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

Topic Discussed:

Pre-Harvest Product Sampling, Testing, and Data Collection

Prepared by:

Western Growers

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Background

Since the inception of the Leafy Green Marketing Agreement (LGMA), Western Growers (WG) has facilitated a systematic amendment process to update the LGMA-approved guidelines (known as the LGMA metrics). On January 31, 2023, Western Growers opened a 15-day-comment period regarding data collection considerations to implement a proposed sampling and testing program for California LGMA members. WG also hosted a webinar on February 15, 20,23 to address additional comments and questions. This comment period and webinar are part of a shorter version of the regular WG amendment process.

WG received online comments from three parties via the www.leafygreenguidance.com website and several comments and questions during the February 15, 2023, webinar. The webinar was attended by 79 participants, listed below in alphabetical order.

Webinar Participants:

Name		Organization
Aaron	Anderson	Pacific International Marketing
Afreen	Malik	Western Growers Association
Alexis	Amao	BioAG Sampling Services
Alyssa	Licata	CA LGMA
Amalia	Jimenez	Western Harvesting,LLC
Amanda	Brooks	Harrison Farms
Amanda	Roach	Coronation Peak
Anna	Haller	Grimmway Farms
Anna	Gonsalves	PrimusLabs
Ariane	Allan	Fresh Kist Produce
Armando	Figueroa	Braga Fresh Family Farms
Ashley	Perez	Dole
Austin	Ju	In-N-Out Burger
Becky	Unwer	Walmart
Bob	Mills	Misionero
Bradley	Zittlow	AZDA
Brendan	Ring	Creme Global
Claudia	Gonzalez	Mellon Farms/Legacy Greens
Colby	Pereira	Braga Fresh Family Farms
Connie	Quinlan	CA LGMA
Cristina	Gomez	Ocean Mist Farms
Cronan	McNamara	Creme Global
Cynthia	Dominguez	Duda
Danny	Andrews	Dan Andrews Farms LLC
De Ann	Davis	Western Growers Association
Diego	Vasquez	Pacific International Marketing
Don	Schaffner	Rutgers University

Drew	McDonald	Taylor Farms
Elsbeth	Colon	Ratto Bros
Ernesto	Bermudez	GreenGate Fresh, LLLP
Felice	Arboisiere	Dole Fresh Vegetables
Fiorella	Cerpa Calderon	Deardorff Family Farms
Francisco	Valdes	Sabor Farms
Gerardo	Valenzuela	TLC Custom Farming Company, LLC.
Gurmail	Mudahar	Tanimura & Antle Fresh foods
Guylaine	Laganière	VegPro International
Herman	Cossio	Ippolito International LP
Jaime	Garcia	Peter Rabbit Farms
Jake	Odello	The Nunes Company
James	Bautista	Organic Girl, LLC
Jenna	Mann	Bonipak
Jessica	Sharkey	Dole
John	Gurrisi	Fresh Express Inc.
Jose	Ortiz	D'Arrigo Bros. Co., of California
Juan Carlos	Mendoza	Sabor Farms
Kami	Van Horn	Rousseau Farming
Karen	Rodriguez	Fresh Harvest, Inc.
Karen	palacios	Bonipak
Kate	Burr	Markon
Kaylee	Jensen	Pasquinelli Produce Company
Kelly	Smekens	Bonduelle Fresh Americas
Laurence	Ménard Laporte	Vegpro Internationnal Inc
Lester	Sandoval	PrimusLabs
Leticia	Reyes	Fresh Express
Lidia	Valdes	Duda Farm Fresh Foods, Inc.
Luis Miguel	Rojas Díaz	Harvest Tek de Mexico
Lupe	Camarena	Nature Fresh Farms, LLC
Mandy	Gilbert	Creekside Organics
Mark	Shakespeare	Walmart
Matt	Amaral	D'Arrigo Bros of CA
Matt	Burke	Tanimura & Antle
Megan	Chedwick	Church Brothers
NARDA	DE LEON	Huntington Farms
Nona	Childress	PrimusLabs
Omar	Espinoza	McSherry and Hudson
Paola	Ruelas	Rousseau Farms
Patricia	Maciel	Ocean Mist Farms
Ron	Ratto	Ratto Bros.
Samuel	Padilla	Pasquinelli Produce Co.
Sarah	Cormany	Peri & Sons Farms

Sukhmani	Johal	Sobeys Inc.
Teressa	Lopez	AZ LGMA
Thea	Eubanks	Organic Girl
Tim	York	LGMA
Tina	Burk	Heritage Farms, LLC
Veronica	Blanco	Innovative Produce, Inc.
Vicki	Scott	Scott Resources
Viridiana	Melgoza	Ready Pac
William	Westerling	Kenter Canyon Farms

The February 15th webinar offered background regarding the proposed sampling and testing program for the CA LGMA members. In summary, it was noted that after a pre-harvest testing program proposal was submitted to the LGMA on July 2022, the CA LGMA requested a data collection/analysis plan for the proposed program. As a result, a Data Task Force (DTF) was formed under the CA LGMA leadership. WG facilitated several meetings and the completion of a data collection proposal.

In addition, the webinar offered an overview of the DTF's data collection proposal, the CA LGMA perspective, and potential changes to the CA-LGMA-approved metrics.

The DTF proposal assumed a standardized sampling and testing protocol for the proposed program. Below are the current parameters under consideration.

- **Sampling Timeline** – Prior to scheduled harvest (7 days or closer to harvest)
- **Target Organisms** –Test for *E. coli* O157: H7
- **Sampling Lot Size** – Lot definition may vary depending on the ranch/farm operation but should not be more than 40 contiguous acres
- **Sample Size** – Total sample mass per lot must equal at least 1,500 grams (4 composite subsamples of 375 g each) weighed and recorded by the third-party service laboratory
- **Sampling Method** –Stratified randomized sampling within a designated lot. Consider stratifying by the number of composite sub-samples collected to reach the 1,500 g total mass. For example, collecting 4 composites of 375 g from roughly 1/4 of each defined lot area
- **Number of Grabs** –A minimum of 60 grabs per sample (1,500 g). More individual grabs per lot improve the probability of detecting contamination
- **Sampler** – Samples must be taken by a trained sampler. Implement mandatory training on the sampling protocol for personnel conducting the pre-harvest product sampling

The complete DTF Proposal is available online at www.leafygreenguidance.com website or as Appendix 1. The proposal has five components, a section that captures assumptions or challenges that need to be addressed, the testing parameters under consideration, the potential value of such program, objectives, goals, and data points to consider. The group proposal identified at least 17 data types that could address 21 questions. The DTF recommended that the objectives of the proposed program should be: 1) To adopt standardized protocols/methods for preharvest product sampling and testing programs for romaine lettuce; and 2) Follow the minimum required testing parameters and collect,

review and analyze data to support the longer-term goals of preharvest testing programs across the industry.

The document explaining the CA LGMA's view on the DTF proposal is available online at the www.leafygreenguidance.com website or as Appendix 2. In summary, the CA LGMA vision and goal are to develop a standardized pre-harvest romaine testing program that enables the leafy greens industry to learn from personal and aggregated data to contribute to industry knowledge, inform food safety programs and obtain learnings from a standardized testing program (noted as a test & learn program). The CA LGMA proposes two revisions to the current testing parameters under consideration and to require as mandatory a select five of the 17 DTF-recommended data types. Below is a table that illustrates the CA LGMA's recommendation, which would help potentially address 3 instead of 21 questions.

Table 1. DTF and CA LGMA recommended data submissions

Data Submission	
Data Task Force recommendation	**CA LGMA recommendation**
PRODUCT RELATED DATA	Acres sampled
Commodity	Commodity
Variety	Regionality
Acres Samples (both total lot size and sub-sample acres)	Sample Date
Target Organism	Target Organism
Test Result	Test Resuls
Sample Mass	
Harvest Date	*Note: The above points would be mandatory, the others points voluntary.
Location/GPS	
Lot ID	
Pre-Season Assessments	
RCA findings/Corrective Actions	
WATER RELATED DATA	
Ag water assessment	
Water Test Result	
Water Treatment information	
Water Irrigation SOP	
Pre-Harvest Inspections/corrective actions	

If the CA LGMA approves a one-year testing program for romaine lettuce, a new section would need to be added. This new section will replace the current testing requirements in the document. The required data types to submit under the one-year program are to be terminated. Below is an example of what the new section would look like (assuming it includes five mandatory data points and CA LGMA's recommendations). The full version of the working document (metrics with tracked changes) is attached to this report.

18. PRE-HARVEST TESTING PROGRAM FOR ROMAINE

Pre-harvest product testing is one of many tools that can assist in developing a long-term view of food safety system performance. Analysis of product testing data can provide valuable insights to demonstrate if implemented preventive measures are effective and to help enhance food safety system performance and inform a broader industry understanding of risk potential and prevention efforts. Industry-standardized and aggregated data can be applied to predictive trend analysis for improved risk assessments and to refine pre-harvest product testing parameters and sampling plan designs over time. For this reason, a one-year program will sample and test monoculture whole-head romaine lettuce for *E.coli* O157:H7.

The pre-harvest product testing goals are to develop a standardized pre-harvest romaine testing program that enables the leafy greens industry to learn from personal and aggregated data that contribute to industry knowledge and informs food safety programs. It is not the goal to justify a long-term, mandated, pre-harvest testing program on romaine or other leafy greens. This is a test-and-learn program to determine the best next steps.

The Best Practices Are:

- Develop a written pre-harvest product sampling and testing program for monoculture whole-head romaine lettuce that provides 95% confidence in detecting 1 CFU/lb of randomly distributed contamination in a lot.
- Submit test results and supporting data to the GreenLink™ system.
- Sampling and Testing Parameters include:
    - Sampling Timeline – No greater than 10 days from the start of harvest
    - Target Organisms – E. coli O157: H7
    - Sampling Lot Size – No greater than 40 contiguous acres
    - Sample Size – Total sample mass per lot must equal at least 1,500 grams weighed and recorded by the third-party service laboratory.
    - Total number of subsamples may vary; for instance, 4 composite subsamples of 375 g each
    - Sampling Method – Stratified randomized sampling within a designated lot
    - Number of Grabs – A minimum of 60 grabs per sample

- Required data submission
    - The following data will be submitted to GreenLink™ at least monthly.
        - Acres sampled (both total lot size and sub-sample acres)
        - commodity
        - regionality
        - sample date
        - target organism
        - test result

Synopsis of Comments and Questions received online and during the webinar.

<u>February 15th Webinar: Q&A session (more comprehensive answers than those given online are noted below).</u>

Q1: Per statistical tables, N60 samples provide 95% confidence only if there is a 5% contamination rate. Is there data available to confirm that romaine being grown and shipped has 5% contamination? That is the same as one head of lettuce in every 24-count box is contaminated.

A1: Statistics tables were used to determine confidence levels to detect 1 CFU/pound contamination. Dr. Matt Stasiewicz with the University of Illinois may provide more information. There is data based on the CFU/pound of product. Refer to the United Fresh Thought experiment based on data from the FDA about a Romaine outbreak. The data from this event was used to reverse engineer a scenario (sampling program) that might have helped to prevent the outbreak (i.e., detect the contamination before the product was placed into distribution).

Q2: Why isn't "test result" included in the CA LGMA recommendation?
A2: This was an error in the slide. Test results are included in the data points to report.

Q3: I currently test for STEC, including E. coli 0157:H7 and Salmonella will this be accepted?
A3: The CA LGMA proposes requiring E. coli 0157:H7 tests. O Testing for additional organisms would also be at the discretion of the individual organization doing the test and learn program.

Q4: Has a standard regionally naming scheme been determined?
A4: The CA LGMA proposed a definition. See the working metrics document for more detail.

Q5: What will be the region? State, LGMA District-3-CA, 2-AZ, the PMA Area of Origin, County, Local Geographic area (north valley, central, south valley)?
A5: The CA LGMA proposed a definition. See the working metrics document for more detail.

Q6: My understanding was that the 1-40 acres were based on widely spread contamination; this says "randomly." To get the 95% confidence, I believe it was based on spot contamination which stated 1-5 acres would be your sampling lot to gain confidence. I am still confused about this.
A6: The 1-40 acres lot size is based on randomly distributed (not equally distributed) systemic contamination. Not localized, point source contamination. Please reach out, and we can explain further.

Q7: Have there been conversations with 3rd party laboratories on the confirmation methodologies in case of an IR or presumptive?
A7: Validated cultural methods exist. Operations can define positives internally. The testing method is not one of the data points recommended by the LGMA in the test-and-learn program proposal. The Data Task Force did recommend them.

Q8: Can you discuss how the pooling of samples will be addressed?
A8: Pooling of samples would have to be addressed between operations and their laboratories. Labs have validated methods in place for pooling, and operations can choose to pool based on the available validated methods.

Q9: Why does this seem to apply to all irrigation regimes? Drip and sprinkler.
A9: Irrigation methodology or water testing data is not one of the data points recommended by the LGMA in the test and learn program proposal. One of the reasons why the Data Task Force recommended irrigation data is to collectively understand factual differences and potential relationships between different irrigation regimes and positive results.

Q10: Can you define "monoculture"?
A 10: Below is the monoculture definition discussed in a previous webinar. See the working metrics document for more detail.
Monoculture Romaine: Whole-head romaine, including petite varieties; it does not include baby romaine, spring mix, and mixed varieties in beds within a field.

Q11: How will a "positive" be determined? Are all positives equal, presumptive vs. confirmed? Will each Handler use their SOP, or will the project identify a method or procedures used?
A11: Individuals may be able to submit positive, presumptive, and confirmed results. In a previous discussion, an approach/definition was discussed. See the description below:
Presumptive positive results: Testing results that are molecularly confirmed positives without culture confirmation.

Q12: Wouldn't randomly mean spot?
A12: No, randomly was defined as widely distributed (but not equally distributed)—spot contamination related to targeted contamination or point source contamination.

Q13: Please provide names and contact of those SMEs who suggested 95% confidence without any contamination history.
A13: SMEs did not suggest a specific confidence level Dr. Matt Stasiewicz from the University of Illinois developed a table that depicts the statistics surrounding numerous contamination levels and testing parameters. The pre-harvest testing proposal submitted to the LGMA in July 2022 included a 90% confidence level, but after additional discussions the CA LGMA Executive Committee asked for a higher confidence level. The 95% comes as the result of industry stakeholder's input.

Q14: Unless the root cause(s) of the pathogenic E. coli O157:H7 contamination events is/are found and CAPAs implemented, why would this project only be for one year? (Instead of continuing to collect more data over the coming years). That makes no sense, how we went from 1-5 to 40, but ok.
A14: Root cause analysis is critical and currently a requirement under the CA LGMA when there is a positive. The CA LGMA executive committee decided to consider a one-year test & learn program. According to the mathematical tables created by Dr. Matt Stasiewicz, there is no significant difference between sampling and testing 1 acre vs. 40 acres when the total mass tested is 1,500 grams (which is recommended in the current protocol). However, it is unlikely that an operation will choose 40 acres as a sampling lot because if there is a positive result, the entire lot would have to be discarded.

Q15: What is the anticipated timeframe for the initiation of this program with growers?
A15: According to Greg Komar, a decision will be made in the next month, but it will take a few months to conduct outreach and help implement the program.

Q16: Will LGMA metrics request a specific test method for *E. coli* O157, or will the larger STEC umbrella suffice? So industry does not have similar issues to those some have had with the Canada certificate requirements requiring O157 to be listed separately from STEC. Thank you.

A16: The LGMA proposed program calls for *E. coli* O157:H7 specifically using a validated method; the intention of the DFT proposal is to be consistent with how operations report it to Canada.

Q17: Will any grant programs or financial assistance be available to smaller players to cover the cost of sampling/testing?

A17: This has been explored but further discussion and approval from the CA LGMA Board is necessary for any potential program to move forward.

Webinar Comments

- We know that cultural confirmation does not work on E coli O157 or STECS-so it is scary to go with a cultural confirmation to report the result.
- Molecularly confirmed positive means pathogens are or were there. This is what is important. Looking for a culture-confirmed positive at this stage is probably not productive.

Critical points from online comments via the www.leafygreenguidance.com website:
To see full comments, access them online or in Appendix 3.

AZ LGMA Comments

The Arizona TSC concurs with the statements regarding the potential benefits of a pre-harvest product testing program and insights into food safety system performance. The Arizona TSC believes a research study should be designed and conducted based on a standardized sampling protocol, assessment of the field and adjacent land hazards and risk factors, mitigation strategies, differences in product characteristics, and evaluation of sampling plan designs at a minimum. The Arizona TSC also asked for clarification regarding the WG amendment process and shorter comment period. In addition, it is looking for the following considerations:

1. Provide a clearer definition of monoculture romaine concerning mini/midi or petite romaine varieties that include these types or offer a days-to-maturity clarifier.
2. Provide a clearer definition of regionality.
3. Clarify expectations of pooling samples.
4. Provide an overview of laboratory expectations and capabilities on the proposed method.
5. Clarify why STEC and *Salmonella* were removed from the original draft.
6. Support the removal of Appendix I until there is scientific research to support the outlined distances.

Response based on previous discussions facilitated by WG:

Questions regarding the Western Growers process were clarified during the February 15th webinar. Western Gowers hosted a modified version of its regular amendment process (a 15-day comment period instead of a 30-day comment period).

New definitions have been added to the working draft; those should provide clarification. Lastly, the CA LGMA Executive Committee asked to reduce the two-year timeframe and remove STEC and *Salmonella* from the testing parameters under consideration.

CA LGMA comments

Below is a proposed recommendation to define California's regions:

- Salinas Valley (North of Gonzales)
- Gilroy, Hollister, and San Juan Batista área
- Santa Maria
- Imperial Valley
- Bard
- Salinas Valley (South of Gonzales)
- Watsonville area (Santa Cruz county)
- Oxnard
- Huron (Central Valley)

Response based on previous discussions facilitated by WG: This definition can be added to the working draft.

Tanimura & Antle Fresh Foods

Dr. Gurmail Mudahar noted assumptions regarding the current Appendix C. He expressed concerns regarding the 95% confidence level when the assumption is that the contamination level is randomly distributed throughout the lot. He expressed concern regarding testing all fields the same way, stating that there should be no need to test those lots that do not qualify for testing based on risk assessment. He emphasized the need to standardize all testing parameters, including lot size, to provide consistency . Also, he noticed that sample preparation and specimen size must be the same. He concluded that a pre-harvest testing plan would not help improve food safety but would provide a false sense of security and mislead customers and consumers. He states that routine testing is not recommended by the ICMSF (International Commission on Microbiology Specifications of Foods).

Response based on previous discussions facilitated by WG: The assumption that contamination is randomly distrusted does not mean it is equally distributed in the field. The recommended approach is to use pre-harvest testing as a verification tool instead of a control process or similar to how food facilities may use it. Any parties with questions regarding Appendix C can contact WG's Afreen Malik at amalik@wga.com.

In addition, the proposed program is not based on high- vs. low-risk fields; it is meant to create a baseline and better understanding of what positives mean. The mathematical model used for the current parameters assumes no significant difference in sampling 1 or 40 acres or any acre size between.