FAQ for WGA Appendix C

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Revision suggestions by: <list names>

1,500 g! What!?! Why???

We understand that sampling and testing 1,500 is a large increase from current practices. And making this change will be expensive. Many groups are asking this question. So, we will use this FAQ to explain the logic, the process, and science behind the choice.

Briefly, WGA was interested in developing sampling guidance powerful enough to detect contamination like what may have caused recent produce outbreaks. This led them to a target contamination level, 1 CFU / lb. And that led to needing 1,500 g for reliable detection of contamination at that level.

Why 1 CFU / lb?

This number came from a food safety working group project coordinated by United Fresh entitled: "Would my sampling plan have detected contamination levels that resulted in an outbreak? A Thought Experiment." That work used the following logic

- FDA provided information that 'An outbreak of *E. coli* O157:H7 traced back to 44.93 acres dedicated to Romaine production caused 62 confirmed illnesses.'
    - That round to 45 acres causing ~1,600 cases, due to under-reporting and diagnosis
- The total yield of romaine is ~38,000 lb/acre
    - This calculated total lb of product in the 45 acres
- Roughly 1.3 million CFU of *E. coli* 157:H7 were likely consumed in this outbreak
    - Two approaches to dose-response calculations supported this number

By then comparing the total CFUs to the total lb of product involved in the outbreak, these calculations resulted in ~ 1 CFU / lb average contamination in the system. Therefore, WGA used this level of contamination as a threshold relevant to modern food safety risk management. Specifically, a testing program designed to detection contamination ≥ 1 CFU / lb.

Why randomly distributed contamination?

Because randomly, uniformly distributed contamination provides a defensible starting point, particularly in the absence of other information about how contamination would be clustered.

It is worth noting that, at this relatively low level of contamination, whole-head products like Romaine, that are > 1 lb, would likely contain only 1 or 0 CFUs.

But is it realistic to assume random, uniform contamination? Isn't produce often contaminated in non-uniform ways? How would that affect these estimates?

It is certainly possible for contamination to be non-unform and have some clustering. But, there is very little data describing actual contamination patterns in commercial-scale fields – because, fortunately, these events are very rare. Therefore, it is not currently possible to describe non-uniform contamination patterns in ways that researchers are confident accurately represent reality. Therefore, this document sticks with random contamination.

That said, research comparing sampling to detect randomly, uniformly distributed contamination to clustered, point-source contamination suggests that clustered contamination is potentially even more difficult to detect. Specifically, detecting clustered contamination requires that many small samples are taken to make up the large composite. This is because there is a reasonable chance at least one of the small samples is drawn from within the zone of clustered contamination.

These insights around clustered contamination are why the WGA guidance document suggest that the 1,500 g composite be taken using many small samples representative of the field – it moves towards a sampling pattern that would also be better for detecting clustered contamination without sacrificing power to detect uniform contamination.

Why 1,500 g?

This sample mass is a consequence of the above procedure. Specifically, 1,500 g is the approximate sample mass that must be tested for 95% of samples to test positive when coming from a field with exactly 1 CFU / lb contamination. This mass was verified by multiple academics using different calculation procedures. One procedure, detailed below, involved simulating contaminated fields and sampling them according to different sampling plans with different sample masses.

OK. We accept the need for the 1,500 g sample. How can we practically implement this?

Implementation may be challenging given the time, labor, and other resource constraints. A few key points that we understand may be difficult are that this guidance requires:

- Collecting a larger total composite mass than is typical, e.g. 1,500 g rather than 375 g
    - This will likely require additional in-field sampling labor to take the grab samples and more logistical support to collect and transport the composite to the testing lab
- Testing a larger total mass of sample than is typical, e.g. the whole 1,500 g rather than a single 375 g composite.
    - As mentioned in the WGA appendix, one possible way to implement this guidance would be to collect a total of 4 of 375 g composites that represent the total lot. Then subject each of those to existing 375 g sample testing procedures
    - Yes, this is essentially 4 X more lab testing.

Stasiewicz Lab Analysis of Frequently Asked Scenarios

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Approach:

Our team provided independent analysis of the power of the sampling plans frequently asked by growers in response to Appendix C. This process involved:

- Assuming hazard pressure of 1 CFU/lb, consistent with Appendix C assumption.
- Extracting sampling plan designs from Appendix C and emails sent to the team by WGA.
- Analyzing the power of all sampling plans to detect these hazards using our 'Food Safety Sampling' app developed as part of our Center for Produce Safety Project
    - http://go.illinois.edu/foodsafetysampling
    - Stasiewicz, MJ. 2021. Final Report: Simulation analysis of in field produce sampling for risk-based sampling plan development.
    - https://www.centerforproducesafety.org/researchproject/438/awards/Simulation_analysis_of_infield_produce_sampling_for_riskbased_sampling_plan_development.html

Assumptions:

- Contamination level: 1 CFU/ lb.
- Contamination distribution: Uniform.
- Field dimensions: Square fields, five or one-acre total area.

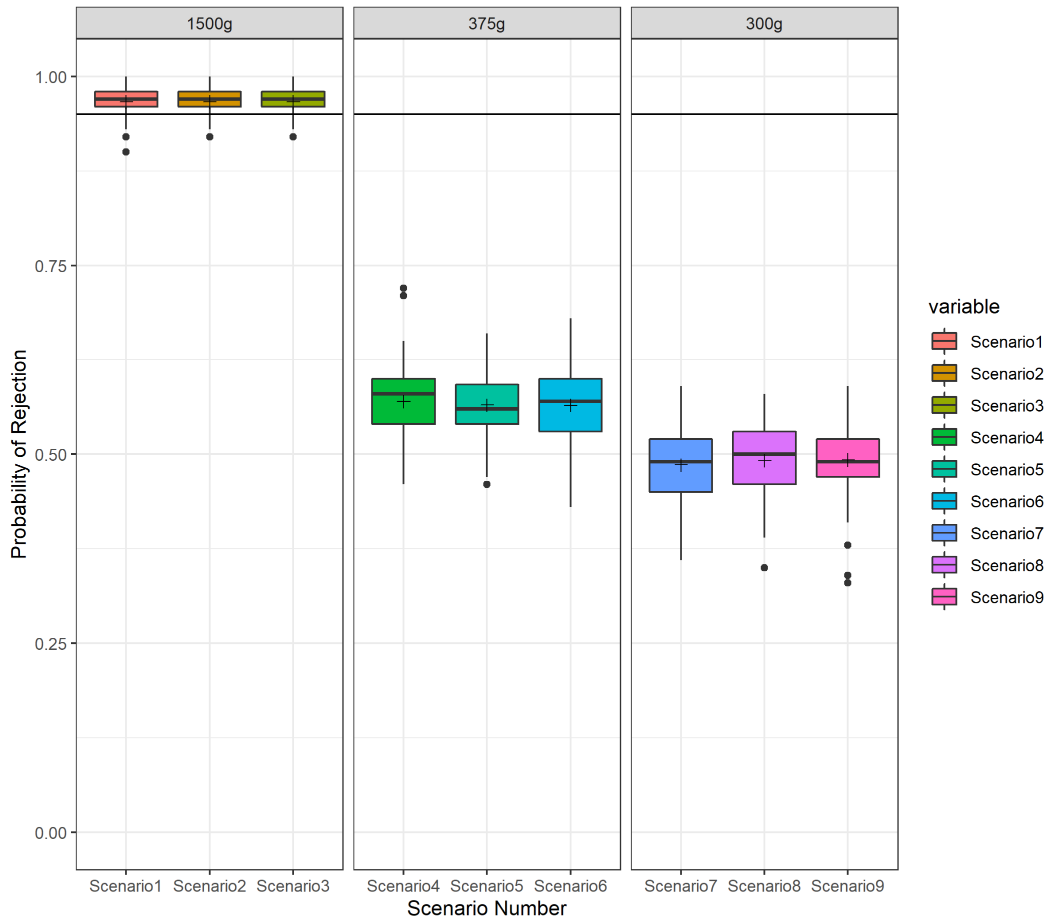
Table 1. Description of sampling scenarios.

All scenarios had a hazard pressure of **uniform contamination of 1 CFU/lb. (-2.7 log (CFU/g))**

Scenario Number - Name	Number of grabs	Composite mass [g]	Acre #	Strata	Sampling Strategy	Probability of Rejection - Median	Probability of Rejection – 95th Percentile
1 – 1500g 5 acre Simple Random	60	1,500	5 (142.2 x 142.2 m)	1	Simple Random	97%	94%
2 – 1500g 1 acre Stratified Random	60	1,500	1 (63.6 x 63.6 m)	5	Stratified Random	97%	94%
3 – 1500g 1 acre Simple Random	60	1,500	1 (63.6 x 63.6 m)	1	Simple Random	97%	94%
4- 375g 5 acre Simple Random	60	375	5 (142.2 x 142.2 m)	1	Simple Random	58%	48%
5- 375g 1 acre Stratified Random	60	375	1 (63.6 x 63.6 m)	5	Stratified Random	56%	48%
6- 375g 1 acre Simple Random	60	375	1 (63.6 x 63.6 m)	1	Simple Random	57%	48%
7 – 300 g 5 acre Simple Random	60	300	5 (142.2 x 142.2 m)	1	Simple Random	49%	40%
8- 300g 1 acre Stratified Random	60	300	1 (63.6 x 63.6 m)	5	Stratified Random	50%	41%
9 – 300 g 1 acre Simple Random	60	300	1 (63.6 x 63.6 m)	1	Simple Random	49%	42%

Figure 1: Analysis results boxplot

The horizontal line represents the 95% probability of rejection. Boxplots above the line represent sampling plans with power above 95% probability of rejection threshold.

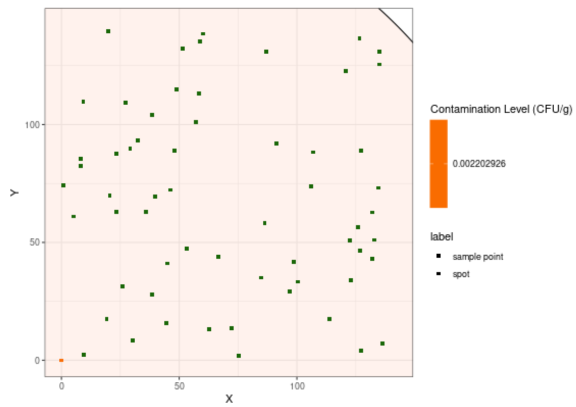


Conclusion:

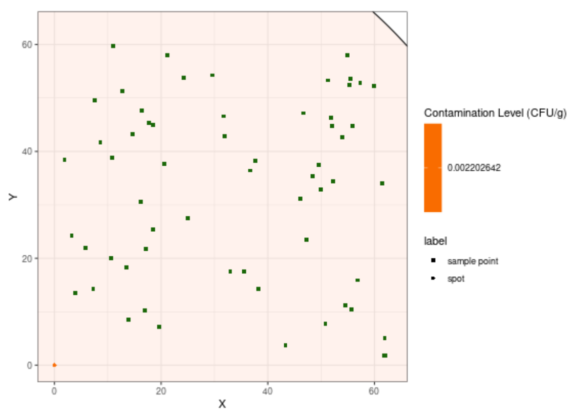
Use of an N60 sample of 1,500 g total does have >95% median probability to reject a field with > 1 CFU/lb of uniformly contaminated product. Based on these uniformity assumptions, plot size does not matter, nor does sampling pattern. When the contamination is uniformly distributed sample mass will be the main driver for the power of the sampling plan. However, plot size will affect the total number of tests required for a given grower production area, this translating to elevated sampling costs and labor. In addition, large plot sizes will cause larger lot rejections in the case of a positive test.

Example fields:

Field 1: 5 acre field. Uniform contamination, N60 simple random sampling:



Field 2: 1 acre field, uniform contamination, N60 simple random sampling



Field 3: 5 acre field, stratified into 5 x 1 acre subplots. Uniform contamination, N60 stratified random sampling: