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Current Science on Pre-Harvest Product Sampling and Testing

September 20, 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 current science, research gaps, and challenges
2. Panel discussion on common questions/myths behind current science
3. Audience Q&A

Background

- WG recently updated Appendix C: Guidance on Pre-harvest Product Sampling and Testing
- This guidance is based on specific assumptions (noted in the document) and also on input from recognized scientists
- Today's webinar focuses on the science behind product testing

Speakers

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Overview of current science, research gaps, and challenges

Science Guided Pre-Harvest Product Testing System for Leafy Greens

WHAT DOES IT TAKE TO BUILD DEFENSIBLE GUIDANCE ON INDUSTRY PRACTICES AND STANDARDS?

- Based on best available science
  - Judgement and expert opinions from “pooled” model outcomes
- Based on historical preharvest testing factors and outbreaks
  - Recalls and outbreaks from preharvest-tested lots
  - Recovery on point-of-purchase product from tested lots
- Balanced by experience and anticipated industry implementation factors
- Incorporates compromise to encompass commercial diversity
  - Lot dimensions, lot size, leafy green type, etc
  - Designed to allow a degree of flexibility within equivalency
  - Designed in anticipation of in-use learning and adjustments

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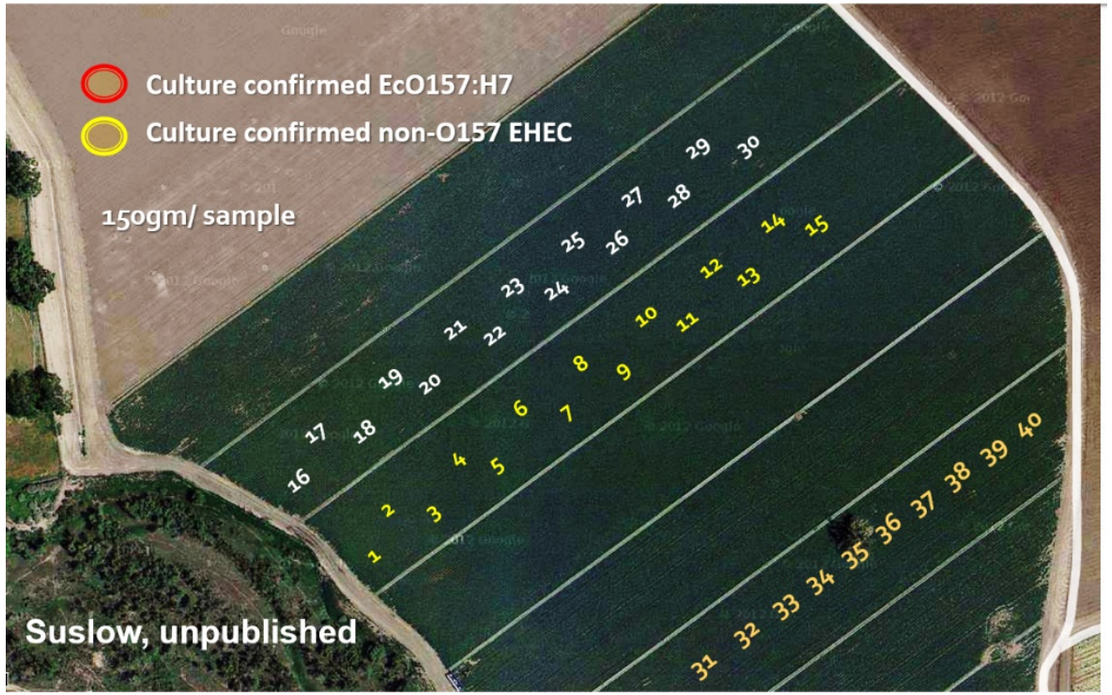
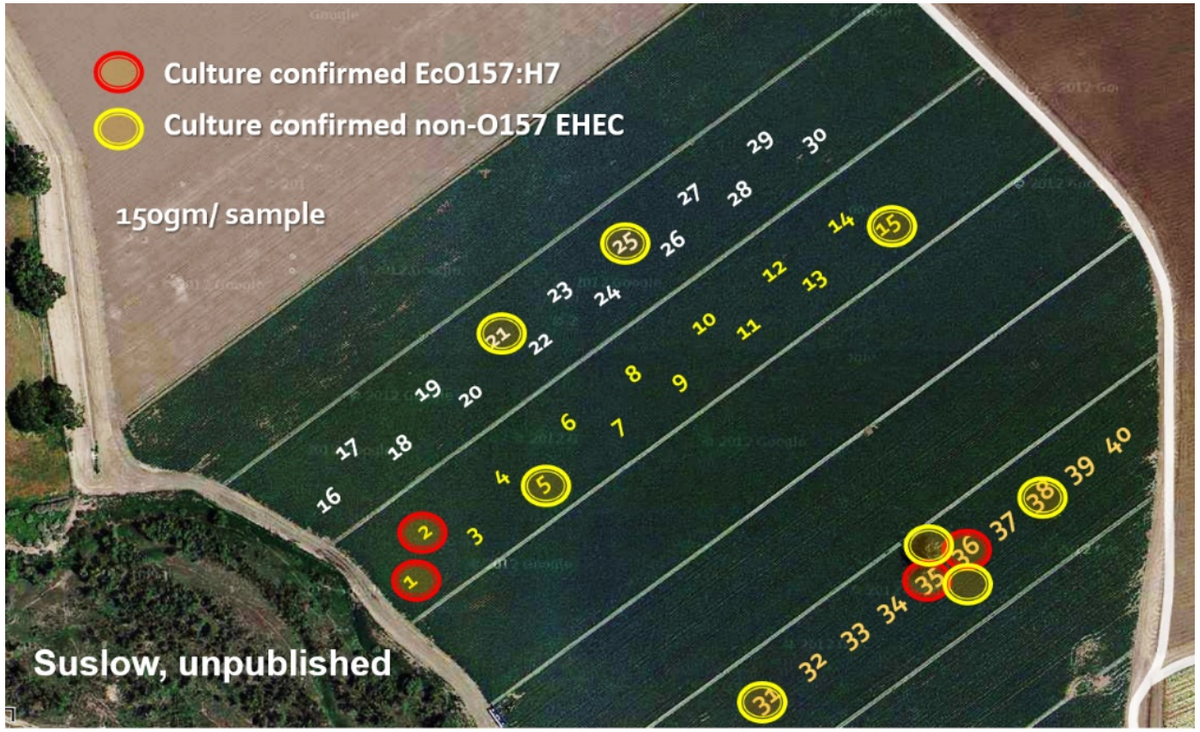
Industry Guidance Is The Product of Incomplete Science

- This does not mean the science is imperfect
  - The availability of data for the diversity of situations is imperfect
- Data used in models is invariably incomplete in open-environment systems
- Models inform us of a defensible path and road map to improvements
- Models set a trail-head for experience and building comparable data sets
  - Sampling guidance for systemic sources of contamination
  - Testing guidance
  - Measurement criteria

What Does a Systemic Contamination Event on LG Look Like?





What Does a Systemic Contamination Event on LG Look Like?

Flood direction

indicator *E. coli*

Plant	log CFU/g of lettuce					
	Flooded			Buffer	Control	
Inner half	1.26	7.00	4.44	1.26	1.26	
	4.28	4.76	2.58	1.26	1.26	1.26
	1.26	4.92	3.90	1.26	1.26	1.26
	3.33	1.78	2.15	1.26	1.26	

Plant	log CFU/g of lettuce					
	Flooded			Buffer	Control	
Outer half	1.26	2.56	1.26	1.26	2.26	
	1.78	4.66	1.26	1.26	1.26	1.26
	1.26	1.26	1.60	1.26	1.26	1.26
	1.26	1.26	1.26	1.26	1.26	

log CFU/g
5
4
3
2
1

Was The "Blended" Guidance Only Targeted for Industry Needs?

- No: The industry response to recurring outbreaks needed to be bold
- Sampling and Testing not to find contamination is not sustainable
  - Existing industry sampling and testing no longer acceptable
  - A non-emotional fix required a strong science backbone
- New insights provided from research and novel predictive models
  - New models were grounded in field sampling efforts
- Pre-harvest testing is just one component of the overall response

How were the Measurement Criteria Chosen and Vetted?

- No one approach satisfied the practical needs of the guidance
- The science is fundamentally complex, but its roots are simple
- Its all about the math!
- Drafts were developed within an extended process of input solicitation
- Technical subject matter experts commented on this blended approach

Is There a Simple Example of That Math?

Yes, but first some background

- Auto-calculator tool allows for comparison of five metrics of system-based contamination in a user defined lot.
- The foundation for these metrics, offered as guidance, are based on information provided by FDA from a 2018 *E. coli* O157:H7 outbreak on Romaine lettuce (United Fresh 2021)
- A uniform standard based on product weight was chosen, rather than the historical but indefensible % "defect" metric, which simply does not apply to open-field production
- The first step was a Good, Better, Best approach to the “simple” math

A Quick Review of Where We have Been Operating

Table 1. Probability of accepting a defective lot with indicated proportion of defective sample units

	Number of Sample Units			
% Defective	**15**	**30**	**60**	**100**
0.1	0.99	0.97	0.94	0.90
0.5	0.93	0.86	0.74	0.61
1	0.86	0.74	0.55	0.37
2	0.74	0.55	0.30	0.13
5	0.46	0.21	0.05	0.01

Adapted From: Microorganisms in Foods 7 - Microbiological Testing in Food Safety Management, 2002 International Commission on Microbiological Specifications for Foods (ICMSF) Kluwer Academic / Plenum Publishers NY, NY

- **0.5% Contamination per acre**
- **60 sample units tested**
- **74% probability of accepting lot**
- **But realistically, how many have requested 100% of samples processed?**

Example 1
Defect Level: 0.5%
Samples Units Tested: 30
Analysis: 86% probability that all 30 samples will be found negative and the lot will be accepted.

Example 2
Defect Level: 0.7%
Number of samples required to detect the defect with 95% probability: 428 sample units
Number of samples required to detect the defect with 90% probability: 329 sample units

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	# Plants with Contamination	
% Contamination Per acre	**Baby Spinach**	**Romaine Lettuce**
0.01	**300**	**24**
0.1	**3,000**	**235**
1.0	**30,000**	**2,350**

So, Let's Get Back to a "Simple Example" of the New Math

	1	cfu/pound			
	0.002	cfu/gram			
			2.5	grams/specimen	
			2	Assumptions of lbs area	
			2.5	grams/specimen x number of total subs to meet equivalency of 1500 g at calculated defect level	
			60	specimen count	
% Confidence in equivalency of detection determined to be protective of public health.					
		N (number of tests as defined above)			
	95%	9		BEST	
	90%	7		BETTER	
	75%	4		GOOD	

1 CFU/pound: 9 x 150 g

Outbreak Based Example | FDA Outbreak Prevention (1 CFU) | FDA Outbreak Prevention (0.7) | USDA ERS

	10	cfu/pound			
	0.022	cfu/gram			
			2.5	grams/specimen	
			2	Assumptions of lbs area	
			2.5	grams/specimen x number of total subs to meet equivalency of 1500 g at calculated defect level	
			60	specimen count	
% Confidence in equivalency of detection determined to be protective of public health.					
		N (number of tests as defined above)			
	95%	1		BEST	
	90%	1		BETTER	
	75%	0		GOOD	

10 CFU/pound: 1 x 150 g

Outbreak Based Example | FDA Outbreak Prevention (1 CFU) | FDA Outbreak Prevention (0.7) | USDA ERS

Another Quick Point on Some FAQs About Retesting

Probability of Detecting an Initial Positive, Then Finding a Second When the Lot is Retested

Initial Positive	Both Initial & Retest Positive
1 in 2	1 in 4
1 in 10	1 in 100
1 in 50	1 in 2,500
1 in 100	1 in 10,000

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Is There a Simple Example of That Math?

Contamination Detection Threshold	Mixed Models Assumption Convergence	Number of 300g subsamples establishes Confidence Level
1 CFU/pound	2.5g per grab	
	60 grabs per subsample	95% Best – 9 (1,350 g)
	Basic subsample unit is 150g but flexibility for validated alternatives up to 375g	90% Better – 7 75% Good – 4
Models vary but sampled mass is the determinate factor over lot size (ac)	Total Sample Tested – 1,500g* Sample weight (mass) calculated to achieve specified detection	

*** 1,500g was arrived at with industry input to accommodate 375g x 4 = 1,500 Total**

Is There a Simple Way to Explain What This Means?

Let's try, and then bring in our panel

- The combination of the sampled mass and detection protocol is critical
- The standard is intended to provide a 95% confidence in detection of ≥ 1 CFU/pound
  - Rejecting a lot likely to be a public health risk
- There is a calculated 5% residual risk of missing this level of contamination in a lot
  - For comparison, selecting 75% (4 x 150g = 600g) it leaves a 25% residual risk
- This is the accepted risk uncertainty, not the acceptable risk

DRAFT Post-Sampling Rough Cost Estimate Per GRL

	Pounds per acre (head lettuce)	Pounds per acre (baby greens)	Range assumption: $40-45/sample	Range assumption: $70-80/sample	Range assumption: $140-150/4 samples (individual PCR)
Individual samples (no pooling)	44000	18000	Price per 375g sample (4 enrichments run individually)	Price per 375g sample (4 enrichments/acre run wet pooled)	Volume Discount (4 samples submitted instead of 1)
Test cost per lb 1- 375g sample	$ 0.0010	$ 0.0025	$45	$75	$145
Test cost per lb for 4-375g sample	$ 0.0041	$ 0.0100			
Volume discount for 4-375g all done @ once (4 PCR rxns)	$ 0.0033	$ 0.0081			
Added cost per lb for 4-375g (4 individual PCR rxns)	$ 0.0031	$ 0.0075			
Added cost per lb for 4-375g (volume discount on 4 indiv. rxns)	$ 0.0023	$ 0.0056			
Oversized samples (wet pooling)					
Test cost per acre for 4 x 375g (pooled)	$ 0.0017	$ 0.0042			
Added cost per acre for 4x375g	$ 0.0007	$ 0.0017			

This calculated DRAFT cost estimate is provided for informational purposes and should not be relied upon for contractual business planning. Always contact your service provider for detailed pricing agreements.

WRAPPING UP

- There will be diversity within the situational implementation
- Following the guidance will provide the desired outcome equivalency
- The in-use data will provide the long-term benefit of informing predictive risk models
  - Data sharing with assured confidential governance is needed

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Panel Discussion


Q&A

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