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Overview of Appendix C:
Pre-Harvest Product Sampling and Testing Guidance Intro

September 1, 2021





Logistics

- This webinar is being recorded.
- Everyone is muted.
- Questions will be addressed during the Q&A session at the end of the presentation. Please use the Q&A or chat windows to send us questions.
- Adjourn (60 minutes).

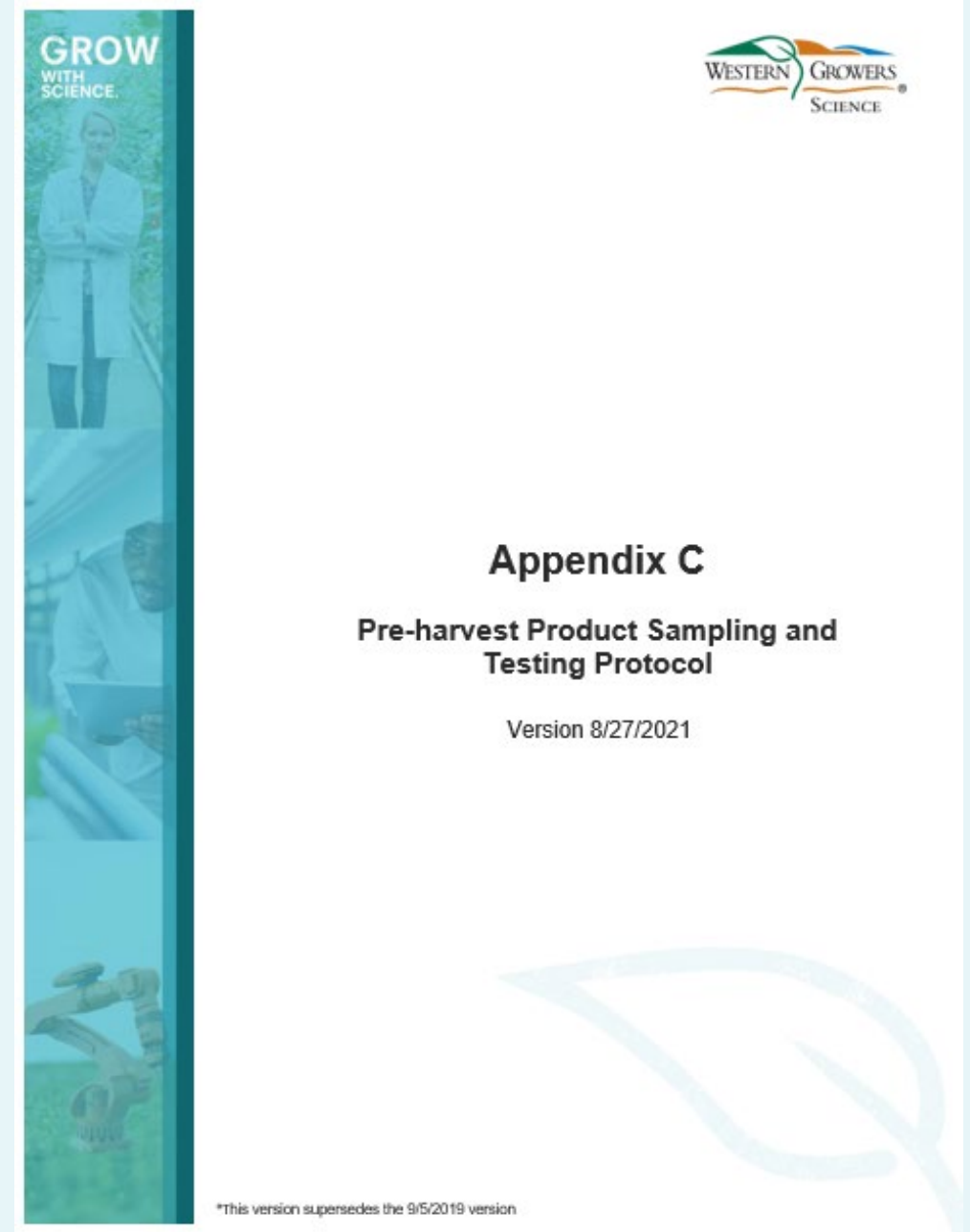


Content Overview

1. Overview of value and limitations of product testing
2. Introduction to Appendix C
3. Common questions regarding Appendix C
4. Q&A session



- WG has developed appendices for the Leafy Green Marketing Agreement over the years
- Appendices developed by WG are:
 - guidance based on current knowledge and science
 - do not go thru a vetting or voting process
 - are reviewed by subject matter experts
- First version of Appendix C: Product Testing Protocol – Sept 2019
- Current version of Appendix C: Pre-harvest Product Sampling and Testing Protocol – August 2021





Speakers



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Science Programs Director
Western Growers



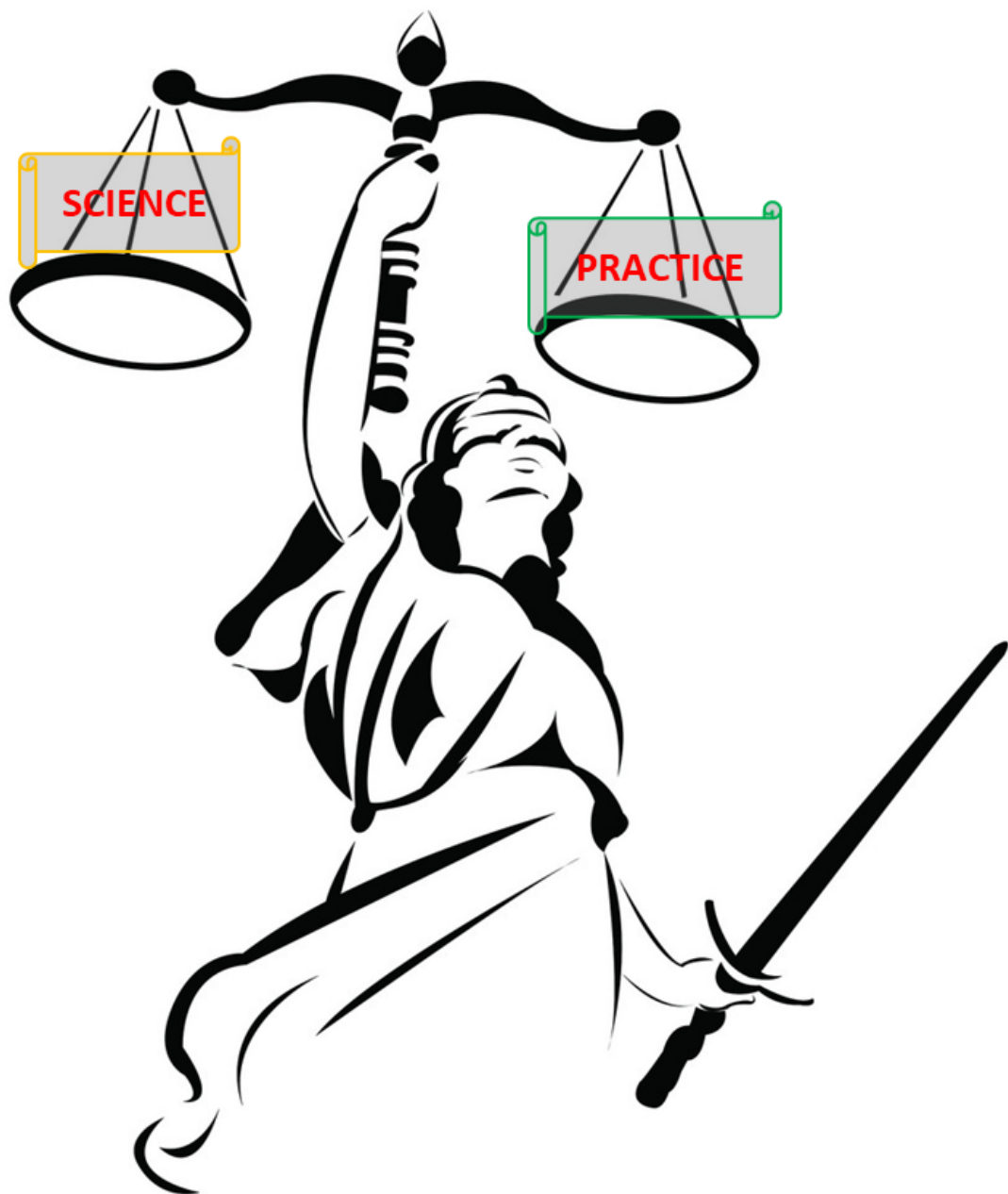
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What Preharvest Testing May and May Not Do for You



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What APX-C preharvest testing is intended to provide

- Spot surveillance and long-term view of food safety system performance
 - Lot to Lot
 - Ranch-based
 - Regional
 - Seasonal/ Annual
- Ability to exclude defined lots harboring predicted “consequential contamination”
 - Routine and Responsive
 - Assessed within statistical limits prior to large incremental costs
- Standardized Targets and Measurement Criteria
 - Consistent
 - Comparable
 - Combinable for analytics
- But flexibility in user-defined lot sampling parameters and testing platforms
- Clear enhanced commitment in safety systems to customers, regulators, and consumers



What APX-C preharvest testing is unlikely to provide

- Absolute freedom from lots harboring actual “consequential contamination”
- Detection of highly biased contaminant “hot-spots” in a lot
- Freedom from lots exposed to post-sampling and harvest-originated actual “consequential contamination” events
- Provide short-term views of risk or pathogen source-tracking
- Short-term relief from “known or reasonably foreseeable hazard” status



Introduction to Appendix C: Pre-harvest Product Sampling and Testing Protocol



Appendix C is a guidance document. It's based on current science and statistical models and was developed with input from SMEs.

We will be reviewing version 8/27/2021

1. Objectives
2. Overall structure of the document
3. Key guidance criteria in each section
4. Review some frequently asked questions



The objectives of Appendix C are to:

1. Offer standardized, science-based guidance for developing/implementing pre-harvest product sampling and testing.
2. Encourage data sharing to enhance and modify this protocol moving forward.



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Section I: Introduction

- Protocol provides guidance for **routine** and **risk-based** product sampling and testing.
- The assumptions on which the protocol is based are outlined:
 - Randomly distributed (systemic) contamination, not highly clustered
 - Capable of detecting low but relevant levels of contamination (≥ 1 CFU per pound)
 - Instead of a confidence level based on % contamination, it is a weight-based metric that provides the required measurement standard relevant for leafy greens
- The protocol is designed to provide a 95% confidence in rejecting a ≥ 1 CFU per pound level of randomly distributed contamination in a lot.



Section I: Introduction

- Going forward, the major value of a standard pre-harvest testing program will be trend analysis for improved risk assessment as data is collected and shared. Following this guidance and sharing of data and experiences throughout the industry is critical for refining and revising these sampling plans.



Section II: Routine Pre-harvest Product Sampling and Testing

1. Target Organisms:
 - *Salmonella Enterica* and;
 - *E.coli* O157 and other pathotoxigenic STEC of clinical significance (including O26, O45, O103, O111, O121 and O145).
2. Measurement criteria: non-detects for target organisms.
3. Sampling timeline: ≤ 7 days prior to the scheduled harvest day.
4. Lot size → recommended best practice is **5-acres or less**. Flexibility is built in up to 40 acres.
 - **When defining a lot size for sampling, keep in mind that one positive test result per designated lot will require destruction of the entire lot. Resampling of a positive lot is not allowed.**



Section II: Routine Pre-harvest Product Sampling and Testing

5. Sample number and sample size: minimum of n=60; 1,500g ($\pm 2\%$, 30 g).
 - Flexibility in total mass sampled and tested is acceptable if based on a scientifically developed and validated protocol which provides an equivalent detection limit.

Table 1. Sampling plan examples

Routine Testing	Timeline	Maximum lot size (acre)	Total sample size (grams) per lot	Required # of grab specimen per subsample	Approximate grab specimen size (grams)	Required # of subsamples	Subsample size (grams)	Sampling location
	Maximum 7 days prior to harvest	≤ 40	1,500	15	25	4	375	Randomized and evenly distributed over the entire lot
				10	25	6	250	
				60	2.5	10	150	

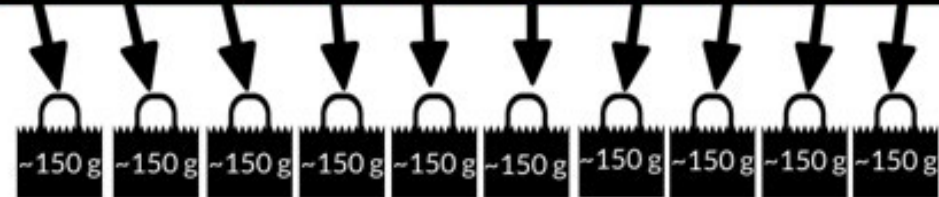
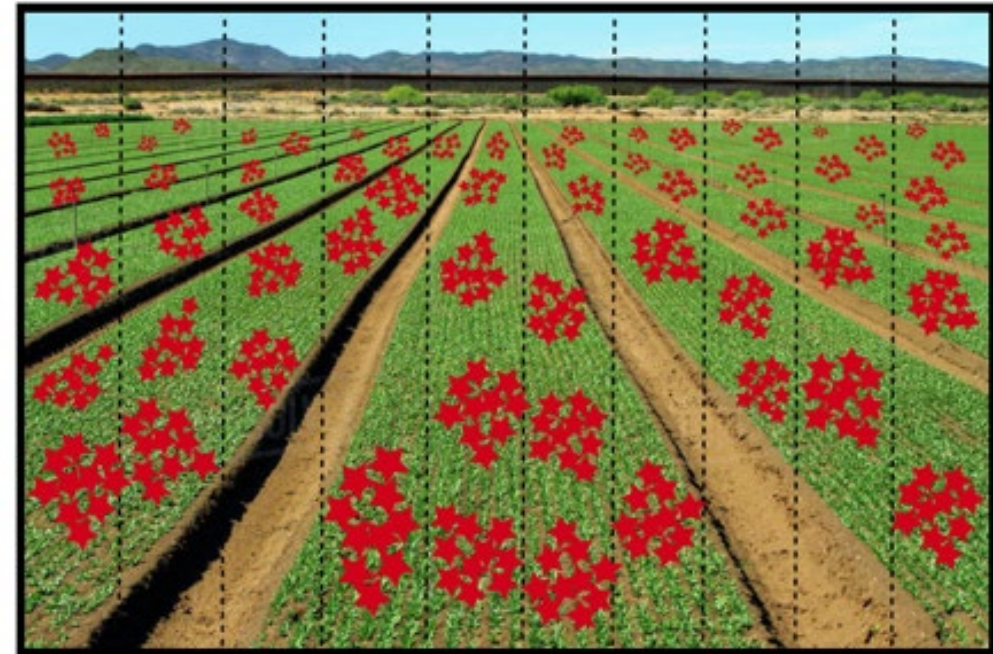


Section II: Randomized and evenly distributed

Supplemental materials:

- FAQ document
- A tool to help individual operations evaluate their sampling programs and related confidence levels

Figure 2. Illustration of n = 600 sampling scheme for baby spinach



= ≤40 acre

★ = 1 grab specimen of 2.5 g

All ★ combined = 1,500 g



Section II: Routine Pre-harvest Product Sampling and Testing

6. Sample collection

- Use aseptic technique to collect leaves from edible portion of the plant that would normally contact harvest tools, harvest equipment or machinery, or worker gloves/apparel.
- Sampling should include full leaves or sections of a full head rather than pinching off the upper quarter of a single leaf or leaves on an individual plant.
- Collect samples in sterile containers and label and deliver to the lab per requirements.
- Select an accredited laboratory to perform the analysis using validated methods.



Section II: Routine Pre-harvest Product Sampling and Testing

7. Remedial Actions

- Conduct RCA to make a concerted effort to determine what may have led to the detectable contamination on product. Based on the findings of your RCA:
 - Consider the potential for recurrence of the hazard or associated risk identified through the RCA. How likely is it that future plantings might be affected by the same hazard?
 - Consider the suitability/safety of the area where a pathogen was detected for replanting a fresh consumed leafy green crop for the remainder of the season.
- **Do not harvest produce from the lot where a pathogen was detected.** Destroy the crop in this area.
- Clean and sanitize all equipment utilized to destroy the crop upon exiting the field. Consider swabbing equipment after crop destruction as part of your RCA effort.
- Document all remedial actions including both considerations adopted and those evaluated but not implemented. All documentation must be available for verification from the responsible grower.



Section III: Risk-based Pre-harvest Product Sampling and Testing



Section III: Risk-based Pre-harvest Product Sampling and Testing

- During pre-harvest environmental assessments, when a potential risk that was mitigated during the pre-plant assessment, changes such that the likelihood of contamination now warrants increased testing.
- When irrigation water that exceeds generic *E. coli* water quality standards or when Type B → A water treatment fails to achieve acceptance criteria as established by the LGMA metrics and that water was applied to unharvested crop.
- When there are hazards with uncertain risk associated with adjacent land conditions, features, or uses (e.g., runoff, potential windborne contamination from animal holding/transfer/feeding operations, composting operations, or staging/application of compost).
- Other unforeseen sources or incidents potentially resulting in crop contamination.
- Situations described in the California LGMA pre-harvest testing guidance, which lists elevated risk factors that can trigger pre-harvest testing.



Section III: Risk-based Pre-harvest Product Sampling and Testing

3. Sampling and testing timeline:

- Conduct risk-based testing as soon as a hazard is first observed to determine if detectable contamination has occurred (1st round of testing).
- Conduct routine product testing at the scheduled product harvest date (2nd round of testing) within 4-7 days of harvest) **only if**:
 - the hazard is observed prior to routine sampling,
 - the initial risk-based test result (1,500g per ac) is negative, and
 - the crop is not destroyed.

4. Lot size → 1-acre or less



Section IV: Rationale

The rationale section provides additional details or definitions of terms. For example, a qualified or accredited lab is defined as one that is certified/accredited to ISO 17025 standard and is accredited to perform the validated method used to conduct product testing.

Section V: References

This section outlines the research and resources used in the development of Appendix C.



Frequently Asked Questions





Question #1: I have a scientifically valid sampling program that gives me sufficient confidence in detecting low level contamination for routine testing. Can I continue to follow my own sampling plan, even if the sample size is smaller (i.e., not 1,500g)?

Answer #1: Yes. Appendix C is not mandatory and (section II, subsection 5) states the following:

Flexibility in total mass sampled and tested is allowed if based on a scientifically developed and validated protocol which provides an equivalent detection limit.





Question #2: My lot definition is 5-acres. If I conduct routine testing on a 10-acre block (2 samples, one from each 5-acre lot) and one of the 2 samples is positive, what should be my next step for the second lot that is negative? Can that be harvested?

 <p>Lot A = 5 acres n=60, 1,500g</p>	 <p>Lot B = 5 acres n=60, 1,500g</p>
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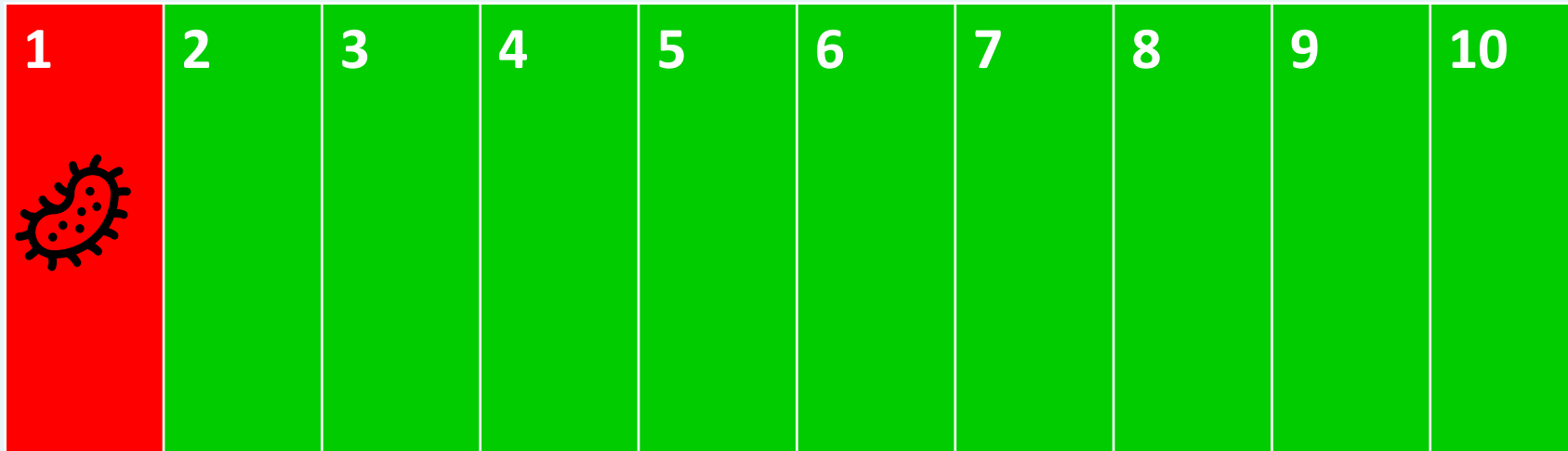
Answer #2: The next steps should be:

- Conduct root cause analysis and follow remedial actions as outlined in Appendix C.
- For the negative lot, conduct risk-based testing as outlined in Appendix C.
- If negative, proceed with harvest.

 <p>Lot A = 5 acres n=60, 1,500g</p>	 <p>Lot B = 5 acres n=60, 1,500g</p>
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Question #3: I conduct risk-based sampling on my 10-acre block. One of the lots is positive. Can I harvest the remaining 9 lots?



Answer #3: The next steps should be:

- Conduct root cause analysis and follow remedial actions as outlined in Appendix C.
- Negative lots may be harvested.



Question #4: What are some ways I can collect my 1500g sample to make it easier for lab analysis?

Figure 3. Illustration of n = 60 sampling scheme

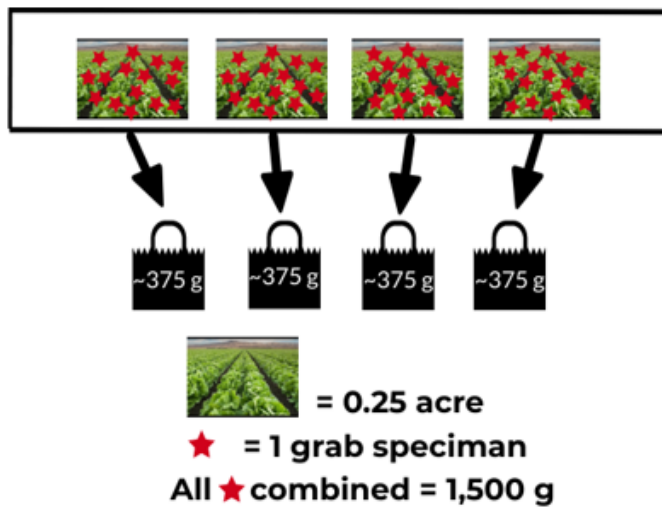


Figure 1. Illustration of n = 60 sampling scheme in head lettuce





1. Appendix C is a guidance document.
2. There is flexibility in the application of the guidance to reflect the various approaches different operations might adopt.
3. The document is based on best available science for designing and executing a robust sampling and testing plan that gives the user a high level of confidence in detecting contamination present at levels scientifically determined to increase the public risk of an outbreak.
4. For scientific references, please look at section V of the document.
5. There is an upcoming webinar where we'll explore the science that helped shape Appendix C.



Q&A





Upcoming Webinar

Current Science on Pre-Harvest Product Sampling and Testing

September 20 from 11:00 a.m. – 12:00 p.m. PT



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