-water line of the flooding and an interval ~~30-100~~ feet beyond this line. If ~~30-100~~ feet is not sufficient to prevent cross-contamination ~~while turning harvesting or other farm equipment in the field,~~ use a greater appropriate ~~interval~~ ~~buffer distance~~. Take photographs of the area for documentation. Do not harvest product within the ~~30-100~~-foot buffer zone.



The Best Practices for Formerly Flooded Production Ground Are:

- Prior to replanting or soil testing, the designated food safety professional for the grower shall perform a detailed food safety assessment of the production field. This designated professional will be responsible for assessing the relative merits of testing versus observing the appropriate time interval for planting and will also coordinate any soil testing plan with appropriate third-party consultants and/or laboratories that have experience in this type of testing.
- Evaluate the source of flood waters (e.g., drainage canal, river, irrigation canal, etc.) for potential significant upstream contributors of human pathogens at levels that pose a significant threat to human health. [This may include testing of the flood water.](#)
- Allow soils to dry sufficiently and be reworked prior to [soil testing and/or](#) planting subsequent crops on formerly flooded production ground.
- Do not replant formerly flooded production ground for at least 60 days following the receding of floodwaters. This period ~~or longer~~ and active tillage of the soil provide additional protection against the survival of pathogenic organisms.
- If flooding has occurred in the past on the property, soil clearance testing may be conducted prior to planting leafy greens. Soil testing may be used to shorten the clearance period to ~~30-7~~ days. If performed, testing must indicate [negative for STEC and/or EHEC, E. coli O157:H7, and Salmonella and all samples must be ≤ 10 MPN/gram of soil for generic E. coli. Soil levels of microorganisms lower than the standards for processed compost. Suitable representative samples should be collected for the entire area suspected to have been exposed to flooding](#)
 - [Historical, baseline data from non-flooded soil testing may be used to support replanting in the event that generic E. coli acceptance criteria cannot be met.](#)
- ~~Sample previously flooded soil for the presence of microorganisms of significant public health concern or appropriate indicator microorganisms.~~
- ~~Evaluate the field history and crop selection on formerly flooded production ground.~~
- ~~Assess the time interval between the flooding event, crop planting, and crop harvest. Comparative soil sample may be utilized to assess relative risk if significant reductions in indicator microorganisms have occurred within this time interval.~~
- ~~Prevent cross-contamination by cleaning or sanitizing any equipment that may have contacted previously flooded soil (also see the section on Equipment Facilitated Cross-Contamination above).~~

The Best Practices for Soil Sampling and Testing Are:

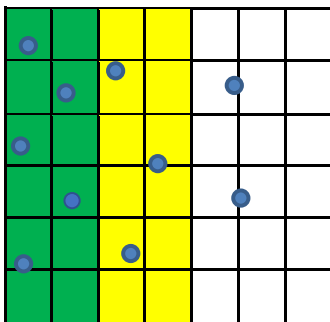
[Microbial soil sampling can provide valuable information regarding relative risks; however, sampling by itself does not guarantee that crops grown within the formerly flooded production area will be free of the presence of human pathogens. The decision to plant, or replant ground that has been flooded, is a risk-based decision.](#)

[The soil sampling parameters below are considered reasonable acceptance criteria when testing previously flooded soil.](#)



- Sample area: Samples shall be collected from the previously flooded area moving from most flooded to least flooded. If available, include at least 2 samples from a non-flood area within the contiguous ranch. See the sampling diagram (Figure X) below.
- Minimum number of samples per defined lot location: A minimum of 10 individual soil samples shall be collected from an individual lot.
- Lot size: Lot size is determined by the grower based on field flooding, ability to work the ground, and future planting.
- Sample depth: Each soil sample shall be collected at a composite depth between 1 – 6 inches from the soil surface. It is important to maintain a consistent sampling depth across the defined lot.
- Sample weight: Sufficient soil weight shall be collected (approximately 100 grams per sample). Request the lab to analyze a minimum of 25 grams per target organism. Based on recent tests on flood-impacted soil, the surface-only nature of boot swab samples was shown to be less sensitive and, therefore, they are not acceptable for this purpose.
- Sampling plan: Random sampling shall be conducted with more samples taken closer to the location where flood waters entered and exited the field and fewer samples from the buffer and non-flooded area.

Figure X. A sampling diagram outlining soil samples collected across a defined lot in a randomized pattern across vertical transects, with more samples collected closest to the flooded area (green) and fewer samples collected away from the flooded area (white).



Green: Flooded area
 Yellow: Buffer (100 ft from water mark)
 White: Non-flooded area (>100 ft from water mark)
 ● = Approximate 100-gram sample

- Testing frequency: Minimum one sampling event.
- Timing: The initial sampling event shall be conducted at least 7 days after flood waters have receded. It is important to note that because of flooded ground saturation, the use of tractors and other implements may take longer than 7 days post-water receding.
- Subsequent sampling events may be conducted until results indicate the acceptance criteria below have been achieved.
- Until these metrics are met, all equipment passing through the flood-impacted areas must be cleaned and sanitized before entering non-flooded areas.
- Target organisms:



- [Generic *E. coli*](#)
- [Salmonella](#)
- [E. coli O157:H7](#)
- [STEC and/or EHEC](#)
- [Acceptance criteria for sample set \(sampling event\):](#)
 - [Generic *E. coli*: All 10 samples <10 MPN or CFU/gram of soil*](#)
 - [Salmonella: Negative or non-detect](#)
 - [E. coli O157:H7: Negative or non-detect](#)
 - [STEC or EHEC: Negative or non-detect](#)
- [Results:](#)
 - [If you meet the acceptance criteria, planting can commence.](#)
 - [If you do not meet the acceptance criteria:](#)
 - [Consider conducting additional groundwork with the use of tractors and implements to turn the soil to encourage drying out and aeration.](#)
 - [Repeat sampling and testing until the criteria have been met or you have reached 60 days from when the water has receded from the ranch.](#)
 - [Perform enhanced pre-harvest product testing per Western Growers' Appendix C: Sampling and Testing Protocol at the sample location of the failure when generic *E. coli* acceptability criteria is not met.](#)

* [Historical baseline data from non-flooded soil testing may be used in lieu of pre-harvest product testing to support replanting in the event that generic *E. coli* acceptance criteria cannot be met.](#)

17. ROMAINE TESTING AND DATA ANALYSIS PROGRAM

[The purpose of a standardized romaine testing program is to enable the leafy greens industry to learn from personal and aggregated data, which contributes to industry knowledge and verifies that current food safety programs are adequate. The goal of this project is to collect and analyze data along with other potential key learnings from standardized romaine testing for a 2-year period.](#)

[LGMA handlers who test their romaine will report those test results using the approved database. Only romaine that is currently being tested, such as for customer and/or regulatory requirements, internal company policies, etc., must be submitted. No additional romaine is required to be tested if a handler member does not have a testing policy in place.](#)

The Best Practices for Sampling and Testing Are:

[Sampling and testing parameters are as follows:](#)

- [Data sources:](#) [Current romaine test results](#)
- [Timeline:](#) [2 consecutive years from program start date](#)
- [Sampling timeline:](#) [≤10 days for pre-harvest or <24 hours for post-harvest samples](#)
- [Test organisms:](#) [STEC and/or EHEC, E. coli O157:H7, Salmonella](#)



- Sampling lot size: ≤ 10 acres for both a pre-harvested product and/or a company-defined post-harvest product lot for product sampled at any step prior to, but not including processing.
- Sample size: Minimum 375 g from $n = 60$ sub-samples *
- Sampling method: Randomized sampling within a designated lot

*The entire 375-gram sample must be analyzed by the laboratory.

The Best Practices for Data Reporting and Analysis Are:

California LGMA members will submit data on a quarterly basis in excel format including the following information:

- Acres sampled; cartons sampled
- Sampling stage (pre-harvest or post-harvest) **
- Commodity and field-packed description (romaine, romaine hearts, top and tail, etc.) †
- Sampling region (District 1-Salinas/Watsonville/San Joaquin Valley, Kern County, District 2-Oxnard/Santa Maria or District 3-Blythe/Imperial Valley)
- Sample date
- Organism tested (STEC and/or EHEC, *E. coli* O157:H7, *Salmonella*)
- Test result (molecular or cultural confirmed positive)

**Note: pre-harvest and post-harvest data will be analyzed separately

†Baby romaine is not included.



APPENDIX II: REVISIONS TO THE ORIGINAL PROPOSAL by CHANNAH ROCK and TREVOR SUSLOW

TABLE 5. Flooding – When evidence of flooding in a production block occurs.

Practice	Metric/Rationale
Flooding Defined	The flowing or overflowing of a field with water outside a grower’s control that is reasonably likely to contain microorganisms of significant public health concern and is reasonably likely to cause adulteration of edible portions of fresh produce in that field. Additional discussion of this definition and implications for production is provided in the text portion of this document.
Allowable Harvest Distance from Flooding	<ul style="list-style-type: none"> • Buffer and do not harvest any product within 30-50 ft. of the flooding. • Required buffer distance may be greater than 30-50 ft. based on risk analysis by food safety professional. • If there is evidence of flooding, the production block must undergo a detailed food safety assessment by appropriately trained food safety personnel (see Glossary) prior to harvest, as defined in the text of this document.
Verification	<ul style="list-style-type: none"> • Documentation must be archived for a period of two years following the flooding event. Documentation may include photographs, sketched maps, or other means of delineating affected portions of production fields.
Time Interval Before Planting Can Commence Following the Receding of Floodwaters	<ul style="list-style-type: none"> • 60 days prior to planting provided that the soil has sufficient time to dry out. • Appropriate soil testing can be used to shorten this period to 30-20 days prior to planting. This testing must be performed in accordance with the sampling and testing requirements explained later in this section.
Rationale	<ul style="list-style-type: none"> • The basis for the 30-50 ft. distance is due to the known potential for subsurface horizontal water movement and seepage that is not necessarily visible.

Commented [RC1]: Buffer Distances from the visible flood transition zone:
 The 30 ft buffer distance to allow for turning of common field ground preparation, cultivation, and harvest equipment was never an adequate preventive and precautionary metric. One SME was in the field, “boots on the ground”, taking head lettuce samples during the April 2006 Flood when that practical decision was made. Several generations of such equipment have occurred since then. Despite suggestions to the contrary, subsurface lateral and preferential flow in cropland soils subject to flooding is a well-studied and documented discipline. The depth of an impeding clay layer strongly influences both lateral and vertical capillary flow under, particularly, extended flooding conditions. Additionally, from practical experience, it can be challenging to accurately define the leading edge of flood water across various ranch soil types and topographies. Clearly, site-specific conditions make this potential uncertain without extensive testing. Therefore, our simple suggestion is to extend this buffer area to a more protective distance.

Commented [SL2]: Channah: TVS - setback of 30 ft was arbitrary; based on work in the field, 100 ft better reflects what is needed to avoid cross-contamination, but the actual metric could be 30<X<100

The Best Practices for Product in Proximity to A Flooded Area, But Not Contacted by Flood Water Are:

- Prevent cross-contamination between flooded and non-flooded areas (e.g., cleaning and sanitizing equipment, eliminating contact of any farming or harvesting equipment or personnel with the flooded area during growth and harvest of non-flooded areas).
- To facilitate avoiding contaminated/adulterated produce, place markers identifying both the high-water line of the flooding and an interval ~~30-50~~ feet beyond this line. If ~~30-50~~ feet is not sufficient to prevent cross-contamination use a greater appropriate buffer distance. Take photographs of the area for documentation. Do not harvest product within the ~~30-50~~-foot buffer zone.

The Best Practices for Formerly Flooded Production Ground Are:

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



- Evaluate the source of flood waters (e.g., drainage canal, river, irrigation canal, etc.) for potential significant upstream contributors of human pathogens at levels that pose a significant threat to human health. This may include testing of the flood water.
- Allow soils to dry sufficiently and be reworked prior to soil testing and/or planting subsequent crops on formerly flooded production ground.
- Do not replant formerly flooded production ground for at least 60 days following the receding of floodwaters. This period and active tillage of the soil provide additional protection against the survival of pathogenic organisms.
- If flooding has occurred in the past on the property, soil clearance testing may be conducted prior to planting leafy greens. Soil testing may be used to shorten the clearance period to 30-7-20 days. If performed, testing must indicate negative for STEC and/or EHEC, *E. coli* O157:H7, and *Salmonella* and all samples must be ≤ 10 MPN/gram of soil for generic *E. coli*.
 - Historical, baseline data from non-flooded soil testing may be used to support replanting in the event that generic *E. coli* acceptance criteria cannot be met.

Commented [RC(3)]: Comment on a universal 7-day pre-sampling interval:
 The original wording provided as a recommendation to the guidance development process was a 7-day interval between chosen soil sampling dates if the initial test results failed to meet acceptance criteria. The intent of the 7 days waiting period was in relation to timing between successive sample collection events after flood waters had receded. We retain and reiterate the recommendation that samples should be collected no less than 7 days apart. An individual grower may choose to re-sample if multiple passes with ground-work equipment have been performed, but a seven-day waiting period is still prudent. As the proposed metric stands, it is recommended to modify the language to reflect current learnings from the CPS Rapid Response study that indicates a setback timing of 20 days once ground is sufficiently dry, and groundwork has commenced to initiate sampling.

The Best Practices for Soil Sampling and Testing Are:

Microbial soil sampling can provide valuable information regarding relative risks; however, sampling by itself does not guarantee that crops grown within the formerly flooded production area will be free of the presence of human pathogens. The decision to plant, or replant ground that has been flooded, is a risk-based decision.

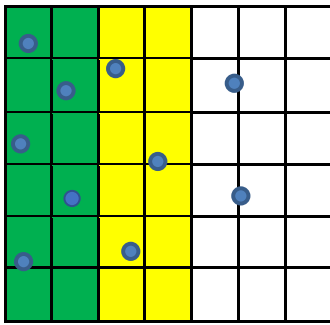
The soil sampling parameters below are considered reasonable acceptance criteria when testing previously flooded soil.

- Sample area: Samples shall be collected from the previously flooded area moving from most flooded to least flooded. If available (depending on gradient of the slope of the adjacent fields e.g., if the gradient is steep, there may be no impacts of flooding), include at least 2 samples from a non-flood area within the contiguous ranch as a baseline control. See the sampling diagram (Figure X) below.
- Minimum number of samples per defined lot location: Per sampling event, collect a minimum of 40-20 individual soil samples to be tested for generic E. coli with 10 of these samples tested for pathogen targets shall be collected from an individual lot.
- Lot size: Lot size is determined by the grower based on field flooding, ability to work the ground, and future planting.
- Sample depth: Each soil sample shall be collected at a composite depth between 4-6 inches from the soil surface. It is important to maintain a consistent sampling depth across the defined lot.
- Sample weight: Sufficient soil weight shall be collected (approximately ≥ 100 grams per sample). Request the lab to analyze a minimum of 25 grams per target organism. Based on recent tests on flood-impacted soil, the surface-only nature of boot swab samples was shown to be less sensitive and, therefore, they are not acceptable for this purpose.
- Sampling plan: Random sampling shall be conducted with more samples taken closer to the location where flood waters entered and exited the field and fewer samples from the buffer and non-flooded area. Composite samples in an oversize bag/container to allow for mixing on-site. A reasonable effort should be made to hand mix the sample prior to sample submission.

Commented [RC(4)]: Number of samples:
 It is recommended that a minimum of 20 samples for generic *E. coli*, and including a minimum of 10 of these samples, to be used in pathogen-targeting, be collected during each sampling event.

Commented [RC(5)]: Weight of samples
 It is recommended that an approximate ≥ 100 -gram soil samples be collected from each unique sample location (taken from 2 to 6 inches below the soil surface). A sample location would consist of an approximate 9ft sq area with 5 composited soil scoops/auger samples per location in an oversize bag/container to allow for mixing on-site. Reasonable effort should be made to hand mix the sample prior to sample submission. A total of 25 grams must be processed in the service laboratory for each of the 20 samples for generic *E. coli* and a separate 25 g may be removed from each of the 10 of the samples for pathogen-targets.

Figure X. A sampling diagram outlining soil samples collected across a defined lot in a randomized pattern across vertical transects, with more samples collected closest to the flooded area (green) and fewer samples collected away from the flooded area (white).



Green: Flooded area
 Yellow: Buffer (100 ft from water mark)
 White: Non-flooded area (>100 ft from water mark)
 ● = Approximate 100-gram sample

- **Testing frequency:** Minimum ~~one~~ **two** sampling events **separated by a minimum of 7 days.**
- **Timing:** The initial sampling event shall be conducted at least ~~7~~ **20** days after flood waters have receded. It is important to note that because of flooded ground saturation, the use of tractors and other implements may take longer than ~~7~~ **20** days post-water receding.
- **After the initial sampling event, all** ~~subsequent~~ **subsequent** sampling events **may shall** be conducted **at > 7-day intervals** until results indicate the acceptance criteria below have been achieved.
- Until these metrics are met, all equipment passing through the flood-impacted areas must be cleaned and sanitized before entering non-flooded areas.
- Target organisms:
 - Generic *E. coli*
 - *Salmonella*
 - *E. coli* O157:H7
 - STEC and/or EHEC
- Acceptance criteria for sample set (**per each** sampling event):
 - Generic *E. coli*: All ~~1~~ **20** samples ≤ 10 MPN or CFU/gram of soil*
 - *Salmonella*: Negative or non-detect
 - *E. coli* O157:H7: Negative or non-detect
 - STEC or EHEC: Negative or non-detect
- Results:
 - If you meet the acceptance criteria, planting can commence.
 - If you do not meet the acceptance criteria:
 - Consider conducting additional groundwork with the use of tractors and implements to turn the soil to encourage drying out and aeration.
 - Repeat sampling and testing until the criteria have been met or you have reached 60 days from when the water has receded from the ranch.

Commented [RC(6): Timing of sample collection:
 It is recommended that a minimum of two sampling events within the identified flood-impacted area would be used to benchmark and more effectively screen for evidence of target foodborne pathogen contamination. Between the two sampling events (minimum 7 days), samples should be collected in different locations based on previous sampling data prioritizing areas where indicator organisms were elevated.

Commented [RC(7): The original wording provided as a recommendation to the guidance development process was a 7-day interval between chosen soil sampling dates if the initial test results failed to meet acceptance criteria. The intent of the 7 days waiting period was in relation to timing between successive sample collection events after flood waters had receded. We retain and reiterate the recommendation that samples should be collected no less than 7 days apart. An individual grower may choose to re-sample if multiple passes with ground-work equipment have been performed, but a seven-day waiting period is still prudent.

Commented [RC(8): Comment on the use of indicator organisms:
 Given the minimal samples that are being proposed, it is suggested that, at this time, generic *E. coli* prevalence and distribution be utilized as the less costly and viable option for evaluating flood-related fecal loading of cropland soil in comparison to direct pathogen testing alone. Though variable as compared to some pathogens, evidence of die-off of generic *E. coli* may be useful in decision-making in combination with results from pathogen testing within specific areas of flooded soils to guide future pathogen test samplings. The purpose of generic *E. coli* testing is not to draw correlations to specific expectations for pathogen die-off. Due to a more likely prevalence, it is suggested that standards be adopted in such a manner as to encourage industry to map broader lot-defined areas to prioritize pathogen testing and record quantitative evidence of die-off timing. The SME's recommend that acceptance criteria of a SSM of ≤ 10 MPN/gram for generic *E. coli* for 20 independent soil samples and non-detect outcomes for all 10, or greater, independent soil samples for pathogen targets.



- Perform enhanced pre-harvest product testing per Western Growers' Appendix C: Sampling and Testing Protocol at the sample location of the failure when generic *E. coli* acceptability criteria is not met.

Historical baseline data from non-flooded soil testing may be used in lieu of pre-harvest product testing to support replanting in the event that generic *E. coli* acceptance criteria cannot be met.



APPENDIX III: THE ORIGINAL REVISIONS PROPOSED by CALGMA TECHNICAL COMMITTEE and GURMAIL MUDAHAR

12. ISSUE: FLOODING

Flooding for purposes of this document is defined as the flowing or overflowing of a field with water outside of a grower’s control, that is reasonably likely to contain microorganisms of significant public health concern and is reasonably likely to cause adulteration of the edible portions of fresh produce in that field. Pooled water (e.g., rainfall) that is not reasonably likely to contain microorganisms of significant public health concern and is not reasonably likely to cause adulteration of the edible portion of fresh produce should not be considered flooding. If flood waters contain microorganisms of significant public health concern, crops in close proximity to soil such as lettuce/leafy greens may be contaminated if there is direct contact between flood water or contaminated soil and the edible portions of lettuce/leafy greens (Wachtel et al. 2002a; 2002b).

In the November 4, 2005, FDA "Letter to California Firms that Grow, Pack, Process, or Ship Fresh and Fresh-cut Lettuce/leafy greens," the agency stated that it considers ready-to-eat crops (such as lettuce/leafy greens) that have been in contact with flood waters to be adulterated due to potential exposure to sewage, animal waste, heavy metals, pathogenic microorganisms, or other contaminants. The FDA is not aware of any method of reconditioning these crops that will provide a reasonable assurance of safety for human food use or otherwise bring them into compliance with the law. Therefore, the FDA recommends that such crops be excluded from the human food supply and disposed of in a manner that ensures they do not contaminate unaffected crops during harvesting, storage or distribution. "Adulterated food may be subject to seizure under the Federal Food, Drug, and Cosmetic Act, and those responsible for its introduction or delivery for introduction into interstate commerce may be enjoined from continuing to do so or prosecuted for having done so. Food produced under unsanitary conditions whereby it may be rendered injurious to health is adulterated under § 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a) (4); (US FDA 2004).

Areas that have been flooded can be separated into three groups: 1) product that has come into contact with flood water, 2) product that is in proximity to a flooded field but has not been contacted by flood water, and 3) production ground that was partially or completely flooded in the past before a crop was planted. The considerations for each situation are described below and presented in Table 5.

The Best Practices for Product That Has Come into Contact with Flood Water Are:

- See Table 5 for numerical criteria for lettuce and leafy greens production fields that have possibly come into contact with flood waters.
- FDA considers any crop that has come into contact with floodwater to be an “adulterated” commodity that cannot be sold for human consumption.
- To reduce the potential for cross-contamination do not drive field equipment through flooded areas reasonably likely to that may contain microorganisms of public health significance (see previous section).

TABLE 5. Flooding – When evidence of flooding in a production block occurs.

Practice	Metric/Rationale
Flooding Defined	The flowing or overflowing of a field with water outside a grower’s control that is reasonably likely to contain microorganisms of significant public health concern and is reasonably likely to cause adulteration of edible portions of fresh produce in that field. Additional discussion of this definition and implications for production is provided in the text portion of this document.

Commented [GM9]: CPS research found very low likelihood of pathogens (<5%), so Reasonably likely is too strong wording and it should be changed to 'May contain'



Allowable Harvest Distance from Flooding	<ul style="list-style-type: none"> • Buffer and do not harvest any product within 30 100 ft. of the flooding. • Required buffer distance may be greater than 30 100 ft. based on risk analysis by foodsafety professional. • If there is evidence of flooding, the production block must undergo a detailed food safety assessment by appropriately trained food safety personnel (see Glossary) prior to harvest, as defined in the text of this document.
Verification	<ul style="list-style-type: none"> • Documentation must be archived for a period of two years following the flooding event. Documentation may include photographs, sketched maps, or other means of delineating affected portions of production fields.
Time Interval Before Planting Can Commence Following the Receding of Floodwaters	<ul style="list-style-type: none"> • 60 days prior to planting provided that the soil has sufficient time to dry out. • Appropriate soil testing can be used to shorten this period to 7 days prior to planting. This testing must be performed in accordance with the sampling and testing requirements explained later in this section.
Rationale	<ul style="list-style-type: none"> • The basis for the 30 100 ft. distance is due to the known potential for subsurface horizontal water movement and seepage that is not necessarily visible, is the turn around distance for production equipment to prevent cross-contamination of non-flooded ground or produce.

Commented [SL10]: CA LGMA Technical Committee: Keep buffer at 30 ft. Additional comments during webinar provided by Greg Komar: What evidence/data was the increase from 30 to 100 ft based on?

Commented [GM11]: No evidence of water seepage upward against gravity. Buffer distance should stay 30 ft

Commented [GM12]: Per Hydrology science, due to gravitational force, water movement occurs down ward. However below soil surface at water table level (it is more than 100 ft deep in most flooded areas, it may travel horizontally at gradient level. Considering non-flood area is higher than the flooded and is several hundreds ft above water table, there is no chance that flooded water will contaminate surface soil further than flood line. Originally 30 ft buffer was implemented due to farm equipment movement and there should not be any change from original 30 ft buffer.

Commented [GM13]: 30 ft buffer distance is appropriate and existing wording should be kept.

The Best Practices for Product in Proximity to A Flooded Area, But Not Contacted by Flood Water Are:

- Prevent cross-contamination between flooded and non-flooded areas (e.g., cleaning and sanitizing equipment, eliminating contact of any farming or harvesting equipment or personnel with the flooded area during growth and harvest of non-flooded areas).
- To facilitate avoiding contaminated/adulterated produce, place markers identifying both the high-water line of the flooding and an interval 30 ~~100~~ feet beyond this line. If 30 ~~100~~ feet is not sufficient to prevent cross-contamination while turning harvesting or other farm equipment in the field, use a greater appropriate buffer distance. Take photographs of the area for documentation. Do not harvest product within the 30 ~~100~~-foot buffer zone.

The Best Practices for Formerly Flooded Production Ground Are:

- Prior to replanting or soil testing, the designated food safety professional for the grower shall perform a detailed food safety assessment of the production field. This designated professional will be responsible for assessing the relative merits of testing versus observing the appropriate time interval for planting and will also coordinate any soil testing plan with appropriate third-party consultants and/or laboratories that have experience in this type of testing.
- Evaluate the source of flood waters (e.g., drainage canal, river, irrigation canal, etc.) for potential significant upstream contributors of human pathogens at levels that pose a significant threat to human health. This may include testing of the flood water.
- Allow soils to dry sufficiently and be reworked prior to soil testing and/or planting subsequent crops on formerly flooded production ground.



- Do not replant formerly flooded production ground for at least 60 days following the receding of floodwaters. This period and active tillage of the soil provide additional protection against the survival of pathogenic organisms.
- If flooding has occurred in the past on the property, soil clearance testing may be conducted prior to planting leafy greens. Soil testing may be used to shorten the clearance period to 7 days. If performed, testing must indicate negative for STEC and/or EHEC, *E. coli* O157:H7, and *Salmonella* and all samples must be ≤ 10 MPN/gram of soil for generic *E. coli*.
 - ~~Historical, baseline data from non flooded soil testing may be used to support replanting in the event that generic *E. coli* acceptance criteria cannot be met.~~

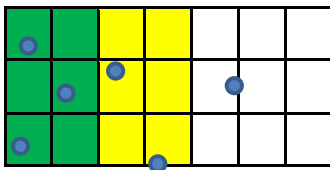
The Best Practices for Soil Sampling and Testing Are:

Microbial soil sampling can provide valuable information regarding relative risks; however, sampling by itself does not guarantee that crops grown within the formerly flooded production area will be free of the presence of human pathogens. The decision to plant, or replant ground that has been flooded, is a risk-based decision.

The soil sampling parameters below are considered reasonable acceptance criteria when testing previously flooded soil.

- **Sample area:** Samples shall be collected from the previously flooded area ~~moving from most flooded to least flooded. If available, include at least 2 samples from a non flood area within the contiguous ranch. See the sampling diagram (Figure X) below.~~
- **Minimum number of samples per defined lot location:** A minimum of 10 individual soil samples shall be collected from an individual lot.
- **Lot size:** Lot size is determined by the grower based on field flooding, ability to work the ground, and future planting.
- **Sample depth:** Each soil sample shall be collected at a composite depth between 1 – 6 inches from the soil surface. It is important to maintain a consistent sampling depth across the defined lot.
- **Sample weight:** Sufficient soil weight shall be collected (approximately ≥ 100 grams per sample). Request the lab to analyze a minimum of 25 grams per target organism. Based on recent tests on flood-impacted soil, the surface-only nature of boot swab samples was shown to be less sensitive and, therefore, they are not acceptable for this purpose.
- **Sampling plan:** Random sampling shall be conducted with more samples taken closer to the location where flood waters entered and exited the field and fewer samples from the buffer ~~and non flooded area.~~

Figure X. ~~A sampling diagram outlining soil samples collected across a defined lot in a randomized pattern across vertical transects, with more samples collected closest to the flooded area (green) and fewer samples collected away from the flooded area (white).~~



Commented [GM14]: E. Coli 0157:h7 should be removed as STEC/ EHEC are suggested as alternatives.

Commented [SL15]: CA LGMA Technical Committee: "Remove generic *E. coli* to simplify testing requirements by removing fecal indicator testing and just test for pathogens." Additional comments during webinar provided by Greg Komar: What is the value of testing for both fecal indicator bacteria and pathogens? Seeking to simplify requirements.

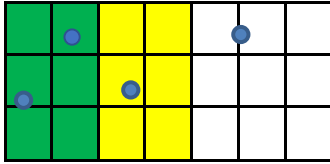
Commented [GM16]: Since soil is tested for STECs, and all pathogenic *E. coli* strains are tested, there is no need to test for indicator organisms including Generic. *E. coli*. It should be removed.

Commented [SL17]: CA LGMA Technical Committee: Use of "historical baseline data" is unnecessary since testing for generic *E. coli* is not required.

Commented [GM18]: Describe difference between Most and Least flooded areas? It should be one language ie flooded area. To avoid confusion.

Non flooded areas should not be included in sampling. There is no scientific evidence of flood water seepage upwards. See my hydrology comments in previous section.o

Commented [GM19]: Non flooded area sampling should be removed as there is no evidence that areas next to flood are contaminated. Fig X needs to be removed. Non flooded areas should not be included in sampling. There is no scientific evidence of flood water seepage upwards. See my hydrology comments in previous section.



Green: Flooded area
 Yellow: Buffer (100 ft from water mark)
 White: Non flooded area (>100 ft from water mark)
 ● – Approximate 100-gram sample

- **Testing frequency:** Minimum one sampling event
- **Timing:** The initial sampling event shall be conducted at least 7 days after flood waters have receded. It is important to note that because of flooded ground saturation, the use of tractors and other implements may take longer than 7 days post-water receding.
- Subsequent sampling events may be conducted until results indicate the acceptance criteria below have been achieved.
- Until these metrics are met, all equipment passing through the flood-impacted areas must be cleaned and sanitized before entering non-flooded areas.
- Target organisms:
 - Generic *E. coli*
 - *Salmonella*
 - *E. coli* O157:H7
 - STEC and/or EHEC
- Acceptance criteria for sample set (sampling event):
 - Generic *E. coli*: All 10 samples ≤ 10 MPN or CFU/gram of soil*
 - *Salmonella*: Negative or non-detect
 - *E. coli* O157:H7: Negative or non-detect
 - STEC or EHEC: Negative or non-detect
- Results:
 - If you meet the acceptance criteria, planting can commence.
 - If you do not meet the acceptance criteria:
 - Consider conducting additional groundwork with the use of tractors and implements to turn the soil to encourage drying out and aeration.
 - Repeat sampling and testing until the criteria have been met or you have reached 60 days from when the water has receded from the ranch.
 - Perform enhanced pre-harvest product testing per Western Growers' Appendix C: Sampling and Testing Protocol at the sample location of the failure when generic *E. coli* acceptability criteria is not met.

* Historical baseline data from non-flooded soil testing may be used in lieu of pre-harvest product testing to support replanting in the event that generic *E. coli* acceptance criteria cannot be met.

Commented [GM20]: Since STECs are tested, there is no need of testing an indicator organism including Generic *E. coli*

Commented [SL21]: CA LGMA Technical Committee: "Simplifying testing requirements by removing testing for fecal indicators and just testing for pathogens."

Commented [GM22]: This option should be removed as this is contradicting 60 days rule.

Commented [GM23]: Soil testing is not done on regular basis. This comment is not clear. This comment should be removed.



APPENDIX IV: ADDED TO REFLECT COMMENT MADE by THE AZ LGMA TECHNICAL SUBCOMMITTEE

4. PERSONNEL QUALIFICATIONS AND TRAINING

Adequate training of on-farm and handler personnel is a critically important element in a successful food safety program. In order to align with federal requirements under the Food Safety Modernization Act (FSMA) and to ensure that all activities prescribed in this document are effectively and adequately implemented, the following minimum training requirements must be maintained and documented:

The Best Practices Are:

- All personnel (including temporary, part time, seasonal, and contracted personnel) who handle lettuce / leafy greens or who have contact with food-contact surfaces, or who are engaged in the supervision thereof, must:
 - Receive adequate training, as appropriate to the person's duties, upon hiring, and periodically thereafter, at least once annually.
 - Have a combination of education, training, and experience necessary to perform the person's assigned duties in a manner that ensures compliance with these best practices.
- Training must be:
 - Conducted in a manner easily understood by personnel being trained.
 - Repeated as necessary and appropriate based on observations or information indicating that personnel are not meeting standards outlined in these best practices.
- Minimum training requirements must include:
 - For all personnel who handle (contact) lettuce/leafy greens or supervise those who do so must receive training that includes the following:
 - Principles of food hygiene and safety.
 - The importance of health and personal hygiene for all personnel and visitors including recognizing symptoms of a health condition that is reasonably likely to result in contamination of lettuce/leafy greens or food-contact surfaces with microorganisms of public health significance.
 - The standards established in these best practices that are applicable to the employee's job responsibilities.
 - For harvest personnel, the training program must also address the following minimum requirements related to harvesting activities:
 - Recognizing lettuce/leafy greens that must not be harvested, including product that may be contaminated with known or reasonably foreseeable hazards.
 - Inspecting harvest containers, harvest equipment, and packaging materials to ensure that they are functioning properly, clean, and maintained so as not to become a source of contamination of lettuce/leafy greens with known or reasonably foreseeable hazards.
 - Correcting problems with harvest containers, harvest equipment, or packaging materials or reporting such problems to the supervisor (or other responsible party), as appropriate to the person's job responsibilities.
 - [For personnel conducting environmental hazard and risk assessments, training must be completed, and the training program must address the following minimum requirements:](#)
 - [When an environmental hazard or risk assessment should be completed.](#)
 - [How to conduct an environmental hazard or risk assessment.](#)
 - [Potential hazard and risk identification.](#)



- [Recognizing product that may be contaminated with known or reasonably foreseeable hazards.](#)
 - [Mitigations and corrective actions.](#)
 - [When an environmental hazard or risk assessment deems pre-harvest product testing is necessary.](#)
- At least one supervisor or responsible party (e.g., the food safety professional) for each grower providing leafy green products must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the FDA.
 - Establish and keep records of training that document required training of personnel, including the date of training, topics covered, and the person(s) trained. Records must be reviewed, dated, and signed, within a reasonable time per companies' SOP after the records are made, by a supervisor or responsible party.