

**Project Title:**

**Flexible risk process models to quantify residual risks and the impact of interventions**

**Project Period:**

January 1, 2025 – December 31, 2025 (extended to January 31, 2026)

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**Objectives:**

- Year 1. Build a supply chain risk model (SCRM) for Shiga toxin–producing *Escherichia coli* (STEC) and *Listeria monocytogenes* (LM) simultaneously in leafy greens to identify important risk factors and the impact of interventions on those risks. [Completed in Y1 of 3-year renewable project]
- Year 2. Improve the STEC and LM model with feedback from CPS stakeholders, and adapt the SCRM to accommodate additional pathogens and commodities. [Completed in Y2]
- Year 3. Define an adaptable SCRM system for assessing the importance of previously unmodeled candidate risk factors. [Completed in Y3]

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## FINAL REPORT

### Summary of Findings and Recommendations

#### Summary of Findings (Y1–Y3)

- We systematically reviewed 11 and 7 recent risk assessments for Shiga toxin–producing *Escherichia coli* (STEC) and *L. monocytogenes* in leafy greens. That review extracted 70 unique parameters that can support the development of future leafy greens risk assessments.
- A retail positive test was an outcome measure that industry stakeholders were willing to engage with.
  - Highest risk lots were those with >1 in 10 chance of a retail positive test, and considered lots of “public health risk”.
  - The overall probability of a positive test across all lots was defined as “recall risk”.
- The Supply Chain Risk Model (SCRM) was used to simulate a leafy green supply chain contaminated with Shiga toxin–producing *Escherichia coli* (STEC) and we assessed tradeoffs between (i) improved process controls and (ii) additional product testing.
  - Rare, high-level contamination events drove recall risk.
  - Implementing improved process controls and additional product testing each reduced public health and recall risks.
  - However, additional product testing reduced recall risk at the expense of rejecting many lower-risk lots.
- Additional scenarios were developed to assess the impact of small-scale failures resulting in contamination or deviations from food safety protocols in leafy green supply chains.
  - Modelling inadequate process wash water control (specifically, maintaining adequate free chlorine only about half the time) increased both public health and recall risks, even when initial contamination variability was low.
  - Modelling preharvest failures resulting in contamination, specifically agricultural water treatment failure, small animal fecal contamination, or inadequate harvest sanitation between harvests, resulted in small changes to public health risk and recall risk.
- Preharvest testing plans with more total mass are more effective at detecting and managing risk from contamination that is spread uniformly across a field, whereas plans with more total grabs are better for managing risk from contamination clustered in specific areas of a field.
- Altering aspects of irrigation water testing plans (such as increasing sample volumes or numbers) can improve the likelihood of detecting contamination in irrigation water and minimize produce safety risks.

#### Recommendations

Industry experts and association representatives could work together to define the frequency and effects on pathogens of common industry practices that are not well represented in the academic literature. Doing so would allow future modelling efforts to analyze different practices and emerging risks where there is not currently enough public data for informed modelling. This would allow modelling to be routinely used in industry discussions around food safety risk and negotiating management strategies.

## **Abstract**

Industry engagement is a crucial aspect to ensuring that decision support tools can be leveraged to address real-world produce industry needs. We developed a supply chain risk model (SCRM) and demonstrated its use by modelling leafy greens contaminated with Shiga toxin–producing *Escherichia coli* (STEC). We initially assessed trade-offs between food safety practices for reducing recall risk and public health risks, showing that rare, high-level contamination events drive risk, but that risk can be managed through improved downstream processing or additional product testing. However, implementing additional product testing results in rejecting many lower-risk lots. We then modelled the impact of small-scale contamination or deviations from food safety protocols for leafy greens, revealing that while most small-scale contamination has a limited impact on risk, inadequate process control substantially increases risk. In the final stage of the project period, we emphasized industry engagement, including revising the SCRM to address industry needs, and subsequently applying the revised SCRM to evaluate scenarios of concern for industry. Revising the SCRM enabled new capabilities, particularly modelling clustered contamination within a lot. Industry partners expressed interest in evaluating preharvest testing plans. Our analysis revealed that preharvest testing plans with more total mass are better at managing risk from lower-level uniform contamination, whereas plans with more total grabs are better for highly-clustered contamination. Additionally, we used the SCRM to address industry interest in evaluating one current and six alternative testing plans for Type A irrigation water. Our analysis revealed that various changes to testing plans, such as increasing sample volume or sample size, could yield comparable risk reductions. Overall, our work supports that proactive industry engagement can encourage the use of computational tools to practically address produce safety risks.

## **Background**

Broadly, this three-year project entailed developing a model to meet the fresh produce industry's need for a flexible tool to identify the most effective food safety management practices for mitigating risk and the impact of food safety system failures on end-product risk. At the beginning of the project period, we addressed uncertainty around the variability of the initial contamination of fresh produce commodities, which management practices best control contamination, and where in the process these practices are most effective, posing a challenge for the industry on how to make science-based decisions for requirements and guide future research priorities. Thus, we developed the initial supply chain risk model (SCRM), selecting leafy greens and Shiga toxin–producing *Escherichia coli* (further referred to as STEC) as our pathogen-commodity combination of interest to parametrize a fresh produce supply chain. A literature review was conducted to identify the most reliable, up-to-date parameters for simulating a leafy green supply chain.

After the initial development of the model and scenarios assessing the trade-offs between food safety management practices, conversations with CPS stakeholders identified the need to develop scenarios simulating deviations from standard food safety protocols or contamination from small-scale failures that could occur during preharvest. We continued to focus on leafy greens and STEC, based on our advisory council feedback, though the model was designed to accommodate other pathogen-commodity combinations. To this end, we developed several what-if scenarios in the second year of this project, covering contamination from agricultural water, small animal feces, and harvester equipment. We also modelled a scenario representing a deviation from a food safety protocol, in which process wash control would be lost. Review of these scenarios with experts in the fresh produce industry indicated that revisions to the model were needed to better represent the spread of contamination. For example, fecal contamination from a small animal would not be expected to affect an entire field of produce uniformly.

To address this feedback, we revised the model to represent non-uniform preharvest contamination. In this revised model, contamination can now variably impact a simulated lot. This enabled us to more accurately represent scenarios that involve deviations from food safety protocols and small-scale failures. In the third year of this project, we began conversations with CPS stakeholders about how the supply chain risk model could be used to answer questions about various food safety practices being implemented across the industry, such as preharvest sampling plans and irrigation water testing. For preharvest sampling plans, stakeholders were interested in which plans would most contribute the most to managing risks from different contamination profiles within a field. We were provided with three industry-relevant sampling plans for leafy greens and evaluated them across preharvest contamination profiles with different contamination patterns, while keeping the same hazard pressure. Similarly, for irrigation water, stakeholders were interested in comparing how various testing plans for Type A water would perform in detecting contamination and minimizing risks throughout the supply chain. We thus evaluated the risk of a product-positive STEC test under the current testing plan and six alternative testing plans for routine verification of Type A water.

## **Research Methods and Results**

### Methods – Literature Review to Inform Parameters for a Leafy Green Supply Chain

To support the development of the SCRM, we identified gaps in the parameters of existing risk assessment models and incorporated parameters through a literature review. The critical review focused on recent risk assessments for STEC and *L. monocytogenes* in leafy greens, and searches of these models were performed in Web of Science and PubMed using a set of predefined search terms. The extracted parameters from the identified risk assessment models were organized into five standard supply chain stages: (i) preharvest, (ii) harvest, (iii) processing, (iv) presentation to consumer, and (v) consumer handling. For each stage, relevant parameters were compiled, along with their underlying data sources and the mathematical formulas used to obtain the data. After compiling key parameters and their associated data sources, we conducted targeted literature searches to address specific gaps identified during the parameter extraction process. These additional data were incorporated into the review to support future risk assessments of leafy greens.

### Results – Literature Review to Inform Parameters for a Leafy Green Supply Chain

We identified 11 and 7 recently published quantitative models and risk assessments for STEC and *L. monocytogenes*, respectively, in leafy greens, and extracted a total of 70 unique key parameters (55 for STEC and 25 for *L. monocytogenes*, 10 shared). Many gaps identified during the review process appear to result from authors making simplifying assumptions, mainly due to a lack of data to fit parameters in their models. Notably, there are limited data available on pathogen concentration in the preharvest and harvest supply chain stages (none of the reviewed *L. monocytogenes* models included key parameters in these supply chain stages), and pathogen transfer parameters that are specific to different leafy green commodities across all supply chain stages. We also observed repeated use of the same data sources, particularly for parameters commonly used in the Presentation to Consumer and Consumer Handling supply chain stages, suggesting a need for new data collection. Overall, our comprehensive review of existing risk assessments not only informed the development of the SCRM but also provided a foundation for improving future risk assessment of leafy greens, thereby enhancing the understanding of risk dynamics within fresh produce supply chains. This work was published in the *Journal of Food Protection*. Tables listing all parameters and relevant sources identified through the review can be found in the published manuscript (i.e., Tables 3-6) (Jung et al., 2025).

### Methods – Initial SCRM Development and Scenarios for Evaluating Tradeoffs Between Food Safety Practices in a Leafy Green Supply Chain

We initially developed a user-adaptable model in @RISK software, but later converted it to R 4.5.2 (R Core Team, 2025) during the first year of the project period. The model was programmed with five stages representing a leafy green supply chain, a contamination event with *E. coli* O157:H7 (further referred to as STEC), and one 300-gram test per lot at retail as the risk outcome measure (see **Figure 1**). Baseline contamination scenarios (mean ( $\mu$ ) =  $-2.65 \log_{10}(\text{CFU/g})$ ) had high (standard deviation ( $\sigma$ ) =  $0.8 \log_{10}(\text{CFU/g})$ ) and low ( $\sigma=0.2 \log_{10}(\text{CFU/g})$ ) variability. The probability of contamination was calibrated to yield a risk of a positive retail test of  $\sim 1$  in 4,000. We modeled adding two industry-relevant management practices to each baseline: finished product testing (8 of 375-gram tests per lot) and improved process controls (an additional  $\mu = -0.87 \log_{10}(\text{CFU/g})$  reduction). Lots were categorized by the risk of producing a positive retail test. Details of the parameter values used for the initial leafy green baseline scenario are provided in the peer-reviewed research article for this model in Table 1 of Pinto et al. (2025).

### Results – Initial SCRM Development and Scenarios for Evaluating Tradeoffs Between Food Safety Practices in a Leafy Green Supply Chain

The baseline risk of a positive test in the low-variability scenario (1 in 20,000) was lower than in the high-variability scenario (1 in 4,500), indicating that rare, high-level contamination drives risk. To evaluate trade-offs, we modeled two well-studied, frequently used interventions: additional product testing (8 of 375-gram tests/lot) and improved process controls (an additional  $-0.87 \pm 0.32 \log_{10}(\text{CFU/g})$  reduction). Improved process controls better reduced recall risk (to 1 in 115,000 and 1 in 26,000 for low- and high-variability, respectively), compared to additional product testing (to 1 in 21,000 and 1 in 11,000 for low- and high-variability, respectively). All results are listed in **Table 1**. For low-variability contamination, no highest-risk lots existed. Under high-variability contamination, both interventions removed all the highest-risk lots (about 0.05% of the total). Yet, additional product testing rejected more lower-risk lots (about 1% of total), suggesting meaningful food waste trade-offs. This model evaluates tradeoffs between interventions using industry-relevant risk metrics to support decision-making and can be adapted to assess other commodities, process stages, and less-studied interventions. This work, published in the *Journal of Food Protection*, contains additional discussion of findings in Tables 2, 3, and 4 of Pinto et al. (2025).

### Methods – Revisions to the SCRM to account for heterogeneous field contamination and using it to assess clustered contamination scenarios

Our previously published work describes the development of the SCRM and parametrization of a baseline scenario for a leafy green supply chain (Pinto et al., 2025). In this initial version of the SCRM, the user could define model step types such as contamination/removal, increase/reduction, product test, or risk output test. Contamination/removal steps and increase/reduction steps were defined by a distribution of values. At each step, the user inputs the probability of occurrence, i.e., the proportion of iterations in which the step occurs. However, a limitation of this model was that within each iteration, the step type (e.g., contamination, reduction) could only be applied uniformly to the entire lot. Specifically, for contamination/removal or increase/reduction model step types, a single point source value was drawn from each distribution per iteration. And, thus, for the product test or risk output test step type, the test is applied to the contamination level, which represents the entire lot. Thus, the SCRM has been revised to address this limitation. Briefly, each iteration of the model still represents one produce field (a lot), but now each is split into 100 segments (**Figure 2**).

At each model step, the probability of occurrence still functions as the user-defined proportion of iterations that receive the defined model step, e.g., a reduction, contamination, etc. However, the user can now also define a new parameter, scope. That is, the proportion of the segments per iteration (which must be an integer) that receive a given step type within one iteration. For example, when the scope is set to 100% for a contamination event, this means all 100 segments receive contamination (functionally, uniform contamination). At a 10% scope for a contamination event, this means 10 of 100 segments receive contamination. When the scope is set below 100% for a contamination event, the user can also define the alignment of the contamination “cluster”, either as left, right, randomly located in a cluster of adjacent segments, or randomly dispersed among segments. Scope can be defined for increase/reduction steps as well. For example, when the scope is set below 100% for an increase/reduction step, the segments within an iteration to which the increase/reduction is applied are randomly selected in the model.

Product and risk output tests are applied to the entire field, and a single segment is randomly selected for testing (**Figure 3B**). Tests yield a probability of being positive, which is subsequently used in a Bernoulli distribution to determine whether a positive test result was recorded (i.e., 1 if positive, 0 if negative). If any tests yield a positive result, the entire iteration is rejected, effectively changing the contamination level to 0, to represent removal from the system prior to the model output, the risk output test.

Following this update, we developed three initial contamination scenarios to test the new system, under both high and low variability contamination:

1. **Low-Level, Uniform Contamination:** All segments are contaminated with an average of 1 CFU/lb (**Figure 2A**). Contamination is lognormally distributed [ $\mu = -2.65 \log_{10}(\text{CFU/g})$ ] with either high [ $\sigma = 0.8 \log_{10}(\text{CFU/g})$ ] or low [ $\sigma = 0.2 \log_{10}(\text{CFU/g})$ ] variability.
2. **Medium-Level, Large Cluster Contamination:** A randomly located cluster set to 10% of the field was contaminated with an average of 10 CFU/lb (**Figure 2B**). Contamination is lognormally distributed [ $\mu = -1.65 \log_{10}(\text{CFU/g})$ ] with either high [ $\sigma = 0.8 \log_{10}(\text{CFU/g})$ ] or low [ $\sigma = 0.2 \log_{10}(\text{CFU/g})$ ] variability.
3. **High-Level, Small Cluster Contamination:** A randomly located cluster set to 1% of the field was contaminated with an average of 100 CFU/lb (**Figure 2C**). Contamination is lognormally distributed [ $\mu = -0.65 \log_{10}(\text{CFU/g})$ ] with either high [ $\sigma = 0.8 \log_{10}(\text{CFU/g})$ ] or low [ $\sigma = 0.2 \log_{10}(\text{CFU/g})$ ] variability.

#### Methods – Sampling Functions and Preharvest Testing Performance

The model’s sampling functions were also redesigned for this new system, allowing SCRM to also simulate more complex sampling operations. This involved redesigning existing sampling functions to operate appropriately within the model’s segment system, enabling us to develop an acre-based preharvest sampling test (**Figure 3A**). An industry partner provided us with three different preharvest sampling plans that could be used for scenario analysis of leafy greens:

1. **Baseline Preharvest Testing Plan:** 375 g total sample mass per test, 60 grabs per test, 1 test per acre
2. **High Grabs Testing Plan:** 375 g total sample mass per test, 100 grabs per test, 1 test per acre
3. **Multiple Tests Plan:** 1,500 g total sample mass per test, 60 grabs per test, 1 test per 2 acres (modelled as 375 g, 15 grabs per test, 2 tests per acre, to represent lab capabilities)

These three plans were tested against three initial contamination scenarios (with both low and high variability) to determine if any plans showed better performance in one or more scenarios.

## Results – Sampling Functions and Preharvest Testing Performance

Simulating different preharvest testing plans revealed that the effectiveness of plan designs depends on the field's contamination pattern and concentration.

Uniform contamination was best managed by the Multiple Tests Plan (**Table 2**). Specifically, the overall risk of a retail positive was lowest for the multiple tests plan (~1 in 462,000) than either the baseline or high grabs plans (~1 in 125,000). The low concentration and high prevalence of contamination in the field is more likely to be detected with a larger number of tests.

In contrast, the Baseline Preharvest Testing Plan and the High Grabs Testing Plan better managed large cluster contamination. Specifically, the overall risk of a retail positive was lowest for these plans (~1 in 1.2 million) compared to ~1 in 300,000 for the multiple tests plan. The larger number of grabs is more important for successfully picking a segment within a contamination cluster. The High Grabs Testing Plan was most effective in managing small-cluster contamination.

## Methods – Scenario development: Small-scale failures or deviation from food safety protocols

Four produce industry-relevant scenarios were developed to represent either (i) small-scale failures through preharvest or harvest contamination or (ii) deviations from food safety protocols through decreased system performance during downstream processing. Briefly, the three small-scale failure scenarios modeled included agricultural water treatment failure, ineffective harvester sanitation, and small animal fecal contamination. The contamination sources for the small-scale failure scenarios were selected based on their relevance, as per recent recalls or outbreak investigations associated with leafy greens, which attributed agricultural water (sediment) (FDA, 2018, 2019), harvester equipment (FDA, 2022), or animal feces (FDA, 2023) as the contamination source. The deviation from the food safety protocols scenario was modeled as an inadequate process wash at the Processing model step. This scenario was chosen because implementing a wash step (when well-controlled) during the processing of fresh-cut leafy greens provides a critical opportunity to achieve microbial reduction. The scenarios were applied to the previously parametrized baseline scenario for leafy green contamination with STEC ( $\mu = -2.65 \log_{10}(\text{CFU/g})$ ), with high ( $\sigma = 0.8 \log_{10}(\text{CFU/g})$ ) and low ( $\sigma = 0.2 \log_{10}(\text{CFU/g})$ ) variability, as shown in **Figure 4**. Lots were, again, categorized by the risk of producing a positive test at retail. Briefly, the scenarios were described, and their inputs were as follows:

1. **Agricultural water treatment failure:** This scenario was developed to assess the impact of irrigating a leafy green field two days before harvest with water that (when hypothetically, if tested, would) have more than one 100-ml sample at the threshold for generic *E. coli* in Type A water, 10 MPN/100 ml, as per the Leafy Green Marketing Agreement (LGMA) *Commodity Specific Food Safety Guidelines* for lettuce and leafy greens (LGMA, 2025) and the LGMA *Appendix A AgWater System Assessments and Remediation Guidelines* (LGMA, 2021). The goal of the scenario was to answer an industry-relevant question, such as, “**What if I discovered the chemical pump for my irrigation tank was broken at harvest (two days after irrigation)?**” We assume the scope of contamination as 100%, representing a sprinkler irrigation system, though evidence suggests contamination can still spread to leafy greens when using other irrigation methods (Solomon et al., 2002). The resultant data were found to best fit a triangular distribution. The input to the SCRUM was a triangular distribution with a minimum of  $-3.92 \log_{10}(\text{CFU/g})$ , a mode of  $-2.84 \log_{10}(\text{CFU/g})$ , and a maximum of  $-2.58 \log_{10}(\text{CFU/g})$ . The probability of occurrence was assumed to be the same as that of the baseline scenario contamination, 8.165%.
2. **Ineffective harvester sanitation:** This scenario was developed to assess the impact of STEC contamination left on equipment from a previous harvest. Here, we assume that a grower

sanitizes their equipment routinely according to industry best practices, such as those outlined in the Western Growers Association *Appendix S: Harvester Equipment Cleaning and Sanitation* (Western Growers Association, 2025). The goal of this scenario was to answer an industry-relevant question, such as, “**What would the impact be to my next harvest if harvester sanitation were ineffective the day prior?**” We assume that each iteration of the model represents a 160,000 lb. field of leafy greens following the same field mass assumed in the leafy green baseline scenario. The scope of contamination was 10% of the field, based on expert opinion. The alignment of the contamination event was selected as left to represent the first 10% of the subsequent harvest receiving contamination. The input to the SCRM was a normal distribution with a mean of  $-3.69 \log_{10}(\text{CFU/g})$  and a standard deviation of  $0.837 \log_{10}(\text{CFU/g})$ . The probability of occurrence was assumed to be the same as that of the baseline scenario contamination, 8.165%.

3. **Small animal fecal contamination:** This scenario was developed to simulate the impact of a single small animal, e.g., a rodent, intruding into and defecating in a leafy green field. This is relevant, as per the LGMA *Commodity Specific Food Safety Guidelines* for lettuce and leafy greens, rodents may transport pathogenic organisms from other nearby “high-risk” sources, e.g., concentrated animal feeding operations (CAFOs), human waste treatment facilities, etc. (LGMA, 2025). Thus, the goal of the scenario was to answer an industry-relevant question, such as, “**What if I found one dead rodent during my preharvest assessment?**” as identifying individual fecal pellets in a produce field is anticipated to be difficult. Again, we assume that each iteration of the model represents a 160,000 lb. field of leafy greens (following the same field mass assumed in the leafy green baseline scenario), but the scope of contamination, i.e., the area covered by rodent feces, is 1% of the field. The alignment of the contamination is assumed to be random. While we recognize that a single rodent would be unlikely to cover an area of 1,600 lb overnight, this is the smallest scope that can be assigned in the SCRM and is a limitation of the model. The input to the SCRM was a triangular distribution with a minimum of  $-1.62 \log_{10}(\text{CFU/g})$ , a mode of  $-1.52 \log_{10}(\text{CFU/g})$ , and a maximum of  $-1.44 \log_{10}(\text{CFU/g})$ . The probability of occurrence was assumed to be 0.2%, in line with the observed prevalence of fecal shedding of *E. coli* O157:H7 on produce farms in Monterey Bay and San Benito counties in California, United States (Kilonzo et al., 2013).
4. **Inadequate process wash control:** This scenario was developed to simulate the impact of a process wash that fails to provide a reduction beyond that expected from water alone. The goal of this scenario was to answer the question, “**What if I did not have consistent control over my process wash?**” While several factors influence whether process wash performance and cross-contamination, such as the pH, free chlorine levels, water temperature, and organic matter (Banach et al., 2017; Fu et al., 2018; Gombas et al., 2017), more sophisticated mathematical models exist to answer questions around specific parameter controls for process washes (Mokhtari et al., 2022). To answer this question, the previously parametrized reduction step for our leafy green baseline scenario during Processing was broken into two steps: (i) the reduction achieved by water alone in a standard wash protocol, and (ii) the additional reduction achieved when there is adequate control over the chemical agent concentration in a process wash, e.g., peracetic acid (PAA), chlorine, etc. The reduction in STEC achieved by water alone was assumed to be  $-1.0 \log_{10}(\text{CFU/g})$  based on expert opinion, consistent with other previously parametrized distributions of STEC reduction from washing with water alone (Pang et al., 2017). The expert opinion also suggested that the additional  $-1.25 \log_{10}(\text{CFU/g})$  reduction we previously parametrized (Pinto et al., 2025) would correspond to a processor with a consistent, high-quality wash. Thus, the inadequate process wash scenario was input in the model as two reduction steps: (i) A normal distribution with a mean of  $-1.0 \log_{10}(\text{CFU/g})$  and a standard deviation of 0, and a 100% probability of occurrence, representing a point value for reduction from water alone. (ii) A

normal distribution with a mean of  $-1.25 \log_{10}(\text{CFU/g})$  and standard deviation of 0.17, and a 42.3% probability of occurrence, representing the additional reduction from a consistent high-quality wash.

#### Results – Scenario development: Small-scale failures or deviation from food safety protocols

Under high variability contamination, inadequate process wash control resulted in a 7.9-fold increase in the overall risk of a positive test at retail compared to the baseline, and a substantial increase in the number of highest public health risk lots (from 22 to 420). Under low variability contamination, inadequate process wash control resulted in a 10-fold increase in overall risk, but no highest public health risk lots were identified. Under high and low variability, all other scenarios each resulted in approximately 1-fold increases in overall risk and negligible changes in the number of highest public health risk lots. All results are listed in **Table 3**.

#### Methods - Scenario development: Evaluation of irrigation water testing plans

Based on input from industry, we outlined six alternative testing plans for routine verification of Type A water, as shown in **Table 4**. For each plan, we conducted two analyses: (i) calculating the power and (ii) evaluating the risk of a product positive test for STEC at retail. To conduct the power calculation, we assumed that the concentration of generic *E. coli* in water could be described by a normal distribution with a standard deviation of  $0.99 \log_{10}(\text{CFU/mL})$  (Benjamin et al., 2013). We simulated sampling of irrigation water, which was assumed to have concentrations of generic *E. coli* ranging incrementally from  $-4$  to  $-1.5 \log_{10}(\text{CFU/mL})$ . At each concentration, we conducted one hundred draws or simulated samplings; for each draw, we recorded whether the simulated water samples would result in failure based on the acceptance criteria for a given testing plan. The hundred draws, at each contamination level, were simulated under one hundred different seeds; the resulting output was summarized to calculate the concentration of generic *E. coli* in irrigation water, at which a given plan would reject (or fail) the water at a power of 80%.

Following this, we utilized the SCRM to characterize the risk of a product positive test for STEC, if the product is irrigated with water that complied with the testing plans. Briefly, we simulated irrigation during the 21-days-before-scheduled-harvest window, assuming a 7-day gap between irrigation events. The concentration of generic *E. coli* in irrigation water (modeled as a normal distribution) was informed by the power calculation. Specifically, the mean value of this normal distribution was selected so that the 80% percentile of the distribution is equivalent to the concentration that can be detected by the plan at a power of 80%; this assumes that the approximately 4 of 5 of the simulated irrigation events use water that is compliant with a given testing plan. Other parameters were obtained from a previously developed scenario (failed irrigation water treatment, please see above); this includes parameters such as: (i) irrigation volume, (ii) ratio of STEC to generic *E. coli* in irrigation water, and (iii) the transfer fraction of STEC from water to plants. We conducted 10,000 iterations of simulated irrigation during the 21-days-to-scheduled-harvest window for each plan, to calculate the STEC concentration on plants at harvest; for simplicity, we assumed there was no STEC on the plants prior to the 21-days-to-scheduled-harvest window. We subsequently fit distributions to output of this framework; these fitted distributions were used as an input for the SCRM, to represent contamination that is introduced onto plants through irrigation.

#### Results - Scenario development: Evaluation of irrigation water testing plans

We compared the effect of changing one or more aspects of the current testing plan on the power to detect generic *E. coli* in irrigation water. We observed a roughly ten-fold improvement in power, relative to the current testing plan, if the sample volume was increased to 1,000-mL (see alternative plan 2, **Table 4**).

A similar improvement was observed when the number of samples were increased from three to ten 100-mL samples (see alternative plan 5b). Comparably, changing the acceptance criteria for the test (e.g., by requiring all collected samples to not have detectable *E. coli*) can also improve the power of the test (see alternative plan 1), but it has a lower impact than increasing either sample volume (to 1,000-mL) or sample numbers (to ten samples). Lastly, while the greatest increase in power was observed for the sampling plan that required three 1,000-mL samples to not have detectable levels of generic *E. coli* (see alternative plan 4), the power of this plan was comparable to that of plans that involved only an increase in: (i) sample volume (to 1,000-mL) or (ii) sample numbers (to ten samples).

Similar to the findings of the power calculation, the greatest reduction is the risk of a product positive test for STEC at retail was linked to the plan that required three 1,000-mL samples to not have detectable levels of generic *E. coli* (see alternative plan 4; **Table 5**). Comparable reductions in the risk of a product positive test were observed with plans that involved only: (i) an increase of sample volume from 100-mL to 1,000-mL (see alternative plan 2), (ii) an increase in sample numbers from three to ten samples (see alternative plan 5b), or (iii) applying a more stringent acceptance criteria by requiring all samples to not have detectable levels of generic *E. coli* (see alternative plan 1).

## Outcomes and Accomplishments

### Year 1

#### *Literature Review*

- A literature review was conducted where we identified 11 *E. coli* O157:H7 (STEC) and 7 *L. monocytogenes* process model and literature reviews.
- Parameters for 5 process stages were extracted and evaluated.
- A total of 70 unique key parameters (55 and 25 for STEC and *L. monocytogenes*, respectively, 10 shared) were extracted from the reviewed models.
- The literature review identified that there is a gap in the literature for preharvest STEC and *L. monocytogenes* contamination events, and their distributions.
- For harvest, the literature review identified no information about cross-contamination between mechanical harvesting equipment and produce and sanitation efficacy of harvesting equipment.
- Processing steps are well characterized. However, there are discrepancies in the overall effectiveness (microbial reduction) of the washing steps.
- For the presentation to the consumer stage, available data for transportation and display temperatures for retail is redundantly used and outdated. The expanded search identified that new storage management practices such as the incorporation of retrofitted doors may meaningfully reduce the display temperature profiles at retail.

#### *Flexible Supply Chain Risk Model*

- We developed the framework of a flexible supply chain risk modeling tool to assess the effectiveness of management practices on the risk of a positive test at retail.
- To demonstrate the use of the tool, we generated a series of industry-relevant scenarios and case studies for STEC and leafy green vegetables.
- The results indicate that improved process controls are **overall** more effective at reducing the risk of a recall than finished product testing, as detecting high risk lots by finished product testing depends on the variability of the initial contamination event.
- The model proved to be an effective tool when presented with industry relevant case studies, showing its potential as a decision-making tool.

## Year 2

### *SCRM Guided User Interface*

- We advanced the accessibility of the SCRM by moving it to a free platform and providing detailed instructions for launching the tool.
- Conversations with our Advisory Council helped identify the most appropriate users for the SCRM and helped us identify a priority area for the third year of this project: intentional roll out of the SCRM to targeted users in the produce industry.
- A “lite” version of the tool can be accessed by any interested user [here](#) to explore the results of running scenarios in the SCRM.

### *SCRM Scenario Evaluation*

- We successfully developed four new industry-relevant scenarios and applied them to our leafy green contamination scenarios previously published.
- The results indicate that inadequate process controls increased both the public health risk and recall risk, even when initial contamination variability was low.
- The results suggest that deviations or small-scale failures may result in small changes to public health risk and recall risk, though building in the functionality for non-homogenous contamination in the model or better data could support alternative conclusions.
- Where good data and reasonable simplifying assumptions exist, these scenario analyses may support risk management decisions.

### *Other*

- We identified our new hazard-commodity combination (*Salmonella* and cantaloupe) and went on a site visit to cantaloupe farms in Indiana to help our team understand whole-cantaloupe production.
- Manuscript Writing (see Publications section)
  - Successfully published the SCRM and initial scenario analyses in the *Journal of Food Protection*.
  - Successfully published the critical review in the *Journal of Food Protection*.

## Year 3

### *Revisions to the SCRM*

- We modified the SCRM to operate using a segmented system, allowing for more realistic uniform contamination and clustered contamination simulations. This new version of SCRM was validated against previously developed scenarios by checking for disparities in results between versions.
- We added preharvest testing mechanics.

### *SCRM Scenario Evaluation*

- We modified a previously developed scenario (failed irrigation water treatment) to address industry interest in comparing irrigation water testing plans.
- The results from power calculation suggests that increasing sample volume or sample numbers, when testing Type A water for routine verification, can help improve the power of detecting generic *E. coli*.
- This risk of a positive test for STEC at retail could be reduced by altering the following aspects of an irrigation water testing plan: (i) increasing sample volume, (ii) increasing sample numbers and/or (iii) applying more stringent acceptance criteria.

## APPENDICES

### Publications and Presentations

#### Publications

- Jung, Y., Pinto, G., Reyes, G., Qian, C., Wiedmann, M., & Stasiewicz, M. J. (2025). A Critical Review of Parameters Relevant for Shiga Toxin-producing *Escherichia coli* and *Listeria monocytogenes* Risk Assessments of Leafy Greens. *Journal of Food Protection*, 88(6), 100497. <https://doi.org/10.1016/j.jfp.2025.100497>
- Pinto, G., Reyes, G.A., Barnett-Neefs, C., Jung, Y., Qian, C., Wiedmann, M., & Stasiewicz, M. J. (2025). Development of a flexible produce supply chain food safety risk model: Comparing tradeoffs between improved process controls and additional product testing for leafy greens as a test case. *Journal of Food Protection*, 88(1), 100393. <https://doi.org/10.1016/j.jfp.2024.100393>

#### Manuscripts in preparation:

- Pinto, G., Jung, Y., Barnett-Neefs, C., Wiedmann, M., & Stasiewicz, M. J. (Expected 2026). Using a Flexible Supply Chain Risk Model to Assess the Impact of Small-scale Failures and Deviations from Best Food Safety Protocols. *Journal of Food Protection*, *Manuscript drafted, in preparation for submission*.
- Sunil, S., Pinto, G., Barnett-Neefs, C., Jung, Y., Reyes, G., Wiedmann, M., & Stasiewicz, M. J. (Expected 2026). Preliminary *in silico* comparison of irrigation water testing plants highlights the need to account for heterogeneity in contamination. *In preparation*.
- Barnett-Neefs, C., Pinto, G., Jung, Y., Sunil, S., Wiedmann, M., & Stasiewicz, M. J., (Expected 2026) One Size Does Not Fit All: Using the Supply Chain Risk Model to Evaluate Pre-Harvest Testing Strategies for Uniform and Clustered Pathogen Contamination of Leafy Greens. *In preparation*.

#### Presentations

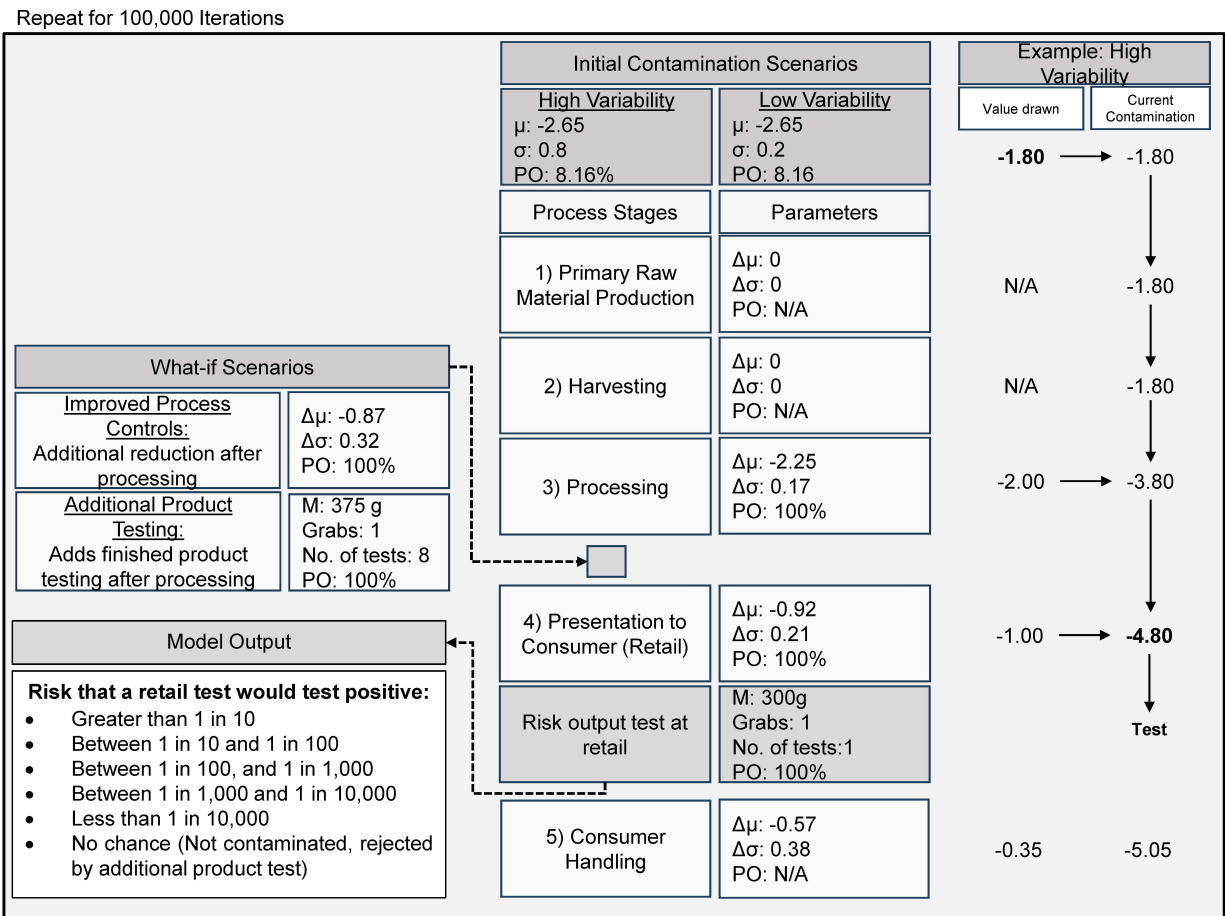
- Stasiewicz, M. J., Wiedmann, M., Pinto, G., Barnett-Neefs, C., Sunil, S., Jung, Y. (2025, November 13). Flexible risk process models to quantify residual risks and the impact of interventions [PowerPoint Presentation]. Virtual.
- Pinto, G., Jung, Y., Barnett-Neefs, C., Wiedmann, M., & Stasiewicz, M. J. (2025, July 30). Using a Fresh Produce Supply Chain Risk Model to Assess the Impact of Deviations from Standard Food Safety Protocols [Poster Presentation]. Cleveland, OH, United States. *2<sup>nd</sup> Place J. Mac Goepfert Developing Scientist Award*
- Pinto, G., Barnett-Neefs, C. & Stasiewicz, M. J. (2025, July 29). Modeling to Assess Tradeoffs in Sampling Plan Attributes and Rejection Rules for Pre-Harvest Produce Safety [Oral Presentation]. International Association for Food Protection Annual Meeting. Cleveland, OH, United States.
- Stasiewicz, M. J., Wiedmann, M. (2025, June 17-18). Flexible risk process models to quantify residual risks and the impact of interventions [Oral Presentation]. Center for Produce Safety Research Symposium. La Jolla, CA, United States.
- Stasiewicz, M. J., Wiedmann, M. (2025, June 17-18). Flexible risk process models to quantify residual risks and the impact of interventions [Poster Presentation]. Center for Produce Safety Research Symposium. La Jolla, CA, United States.
- Stasiewicz, M. J., Wiedmann, M. (2025, March 24). Flexible risk process models to quantify residual risks and the impact of interventions – Industry need assessment [PowerPoint Presentation]. Virtual.

- Stasiewicz, M. J., Wiedmann, M. (2024, November 20). Flexible risk process models can be used to quantify residual risks and the impact of interventions on residual risks CPS Site Visit & Update [PowerPoint Presentation]. Virtual.
- Pinto, G., Reyes, G.A., Jung, Y., Qian, C., Wiedmann, M., & Stasiewicz, M. J. (2024, July 16). Using a Flexible Supply Chain Risk Model for Leafy Greens to Compare Tradeoffs between Contamination Variability, Finished Product Testing, and Improved Process Controls [Poster Presentation]. Long Beach, CA, United States.
- Stasiewicz, M. J., Wiedmann, M. (2024, July 10). CPS Research Symposium Takeaways, Moving Forward with Industry Access to The Tool [PowerPoint Presentation]. Virtual.
- Stasiewicz, M. J. (2024, June 18-19). Flexible risk process models to quantify residual risks and the impact of interventions [Poster Presentation]. Center for Produce Safety Research Symposium. Denver, CO, United States.
- Stasiewicz, M. J. (2024, June 18-19). Flexible risk process models to quantify residual risks and the impact of interventions [Oral Presentation]. Center for Produce Safety Research Symposium. Denver, CO, United States.
- Stasiewicz, M. J., Wiedmann, M., Pinto, G., Barnett-Neefs, C., Jung, Y., Qian, C. (2024, April 24). Year 2 Kickoff: Development of “what-if” scenarios to guide stakeholder discussion [PowerPoint Presentation]. Virtual.
- Pinto, G. Stasiewicz, M. J. (2024, January 8). Technical Review Foundational Content and Model Walkthrough Meeting.
- Stasiewicz, M. J., Wiedmann M., Pinto, G., Reyes G.A. (2023, December 7). Technical Review Committee Meeting [PowerPoint presentation].
- Stasiewicz, M. J., Wiedmann, M., Reyes, G. A. (2023, November 8-9). Residual Risk Modelling [Workshop]. University of Illinois at Urbana Champaign, Urbana, IL.
- Stasiewicz, M. J., Wiedmann, M., Reyes, G. A., Pinto, G., Jung, Y., Qian, C. (2023). Flexible risk process models can be used to quantify residual risks and the impact of interventions on residual risks: CPS Site Visit & Update [PowerPoint presentation].
- Stasiewicz, M. J., Wiedmann, M., Reyes, G. A., Pinto, G., Jung, Y., Qian, C. (2023). Supply Chain Risk Model Advisory Meeting: Analysis of literature-based parameters to inform the development of our supply chain process model [PowerPoint presentation].
- Stasiewicz, M. J., Wiedmann, M. (2023, June 20-21). Flexible risk process models to quantify residual risks and the impact of interventions [Poster presentation]. Center for Produce Safety Research Symposium. Atlanta, GA, United States.
- Stasiewicz, M. J., Wiedmann, M., Reyes, G. A., Pinto, G., Jung, Y., Qian, C. (2023). Introductory Advisory Council Meeting [PowerPoint presentation].

## **Budget Summary**

We have spent approximately \$433,997 of the \$446,989 budget as of the end of the main performance period ending Jan 31, 2026 (following a 1-month no-cost extension from Dec 31, 2025). We expect to fully expend the remaining \$12,828 for required travel to the 2026 CPS Research Symposium, as well as publication fees for the remaining peer-reviewed manuscripts.

Tables and Figures



**Figure 1:** Model and scenario analysis framework. The model consists of five main process stages, an initial contamination event, reductions and/or increases ( $\Delta$ ), and a retail sample as the risk output test. Mean ( $\mu$ ), standard deviation ( $\sigma$ ), and the probability of occurrence (PO) are defined for each process stage where contamination or increase/reduction occurs. When a product test is implemented, the mass, grabs, number of tests, and probability of occurrence are defined. For the analysis, two baseline contamination scenarios were developed, high and low variability. In addition, two industry-relevant management scenarios were evaluated, improved process controls and additional product testing.

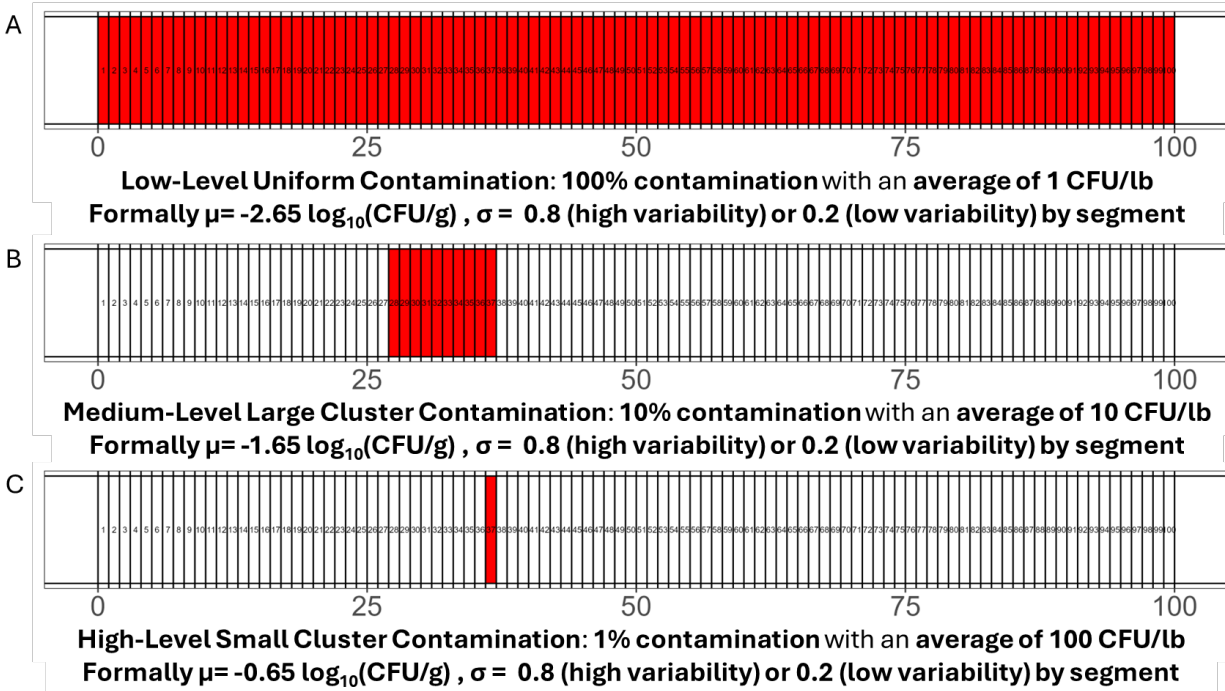
**Table 1:** Scenario analysis results for risk of a positive product test at retail for each baseline contamination scenario, high and low variability, and the management scenarios: Improved Process Controls and Additional Product Testing.

Scenario	Number of lots categorized by the risk that a product test at retail <sup>a</sup> would test positive			The overall risk of a positive retail sample
	>1 in 10	>1 in 100	Non-contaminated or Removed by Product Test	
	<i>Highest</i>	<i>High</i>	<i>Lowest</i>	
<i>High Variability Contamination Scenario (<math>\mu = -2.65, \sigma = 0.8, P(O) = 8.165\%</math>)</i>				
Baseline	16	425	91,835	1 in 4,500
Improved Process Controls <sup>b</sup>	<1	55	91,835	1 in 26,000
Additional Product Testing <sup>c</sup>	<1	130	92,785	1 in 11,000
<i>Low Variability Contamination Scenario (<math>\mu = -2.65, \sigma = 0.2, P(O) = 8.165\%</math>)</i>				
Baseline	<1	1	91,835	1 in 20,000
Improved Process Controls	<1	<1	91,835	1 in 115,000
Additional Product Testing	<1	<1	92,196	1 in 21,000

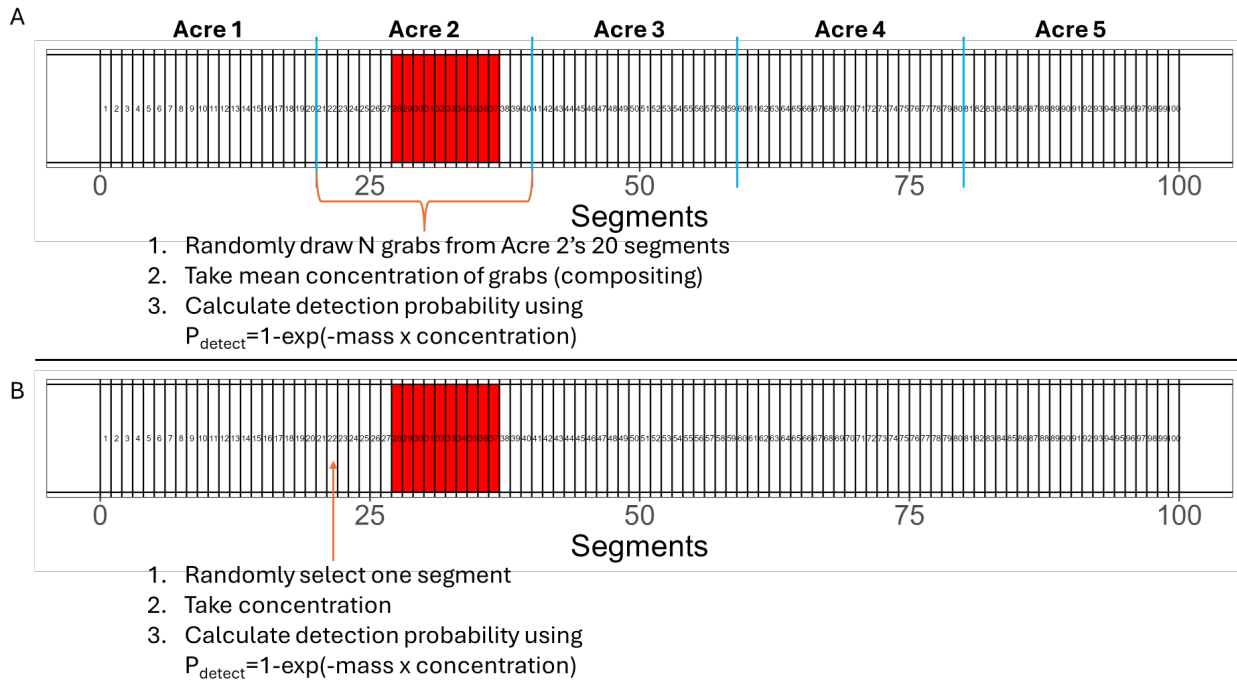
<sup>a</sup> Where a product test consists of 1, 300 g sample.

<sup>b</sup> The Improved Process Controls scenario has a mean reduction in contamination of ( $\Delta\mu$ ) -0.87  $\log_{10}(\text{CFU/g})$  and a standard deviation change in concentration ( $\Delta\sigma$ ) of 0.32  $\log_{10}(\text{CFU/g})$ , which is in addition to the reductions provided by the baseline system.

<sup>c</sup> The Additional Product Testing scenario consists of adding product tests at the end of the Processing stage, which consists of 8 product tests, each of 375 g.



**Figure 2: Contamination scenarios in the SCRМ modified to include clustering.** (A) Low-Level Uniform Contamination: each segment is contaminated with an average 1 CFU/lb. (B) Medium-Level Large Cluster Contamination: a randomly located cluster of segments covering 10% of the field are contaminated with an average of 10 CFU/lb. (C) High-Level Small Cluster Contamination: a randomly located segment covering 1% of the field is contaminated with an average of 100 CFU/lb.

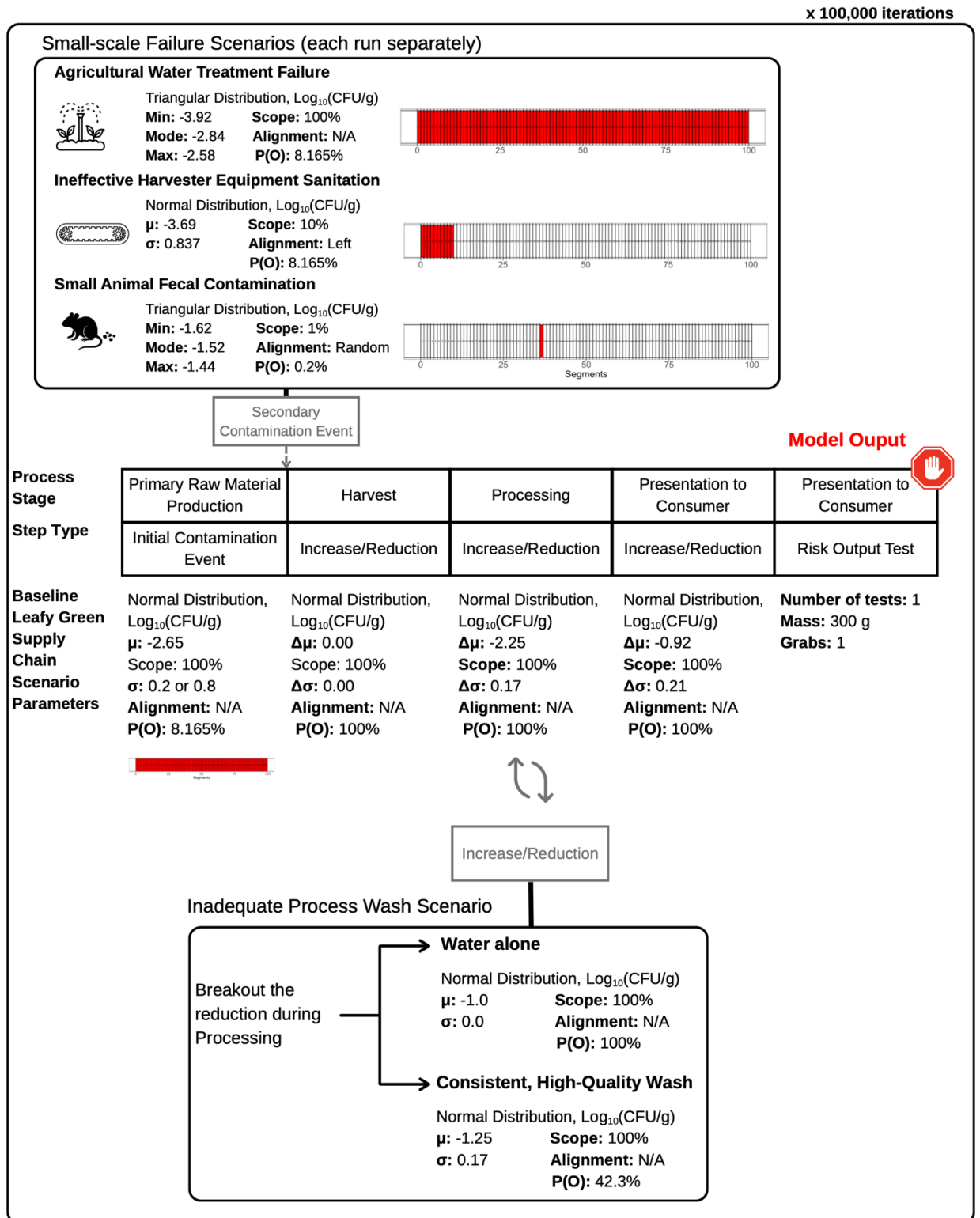


**Figure 3: Process for preharvest, risk output, and product testing functions in SCRM.** (A) Simulation of preharvest testing: the field is split into five acres, with N grabs randomly taken from segments in each acre and used to calculate an average concentration for each one. The probability of a positive test per acre is then calculated using the average concentration and mass parameter. (B) Simulation of risk output testing and product testing: a single segment is randomly chosen from the entire field and is used to calculate probability of a positive test on a total basis.

**Table 2:** Comparison of the effect of different preharvest sampling plans on the risk of a positive product test at retail, with different initial contamination scenarios representing the same hazard pressure

Scenario	Number of lots categorized by the risk that a product test at retail <sup>a</sup> would test positive						The overall risk of a positive retail sample
	>1 in 10	>1 in 100	>1 in 1,000	>1 in 10,000	< 1 in 10,000	Non-contaminated or Removed by Product Test	
	<i>Highest</i>	<i>High</i>	<i>Med-High</i>	<i>Med-Low</i>	<i>Low</i>	<i>Lowest</i>	
<i>High Variability Contamination Scenario (<math>\mu = -2.65, \sigma = 0.8, P(O) = 8.165\%</math>)</i>							
<i>Baseline</i>							
Uniform Contamination	22	396	2,415	3,584	1,748	91,835	1 in 4,400
Large Random Cluster	31	246	363	132	23	99,205	1 in 6,000
Small Random Cluster	33	38	12	5	0	99,912	1 in 8,400
<i>Baseline Preharvest Testing Plan</i>							
Uniform Contamination	0	16	161	304	179	99,340	1 in 112,100
Large Cluster	0	2	12	10	1	99,975	1 in 1,244,700
Small Cluster	1	6	15	0	0	99,978	1 in 193,100
<i>High Grabs Testing Plan</i>							
Uniform Contamination	0	16	149	296	183	99,356	1 in 125,100
Large Random Cluster	0	1	14	9	1	99,975	1 in 1,380,800
Small Random Cluster	0	3	16	0	0	99,981	1 in 750,400
<i>Multiple Tests Plan</i>							
Uniform Contamination	0	3	50	73	57	99,817	1 in 462,100
Large Random Cluster	1	4	6	4	0	99,985	1 in 324,700
Small Random Cluster	7	8	14	1	0	99,970	1 in 28,500
<i>Low Variability Contamination Scenario (<math>\mu = -2.65, \sigma = 0.2, P(O) = 8.165\%</math>)</i>							
<i>Baseline</i>							
Uniform Contamination	0	0	1,254	6,713	198	91,835	1 in 19,900
Large Random Cluster	0	113	663	19	0	99,205	1 in 21,100
Small Random Cluster	17	65	6	0	0	99,912	1 in 18,100
<i>Baseline Preharvest Testing Plan</i>							
Uniform Contamination	0	0	491	2,587	85	96,837	1 in 51,300
Large Random Cluster	0	5	37	0	0	99,958	1 in 479,100
Small Random Cluster	0	6	0	0	0	99,994	1 in 552,200
<i>High Grabs Testing Plan</i>							
Uniform Contamination	0	0	491	2,598	86	96,825	1 in 51,200
Large Random Cluster	0	4	38	0	0	99,958	1 in 499,800
Small Random Cluster	0	2	0	0	0	99,998	1 in 1,082,700
<i>Multiple Tests Plan</i>							
Uniform Contamination	0	0	203	1,079	39	98,679	1 in 125,700
Large Random Cluster	0	2	14	0	0	99,984	1 in 1,002,000
Small Random Cluster	2	18	0	0	0	99,980	1 in 90,200

<sup>a</sup> Where a product test consists of one 300 g sample.



**Figure 4:** Model steps and output representing the leafy green baseline scenario in the supply chain risk model (SCRM). Grey boxes represent the new model steps entered for each of the new scenarios, where each scenario was run independently.

**Table 3:** Scenario analysis results for risk of a positive product test at retail for each baseline scenario with high and low contamination variability, small-scale failure (contamination) scenarios, and inadequate process wash control

Scenario	Number of lots categorized by the risk that a product test at retail <sup>a</sup> would test positive			The overall risk of a positive retail sample
	>1 in 10 <i>Highest</i>	>1 in 100 <i>High</i>	Non-contaminated <i>Lowest</i>	
<i>High Variability Baseline Contamination (<math>\mu = -2.65 \log_{10} \text{CFU/g}</math>, <math>\sigma = 0.8</math>, Probability of Occurrence = 8.165%)</i>				
Baseline	22	396	91,835	1 in 4,400
Agricultural Water Treatment Failure <sup>b</sup>	25	422	84,350	1 in 4,000
Ineffective Harvester Sanitation <sup>c</sup>	25	427	91,108	1 in 4,300
Small Animal Fecal Contamination <sup>d</sup>	19	462	91,832	1 in 4,300
Inadequate Process Wash Control <sup>e</sup>	420	1,998	91,835	1 in 560
<i>Low Variability Baseline Contamination (<math>\mu = -2.65 \log_{10} \text{CFU/g}</math>, <math>\sigma = 0.2</math>, Probability of Occurrence = 8.165%)</i>				
Baseline	< 1	<1	91,835	1 in 20,100
Agricultural Water Treatment Failure	<1	<1	84,350	1 in 14,600
Ineffective Harvester Sanitation	<1	4	91,108	1 in 18,900
Small Animal Fecal Contamination	<1	1	91,832	1 in 20,000
Inadequate Process Wash Control	<1	1,828	91,835	1 in 2,000

<sup>a</sup> Where a retail test consists of 1, 300-gram sample.

<sup>b</sup> The agricultural water treatment failure scenario has an additional contamination event; where the scope of contamination is assumed to affect 100% of the field with a 8.165% probability of occurrence. Contamination is drawn from a triangular distribution where the minimum is  $-3.92 \log_{10}(\text{CFU/g})$ , the mode is  $-2.84 \log_{10}(\text{CFU/g})$ , and the maximum is  $-2.58 \log_{10}(\text{CFU/g})$ .

<sup>c</sup> The ineffective harvester sanitation scenario has an additional contamination event; where the scope of contamination is assumed to affect 10% of the field with a 8.165% probability of occurrence. Contamination is drawn from a normal distribution where the mean is  $-3.69 \log_{10}(\text{CFU/g})$  and the standard deviation is 0.837.

<sup>d</sup> The small animal fecal contamination scenario has an additional contamination event; where the scope of contamination is assumed to affect 1% of the field with a 0.2% probability of occurrence. Contamination is drawn from a triangular distribution where the minimum is  $-1.62 \log_{10}(\text{CFU/g})$ , the mode is  $-1.52 \log_{10}(\text{CFU/g})$ , and the maximum is  $-1.44 \log_{10}(\text{CFU/g})$ .

<sup>e</sup> The inadequate process wash control scenario has reduced probability of occurrence of a high-quality wash during Processing. Every iteration receives a reduction of  $-1.0 \log_{10}(\text{CFU/g})$  (from water alone) with a 100% probability of occurrence. However, there is only a 42.3% probability of occurrence of an additional reduction of  $-1.25 \pm 0.17 \log_{10}(\text{CFU/g})$ .

**Table 4.** Sample numbers, sample volume, acceptance criteria and statistical power associated with the current testing plan, and six alternative testing plans, for routine verification of Type A irrigation water

Testing plan	Number of samples, sample volume and acceptance criteria	Concentration (CFU/L) of generic <i>E. coli</i> , at (and above) which a sampling plan has a detection rate $\geq 80\%$ :
Current plan	Three 100 mL samples, 2 < 1 MPN/100 mL 1 < 10 MPN/100 mL	12.4
More stringent acceptance criteria (Alternative plan 1)	Three 100 mL samples, 3 < 1 MPN/100 mL	2.89
Larger volumes, with more stringent acceptance criteria (Alternative plan 2)	Three 1,000 mL samples, 2 < 1 MPN/1,000 mL, 1 <10 MPN/1,000 mL	1.31
Larger volumes, with current acceptance criteria (Alternative plan 3)	Three 1,000 mL samples 2 < 1 MPN/100 mL, 1 <10 MPN/100 mL	19.6
Larger volumes, with the most stringent acceptance criteria (Alternative plan 4)	Three 1,000 mL samples 3 < 1 MPN/1,000 mL	0.31
Greater sample numbers; option 1 (Alternative plan 5a)	Five 100 mL samples 4 < 1 MPN/100 mL, 1 <10 MPN/100 mL	3.89
Greater sample numbers; option 2 (Alternative plan 5b)	Ten 100 mL samples 9 < 1 MPN/100 mL, 1 <10 MPN/100 mL	1.14

**Table 5.** Scenario analysis results for the current, and six alternative, testing plans for routine verification of Type A irrigation water.

Irrigation Water Testing Plan <sup>a</sup>	Number of samples, sample volume and acceptance criteria	Number of lots with a risk of a positive test:			Overall risk of a positive test at retail
		>1 in 10 <i>Highest</i>	>1 in 100 <i>High</i>	Non-contaminated <sup>b</sup> <i>Lowest</i>	
<i>High Variability Baseline Contamination (<math>\mu = -2.65 \log_{10} \text{CFU/g}</math>, <math>\sigma = 0.8</math>, Probability of Occurrence = 8.165%)</i>					
Baseline	NA	22	396	91,835	1 in 4,400
Current plan	Three 100 mL samples, 2 < 1 MPN/100 mL 1 < 10 MPN/100 mL	25	436	0	1 in 3,877
More stringent acceptance criteria (Alternative plan 1)	Three 100 mL samples, 3 < 1 MPN/100 mL	25	423	0	1 in 4,228
Larger volumes, with more stringent acceptance criteria (Alternative plan 2)	Three 1,000 mL samples 2 < 1 MPN/1,000 mL, 1 <10 MPN/1,000 mL	25	421	0	1 in 4,293
Larger volumes with current acceptance criteria (Alternative plan 3)	Three 1,000 mL samples 2 < 1 MPN/100 mL, 1 <10 MPN/100 mL	25	447	0	1 in 3,642
Larger volumes, with the most stringent acceptance criteria (Alternative plan 4)	Three 1,000 mL samples 3 < 1 MPN/1,000 mL	25	421	0	1 in 4,347
Greater sample numbers; option 1 (Alternative plan 5a)	Five 100 mL samples 4 < 1 MPN/100 mL, 1 <10 MPN/100 mL	25	424	0	1 in 4,195
Greater sample numbers; option 2 (Alternative plan 5b)	Ten 100 mL samples 9 < 1 MPN/100 mL, 1 <10 MPN/100 mL	25	421	0	1 in 4,306

Irrigation Water Testing Plan <sup>a</sup>	Number of samples, sample volume and acceptance criteria	Number of lots with a risk of a positive test:			Overall risk of a positive test at retail
		>1 in 10 <i>Highest</i>	>1 in 100 <i>High</i>	Non-contaminated <sup>b</sup> <i>Lowest</i>	
<i>Low Variability Baseline Contamination (<math>\mu = -2.65 \log_{10} \text{CFU/g}</math>, <math>\sigma = 0.2</math>, Probability of Occurrence = 8.165%)</i>					
Baseline	NA	0	0	91,835	1 in 19,900
Current plan	Three 100 mL samples, 2 < 1 MPN/100 mL 1 < 10 MPN/100 mL	0	15	0	1 in 12,794
More stringent acceptance criteria (Alternative plan 1)	Three 100 mL samples, 3 < 1 MPN/100 mL	0	2	0	1 in 17,614
Larger volumes, with more stringent acceptance criteria (Alternative plan 2)	Three 1,000 mL samples 2 < 1 MPN/1,000 mL, 1 <10 MPN/1,000 mL	0	0	0	1 in 18,802
Larger volumes with current acceptance criteria (Alternative plan 3)	Three 1,000 mL samples 2 < 1 MPN/100 mL, 1 <10 MPN/100 mL	0	26	0	1 in 10,546
Larger volumes with the most stringent acceptance criteria (Alternative plan 4)	Three 1,000 mL samples 3 < 1 MPN/1,000 mL	0	0	0	1 in 19,881
Greater sample numbers; option 1 (Alternative plan 5a)	Five 100 mL samples 4 < 1 MPN/100 mL, 1 <10 MPN/100 mL	0	2	0	1 in 17,055
Greater sample numbers; option 2 (Alternative plan 5b)	Ten 100 mL samples 9 < 1 MPN/100 mL, 1 <10 MPN/100 mL	0	0	0	1 in 19,068

<sup>a</sup> The baseline represents the effect of impact of the initial contamination event, assuming high or low variability in contamination concentration. The contamination associated with the different water testing plans was added, in addition to the initial contamination event, in the SCRM.

<sup>b</sup> We assumed that contamination spread by irrigation water would be distributed uniformly across a fields and their associated lots. Thus, there are no non-contaminated lots for the risk outcomes associated with the various irrigation water plans.

## References

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