Pre-harvest Product Testing Sampling Scenario Analysis

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Developed in collaboration with

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I. Comparison of Various Scenarios

Overall

Existing work on preharvest food safety sampling and testing plans (including work by Dr. Stasiewicz's lab as part of Center for Produce Safety Projects) support the general points that (i) increasing the total number of grab samples taken from a field will increase the chance of detecting a point-source of contamination in that field, and (ii) increasing the total composite sample mass tested will increase the chance of detecting widespread, low-level contamination in that field.

Based on these general findings, WG developed guidance for how to apply increasing total grab sample numbers and total composite sample mass during preharvest sampling. That guidance allows some flexibility to balance the increased costs of these increased sampling requirements by allowing (i) a range of the number of grab samples, (ii) sampling across larger than 1-acre lots, and (iii) different sampling for standard testing and intensified testing.

To assess the performance of the WG sampling plan guidance, Dr. Stasiewicz applied a previously developed preharvest sampling simulation to compare industry typical 1-acre sampling performance to various hypothetical and in-use scenarios consistent with WG Appendix C: Pre-harvest Product Sampling and Testing Protocols (as of Sept. 2021). These scenarios include testing across a range of (i) 1 to 40 acres of harvest fields, (ii) hypothetically contaminated with a pathogen either as widespread contamination at 1 CFU/lb or the same total number of pathogen cells in point sources cover 1% or 0.1% of the field, and (iii) applying sampling compositing 60 to 600 grabs of total mass of 375 to 15,000 g, depending on the plan and total acreage.

Results for all sampling plan analyses are presented in Table 1, with specific comparisons between some of the 12 scenarios described in the following results section. In addition, Figure 1 presents the power of each sampling plan to reject all three contamination types. Overall, all sampling plans that collected at least 1,500 g from the field were able to detect widespread contamination at 1 CFU/lb more than 95% of the time (which was expected, as the 1,500 g mass target was determined based on detecting this scenario. In addition, sampling plans that collected 240 grabs or more

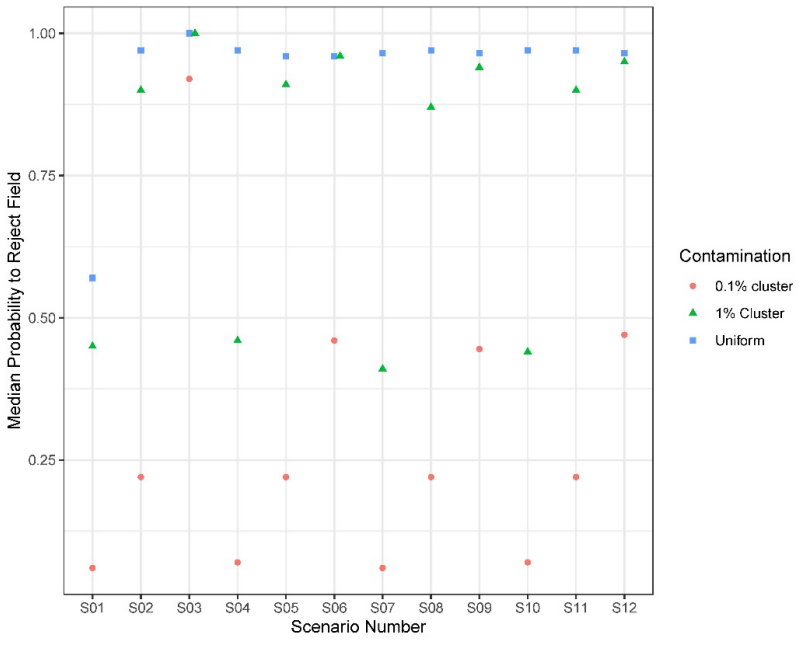

Figure 1. Power of sampling scenarios to detect three different contamination scenarios. See Table 1 for details of each plan.

generally has high power (87% or more) to detect a cluster of contamination covering 1% of the field. Most plans were not able to detect a cluster of contamination covering 0.1% of the field with high power.

Comparison scenarios – 1 to 40 acre, testing each acre

Scenarios 1-3 represent **typical 1-acre sampling recommendations** for pre-harvest testing of leafy greens. Essentially **one N60 composite totaling 375 g for every 1-acre field**. The **lot size range of 1, 4, and 40 acres** illustrates how the total mass and total grabs grow large when the total production acres are also large.

Findings: A single N60 composite of 375 in a 1-acre lot does not reliably detect either the widespread or point source contamination. 4 composites over 4 acres will detect widespread contamination, at 1,500 g total mass and 240 grabs. 40 composites over 40 acres will detect both widespread contamination and a 1% cluster (with a good, 92%, chance of detecting a 0.1% cluster. But this requires 15,000 g and 2,400 total grabs.

Comparison scenarios – 4 acre, taking 60 to 600 grabs

Scenarios 4-6 represent current **WG Appendix C guidance** for **standard testing** of leafy greens, in a **4 acre lot**. Essentially composite sampling totaling 1,500 g by taking at least 60 grabs, limiting each composite to 375 g to match current lab capabilities. Because that requires 4 composites, scenarios use stratified sampling by those 4 composites, which happen to each be 1 acre subsamples. The range of 60, 240, and 600 total grabs represents grabs consistent with current N60 practices up to a 10-fold increase from current and consistent with WG Appendix C guidance. **Critically, scenario 5 represents a plan that is equivalent to the comparison scenario 2.**

Findings: As expected, scenarios 5 and 2 match. If one is doing typical 1-acre sampling, they could be consistent with both their current practices and WG Appendix C by using a 4-acre lot size and taking 60 grab sample composites of 375 g each acre, for a total of 1,500 g total mass and 240 grabs. This would detect hazards at 1 CFU/lb over the whole field and have a good chance of detecting a similar hazard level spread across only 1% of the total field (here 400 lb).

If one used the most stringent Appendix C recommendations, taking 1,500 g using 600 total grabs (of 2.5 g), not only would this reliably detect widespread contamination at 1 CFU/lb, **this would also reliably detect a cluster of contamination covering 1% of the 4-acre lot**.

If one used the less stringent Appendix C recommendation to take 1,500 g using 60 total grabs (now of 25 g, **equivalent to a typical N60-style plans**), **this would still reliably detect widespread contamination** but would **not be likely to detect clusters of contamination covering 1% or less of the 4-acre lot**.

Comparison scenarios – 40 acre, taking 60 to 600 grabs

Scenarios 7-9 are **WG Appendix C guidance** for a 40-acre lot, **the maximum lot size**. These stratify sampling by the 4 composites, which happen to each be 10-acre subsamples. **Critically, scenario 9 shows how the most stringent Appendix C plan for 40 acres represent reduced testing requirements compared to the comparison scenario 3 for the**

same acreage. A reduction from 15,000 to 1,500 total mass, i.e. from 10 to 4 subsamples of 375 g; A reduction from 2,400 to 600 individual grabs.

Findings: As expected, all the Appendix C recommendations for 40-acre sampling taking 1,500 total g reliably detect widespread contamination. As the total grab sampling number increases from 60 to 600 total grabs, the power to detect a cluster covering 1% of the field increases from 41% to 94%.

It is worth noting this **standard testing plan for 40 acres** using 600 grabs has a **pretty good chance (94%) of detecting a 1% cluster** at a **10-fold reduction in total sample mass** and a **4-fold reduction in total sample grabs** compared to typical 1-acre testing which has a very good chance (~100%) of detecting the same 1% cluster. Plans differ at the 0.1% cluster, where 1-acre testing has a 92% chance of detection, and WGA standard testing has only a 45% chance of detection.

Comparison scenario – 1 acre, taking 60 to 600 grabs

Scenarios 10-12 represent **WG Appendix C guidance** for **intensified testing** of leafy greens, **requiring a 1-acre lot**. For comparisons, **scenario 10 represents a 4-fold increase in sample mass compared to comparison scenario 1 for the same acreage**. Similarly, **scenario 12 represents also a 10-fold increase in the number of grabs compared to scenario 1**.

Findings: As expected, scenarios 1 and 10 give similar results. This confirms that **typical 1-acre sampling is equivalent to growers performing what WG is calling their 'intensified' testing in Appendix C**. Intensified testing **reliably detects widespread contamination**. The risk-based testing using **600 total grabs over 1 acre also reliably detects a cluster of contamination covering 1% of the field**.

Comparison scenario – 4 or 5 acres

Scenarios 2A and 4-5A represent WG Appendix C Guidance for standard testing on either **4 or 5-acre lots**. These are meant to directly compare performance between the 4-acre scenarios that match with extensions of typical 1-acre testing amounts, and the 5-acre scenarios that directly match Appendix C guidance.

Findings: The **results for 4 and 5-acre testing are not meaningfully different**. Therefore, the primary scenario analysis using 4 acres provides appropriate guidance for the performance of 5-acre testing.

II. Comparisons Between WG Sampling Plans and Other Sampling Plans

Table 1. Comparison of sampling plans by median power to detect a pathogen in a field with a product density of 10,000 lb/acre, at a given pathogen hazard level, covering a given portion of the field.

Sampling Plan Description		**Overall Parameters**			**Distribution of grabs by size, subsample, and location**					**Hazard level**	**Power to detect at least 1 pathogen cell with**		
Testing Type	Scenario Number	**Lot size** (acre)	**Total sample size** (grams) per lot	**Total sample grabs** (number) per lot	Required # of grab specimen per subsample	Approximate grab specimen size (grams)	Required # of sub-samples	Sub-sample size (grams)	Sampling location	Total pathogens in lot (CFU)*	**1 CFU/lb*** widespread contamination covering 100% of lot	**Cluster covering 1%*** of lot	**Cluster covering 0.1%*** of lot
Typical 1-acre Testing (1-40 acres)	1**	**1**	**375**	**60**	60	6.3	**1**	375	Random, stratified by 1 subsample per acre	10,000*	57%	45%	6%
	2	**4**	1,500	240	60	6.3	**4**	375		40,000	97%	90%	22%
	3	**40**	**15,000**	**2,400**	60	6.3	**40**	375		400,000	100%	100%	92%
WG Standard Testing (4 acres)	4	4	1,500	60	15	25.0	4	375	Random, stratified by 1 subsample per acre	40,000	97%	46%	7%
	5	**4**	**1,500**	**240**	60	6.3	**4**	375		40,000	96%	91%	22%
	6	4	1,500	600	150	2.5	4	375		40,000	96%	96%	46%
WG Standard Testing (40 acres)	7	40	1,500	60	15	25.0	4	375	Random, stratified by 1 subsample per 10 acres	400,000	97%	41%	6%
	8	40	1,500	240	60	6.3	4	375		400,000	97%	87%	22%
	9	**40**	**1,500**	**600**	150	2.5	**4**	375		400,000	97%	94%	45%
WG Intensified Testing (1 acre)	10	**1**	**1,500**	**60**	15	25.0	**4**	375	Random, stratified by 1 subsample each 1/4 acre	10,000	97%	44%	7%
	11	1	1,500	240	60	6.3	4	375		10,000	97%	90%	22%
	12	**1**	**1,500**	**600**	150	2.5	**4**	375		10,000	97%	95%	47%

*To have the same number of pathogen in the cluster a 1% cluster contains 100 CFU/lb covering between 100 to 4,000 lb of product (for 1 acre to 40 acres, respectively). The 0.1% cluster contains 1,000 CFU/lb over 10 to 400 lb of product.

**Colored rows and bolded text are mentioned in the text comparisons.

III. Comparisons Between 4 acre and 5 acre Sampling Plans

Table 2. Comparison of sampling plans by median power to detect a pathogen in a field with a product density of 10,000 lb/acre, at a given pathogen hazard level, covering a given portion of the field.

Sampling Plan Description		**Overall Parameters**			**Distribution of grabs by size, subsample, and location**					**Hazard level**	**Power to detect at least 1 pathogen cell with**		
Testing Type	Scenario Number	**Lot size** (acre)	**Total sample size** (grams) per lot	**Total sample grabs** (number) per lot	Required # of grab specimen per subsample	Approximate grab specimen size (grams)	Required # of sub-samples	Sub-sample size (grams)	Sampling location	Total pathogens in lot (CFU)*	**1 CFU/lb*** widespread contamination covering 100% of lot	**Cluster covering 1%*** of lot	**Cluster covering 0.1%*** of lot
Typical 1-acre Testing (1-40 acres)	2	**4**	1,500	240	60	6.3	**4**	375	Random, stratified by 1 subsample per acre	40,000	97%	90%	22%
	2A	5	**1875**	**300**	60	6.3	5	375		50,000	99%	95%	27%
WG Standard Testing (4 acres)	4	4	1,500	60	15	25.0	4	375	Random, stratified by 1 subsample per acre	40,000	97%	46%	7%
	5	**4**	**1,500**	**240**	60	6.3	**4**	375		40,000	96%	91%	22%
	6	4	1,500	600	150	2.5	4	375		40,000	96%	96%	46%
WG Standard Testing (5 acres)	4A	5	1500	60	15	25.0	5	375	Random, stratified by 1 subsample per acre	50,000	97%	44%	7%
	5A	5	1500	240	60	6.3	5	375		50,000	97%	91%	23%
	6A	5	1600	600	150	2.5	5	375		50,000	97%	96%	45%

*To have the same number of pathogen in the cluster a 1% cluster contains 100 CFU/lb covering between 100 to 4,000 lb of product (for 1 acre to 40 acres, respectively). The 0.1% cluster contains 1,000 CFU/lb over 10 to 400 lb of product.

IV. Comparison of Sampling Plans based on 90% confidence level

Table 3. Sampling plans by median power to detect a pathogen in a field with a product density of 10,000 lb/acre, at a given pathogen hazard level, covering a given portion of the field.

Overall Parameters			**Distribution of grabs by size, subsample, and location**					**Power to detect at least 1**	**Power to take at least 1 sample within a**		
Sampling Lot size (acre)	**Total sample size** (grams) per lot	**Total sample grabs** (number) per lot	Required # of grab specimen per subsample	Approximate grab specimen size (grams)	Required # of sub-samples	Sub-sample size (grams)	Sampling location	**1 CFU/lb*** widespread contamination covering 100% of lot	**Cluster covering 1%*** of lot	**Cluster covering 0.1%*** of lot	**Cluster covering 400 lb** of lot ***
1	1,025	60	20	18	3	350-375	Stratified random sampling with 1 subsample per 1/3 acre#	90%	45%	6%	91%
1	1,025	180	60	6	3	350-375		90%	84%	16%	100%
1	1,025	600	200	1.7	3	350-375		90%	100%**	45%	100%
3	1,025	60	20	18	3	350-375	Stratified random sampling with subsample per 1 acre#	90%	45%	6%	55%
3	1,025	180	60	6	3	350-375		90%	84%	16%	91%
3	1,025	600	200	1.7	3	350-375		90%	100%**	45%	100%
30	1,025	60	20	18	3	350-375	Stratified random sampling with 1 subsample per 10 acres#	90%	45%	6%	8%
30	1,025	180	60	6	3	350-375		90%	84%	16%	21%
30	1,025	600	200	1.7	3	350-375		90%	100%**	45%	55%

*To have the same number of pathogens in the cluster, a 1% cluster contains 100 CFU/lb covering between 100 to 4,000 lb of product (for 1 acre to 40 acres, respectively). The 0.1% cluster contains 1,000 CFU/lb over 10 to 400 lb of product.

** This 100% power is just about if a sample is taken from the contaminated zone. That is true regardless of the pathogen level in zone. The overall power may be overstated if the individual grab sample mass is too small to be confident once would always recover a pathogen. Under the assumptions in this table the 1% cluster contains pathogens 100 CFU / lb, which is 0.22 CFU / g or about 1 pathogen in 4.5 g. Therefore, one would need a grab sample mass of at least 4.5 g to be very confident a single grab from the cluster would recover the pathogen.

*** A 400 lb lot covers 4% of the 1 acre field, 1.3% of the 3 acre field, and 0.13% of the 30 acre field.

Take the 3 acre sampling lot as an example. This would mean dividing the lot into three 1 acre sublots. Within each 1 acre sublot, take one composite sample of 350-375 grams. To gather the composite, take the desired number of grabs per subsample at random locations within the sublot.