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

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Summary

The produce industry needs a tool to evaluate the most effective food safety management practices to prioritize safety investments. Thus, a user-adaptable, open-source model was programmed with five basic stages representing a generic produce supply chain, a contamination event, and the risk of one, 300-gram test (per lot) at retail testing positive as the outcome measure. Using previously collected literature review data, we parametrized a leafy green supply chain contaminated with Shiga-toxin-producing *Escherichia coli* (STEC). We modeled two scenarios applying industry-relevant management practices – additional product testing and improved process controls – and used our tool to compare tradeoffs between these practices. We also worked with industry to develop new scenarios, such as inadequate harvester sanitation and process wash, and improved these through an expert review process.

Objectives

1. Build the flexible tool for STEC in leafy greens to evaluate the effect of literature-based and industry-suggested contamination scenarios and management strategies on the risk of a positive test at retail.
2. Evaluate and compare the effectiveness of industry-relevant practices in reducing the overall risk of a positive test at retail and at removing lots with the highest levels of contamination.
3. Work with industry partners to develop new scenarios, parametrize these using available data, and improve them through a review with domain-specific experts.

Methods

The supply chain risk model (SCRM) framework consists of five main process stages: (1) Primary raw material production, (2) Harvesting, (3) Processing, (4) Presentation to consumer (Retail), and (5) Consumer handling, representing a generic produce supply chain. Under any of the five process stages, a contamination event, increase/reduction, or product test may occur, given the probability of occurrence (PO). The risk of observing a positive test at retail is our primary model output. The overall model process involved implementing the three types of events (contamination, increase/reduction, and product testing) throughout the stages of the supply chain as appropriate and realizing this as our model baseline.

For new scenarios, an expert review process was employed, consisting of scenario identification, development, technical review, revisions, and finalization, **Figure 1**.

Results to Date

We successfully developed the SCRM for a leafy green supply chain, where we modeled Shiga-toxin-producing *E. coli* contamination being introduced approximately 8% of the time to an otherwise well-controlled supply chain, **Figure 2**.

Through our scenario analysis, we show that rare, high-level contamination drives overall risk, shown by comparing high and low variability contamination scenarios in **Table 1**. Implementing improved process controls lowers overall risk approximately 6-fold under both contamination scenarios, and removes all lots that carry the highest level of contamination. Additional product testing reduces overall risk less, and results in rejection of lots that would otherwise be below the detection threshold at retail, **Table 2**.

Benefits to the Industry

The key beneficiaries of this project are growers, producers, and buyers. The flexible risk model and user-adaptable tool we developed will allow the industry to understand which hazards or management strategies are the most effective in their system, and where to invest resources to reduce the risk of positive tests at a retail store. We also directly worked with industry to (i) determine new scenarios of interest, (ii) parametrize scenarios based on literature data, and (iii) modify the parameters based on input from domain-specific experts. In scenarios built from good data and expert agreement, results could drive action. In scenarios where data is lacking or are based on thought experiments, results can identify areas that require more research.

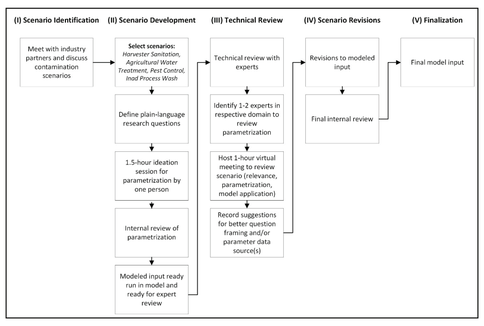

Figure 1: Description of the scenario development and expert review process consisting of five main steps: identification, development, technical review, revision and finalization.

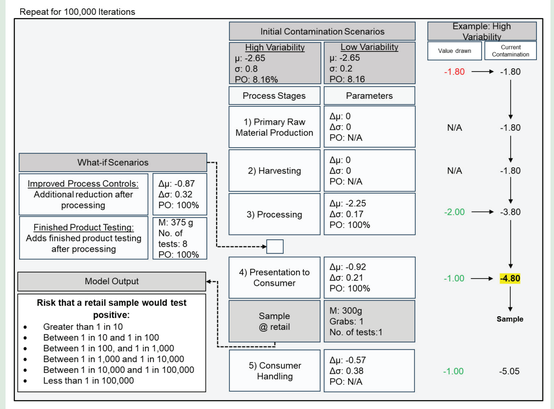

Figure 2: Model and scenario analysis framework. The model consists of five main process stages, contamination events, and sampling at retail. For the analysis, two contamination events are evaluated, high and low variability. In addition, two what-if scenarios are evaluated improved process controls and finished product testing. Mean (μ), and Standard deviation (σ), and the probability of occurrence (PO) are defined for contamination events at any process stage. For finished product testing and a sample at retail, the mass of the test (M), grabs, number of tests, and PO are defined.

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

Scenario	Overall Risk	Number of Lots with Highest Level of Contamination (-3.45 Log_{10}(CFU/g), gives >1 in 10 chance of + retail test)
High Variability Contamination Scenario (μ= -2.65, σ = 0.8, P(O) = 8.165%)		
Baseline	**1 in 4,400**	**18**
Good Data and Expert Agreement		
Improved Process Controls	1 in 26,000	0
Additional Product Testing	1 in 11,000	1
Varying Confidence in Data		
Inadequate Harvester Equipment Sanitation	1 in 4,500	16
Inconsistent Process Wash	1 in 800	267
Low Variability Contamination Scenario (μ= -2.65, σ = 0.2, P(O) = 8.165%)		
Baseline	**1 in 20,000**	0
Good Data and Expert Agreement		
Improved Process Controls	1 in 120,000	0
Additional Product Testing	1 in 21,000	0
Varying Confidence in Data		
Inadequate Harvester Equipment Sanitation	1 in 20,000	0
Inconsistent Process Wash	1 in 3,300	0

Table 2: Number of lots that test positive at retail in baseline scenario in each risk category compared to the estimated amount of positive tests in each risk category by adding additional product testing at the end of the processing stage.

Scenario	Number of Positive Tests by Contamination Level Category					
	Total	Highest	High	Medium-High	Medium-Low	Low
High Variability Contamination Scenario (μ= -2.65, σ = 0.8, P(O) = 8.165%)						
Baseline	**9**	**1**	**6**	**2**	**0**	**0**
Additional Product Testing	991	17	317	466	178	13
Low Variability Contamination Scenario (μ= -2.65, σ = 0.2, P(O) = 8.165%)						
Baseline	**3**	**0**	**0**	**1**	**2**	**0**
Additional Product Testing	358	0	0	54	292	12