ONE-YEAR PRE-HARVEST TESTING PROGRAM
FOR ROMAINE LETTUCE
Data Collection/Analysis Proposal

This document includes recommendations from discussions of members of the Data Task Force formed in October of 2022 under the leadership of the CA LGMA in collaboration with Western Growers. Members of the Data Task Force are noted below.
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Introduction.-
The Data Task Force identified important considerations for the CA LGMA to address for a successful 1-year Pre-Harvest Testing Program for romaine lettuce. For instance, addressing laboratory capacity, clearly communicating the value and limitations of pre-harvest product testing to leafy green operations, using data sharing agreements to collect/analyze data (via GreenLink™), communicating data ownership protections, engaging with diverse stakeholders, advancing Rood Cause Analysis (or Problem Investigations), and clearly defining a process/plan to interpret data.

Data Collection/Analysis Proposal.-
The proposal below assumes the following

1) That standardized testing parameters are followed during a 1-year program.
2) That company-specific data access is limited to the individual entity; access to aggregated data is allowed to the industry.
3) That data wouldn't go into GreenLink™ in real-time but after the product is harvested based on an agreed minimum frequency with the data owner (at least monthly).

Below are the program value propositions, testing parameters, suggested data collection points, and questions to consider under this program.

Value Propositions
#1. Industry would set a baseline pre-harvest test protocol for Romaine for 1 year. All Handlers would be required to meet the protocol. This accomplishes a minimum food safety standard and a level playing field across all Handlers.

#2. Industry would learn from data outcomes, contribute to industry knowledge and inform LGMA on a future pre-harvest test program.

Testing Parameters
The parameters listed below are primarily based on the original Preharvest Testing Working Group proposal, with a few adjustments, which include the target organism and the confidence in detecting 1CFU/lb. Note: Revision of these parameters was not the focus of the Data Task Force members.

- **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. When deciding on sampling plans, see Appendix L for sampling plan options.
- **Sampler** – Samples must be taken by a trained sampler. Implement mandatory training on the sampling protocol for personnel conducting the pre-harvest product sampling.
- **Periodic Data Analysis** –Analyse the data collected through your program periodically. Data analysis can provide valuable insights to help you enhance your food safety system performance and inform a broader industry understanding of risk potential and prevention efforts.

Note 1: The CA LGMA Technical Committee may assist with recommended targets when parameters have a range (for instance, sampling timeline and sampling lot size).

Note 2: This program's proposed definitions for positive results are noted here. Presumptive positive results mean molecularly confirmed positives without culture confirmation. Positive results mean culturally confirmed positives. Both types of results could be recorded as positives or captured separately.

Program Objectives for the 1-Year Romaine Pilot Program.
1) Adopt standardized protocols/methods for preharvest raw product sampling programs for romaine lettuce.
2) Follow the minimum required testing parameters, which are to be collected and reviewed to support the longer-term goals of preharvest testing programs across the industry.

Long term Goals
1. Pursue collaborative approaches with regulators and buyers and inform regulatory actions.
2. Identify hazards, potential risks, and best practices that can drive updates to the LGMA-approved metrics.
3. Use data-backed science to promote buyer/consumer trust in fresh produce safety
4. Drive learning, fill knowledge gaps, and assess the value of pre-harvest testing, the overall program, and the next steps.
5. Determine how frequently pre-harvest E. coli positives represent an increased food safety risk versus random detection of background prevalence
6. Offer a learning opportunity from real-time support through access to SMEs during industry investigation activities (Root Cause Analysis – RCA)
7. Share collective learnings with others beyond romaine lettuce operations (once the program has been assessed and insights are gained)

Suggested Industry Data Collection Points. -
Product related data
1. Commodity
2. Variety
3. Acres Sampled (both total lot size and sub-sample acres)
4. Target Organism
5. Test Result
6. Sample Mass

7. Sample Date
8. Harvest Date
9. Location/GPS *****
10. Lot ID
11. Pre-Season Assessments
12. RCA findings/Corrective Actions

Water-related data

13. Agricultural Water Assessment (source, distribution, location/GPS, adjacent land use) ******
14. Water Test Result ******
15. Water Treatment information ******
16. Water Irrigation SOP ******
17. Pre-harvest inspections/corrective actions

Industry Questions to consider for the data collection/analysis of this program. -
These questions could add to industry knowledge.
1. How many romaine lettuce acres are tested?
2. How many tests, positives and negatives (water and product tests)?
3. If there is a positive, was a Root Cause Investigation conducted (RCI)?
4. What contributing factors were identified after the investigation?
    a. Was a point source identified?
5. Are weather and location (distance and landscape features) factors associated with an increased likelihood of positive samples?
    a. What are specific conditions during those weather events (certain temperature ranges, wind speed, direction, rainfall duration, others)?
    b. Is there a relationship between these weather events, pre-harvest testing interval, and positive test outcomes?
6. How frequently do generic E. coli positives represent an increased food safety risk versus random detection of pathogens?
7. What is the prevalence rate per month and season? What is the prevalence rate based on variety?
8. Do setback distances or types of animals, or size of operations (animal operations as defined in the metrics) impact testing results?
9. Is there a relationship between water treatment (type of treatment, chemistry, dose irrigation hours, last irrigation event, last water test result) and testing results?
10. What water treatments is industry using?

Industry Questions that could be answered with data analytics. -
11. Is there a relationship between field location (distance, landscape features) and testing results?
12. Is there a relationship between other factors and positive or negative results (other data points submitted/available)?
13. Has data analysis identified what hazard variables or hazard attributes are associated with positive or negative tests (all hazard data submitted/available)?
14. Has data analysis identified potential food safety standards that should be further reviewed?
15. Is there a confirmed relationship between the likelihood of a positive test and the sampling method or specific lab?
16. Is there a relationship between the type of irrigation system (including water source, distribution,
17. Is there a relationship between the likelihood of a positive test and field location (such as fields adjacent to animal operations or adjacent land uses)?
18. Does a larger sample (total mass, number of subsamples, total lot size, sub-sample area and/or more targeted sample selection) net a higher prevalence rate (across a region)?

Company-specific Questions to consider under the data collection/analysis part of this program.-
Only Individual entities could see answers to these questions
1. Is there a relationship between farming practices (application of inputs) interventions and positive test results?

      a.   What is the timing of intervention, the type of intervention, and the applied pesticide concentration?

2. Are there any pre-harvest inspection findings and corrective actions that can explain testing results (based on all data submitted/available)?

      a.   (Bird activity, irrigation system maintenance activities, or other observations and corrective actions)?

3. Are any recurring issues noted as a result of Root Cause Investigations (RCI)?