



CPS 2023 RFP FINAL PROJECT REPORT – Year 1

Project Title

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

Project Period

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Objectives

1. *Build a supply chain risk model for Shiga toxin–producing Escherichia coli and Listeria monocytogenes simultaneously in leafy greens to identify important risk factors and the impact of interventions on those risks.*

Literature Review: *Review current literature on leafy green models and risk assessments for Shiga toxin–producing Escherichia coli (STEC) and Listeria monocytogenes and develop consensus on key parameters which can be used for building our flexible supply chain risk model (SCRM).*

SCRM model: *Build the SCRM for STEC and L. monocytogenes simultaneously in leafy greens to identify important risk factors and the impact of interventions on those risks.*

Work with industry partners *to identify additional industry-relevant intervention scenarios to evaluate their impact.*

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FINAL REPORT

Abstract

The produce industry needs a tool to identify which food safety management practices most effectively control food safety risks, such as contamination of leafy greens with *Escherichia coli* O157:H7 and *Listeria monocytogenes*. This tool would be used to guide future research priorities and establish realistic and effective requirements for growers and processors.

Executive Summary: Literature Review

In the past, several risk assessments have been developed for *E. coli* O157:H7 and *L. monocytogenes* and various fresh produce commodities (e.g., leafy greens). There however is a need to summarize and understand the sources of the parameters used in these models to (i) better assess past risk assessment and (ii) develop future improved risk assessments. We identified 9 and 7 recently (since 2017 and 2007) published relevant risk assessments for *E. coli* and *Listeria monocytogenes* in produce, respectively. These sources were used to extract parameter estimates for five key stages in the produce supply chain, including (i) primary production; (ii) harvest; (iii) packinghouses and processing facilities, (iv) retail/foodservice, and (v) consumer storage and handling. In addition, we also extracted (i) growth model and (ii) dose response parameters for STEC and LM. While these analyses provided information on what could be considered “consensus” parameters for risk assessments, we also found that parameters used across different risk assessments often came from a single or few sources. This may impact the ability to develop accurate risk assessments that appropriately account for variability and uncertainty. While the summaries of parameter values presented here may be valuable for future risk assessments, our data will also help define future data needs, for example, to provide additional data for parameter estimates that are based on very small or limited datasets.

Executive Summary: Development of a Flexible Supply Chain Risk Model (SCRM)

Here, we developed a user-adaptable model in @RISK for Excel that was programmed with five stages representing a leafy green supply chain, a contamination event with *E. coli* O157:H7, and one 300-gram test per lot at retail as the risk outcome measure. Baseline contamination scenarios (mean (μ) = -2.65 log(CFU/g)) had high (standard deviation (σ) = 0.8 log(CFU/g)) and low (σ =0.2 log(CFU/g)) variability. Probability of contamination was calibrated so the risk of a positive retail test was ~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 (additional μ =-0.87 log(CFU/g) reduction). Lots were categorized by the risk of producing a positive retail test. The overall risk of a positive test in the low-variability scenario (1 in 20,065) was ~5-fold lower than for the high-variability scenario (1 in 4,020), implying that rare high-level contamination drives overall risk. Improved process controls reduced overall

risk another ~5-fold (to 1 in 113,178 and 1 in 20,063 for low- and high-variability, respectively). Finished product testing reduced overall risk less (~3-fold) in the high variability scenario (to 1 in 11,048) but moved all (23/23) lots categorized as highest-risk for a positive retail test to lower risk categories. Conversely, finished product testing had limited effect (1 in 21,431) in the low variability scenario, likely because there were no highest-risk lots to move. We developed a tool that can evaluate tradeoffs between different produce safety management practices, and used it to find, broadly, that reducing relatively rare, high-level contamination events reduces our chosen indicator of risk, a positive test at retail.

Exploring Additional Industry-Relevant Scenarios for the SCRM

Finally, a two-day workshop with our industry partners was conducted. The workshop was used to discuss uses for the developed SCRM and develop scenarios from industry case studies. During the meeting, preliminary case studies were developed and translated into the model, showing great potential for the model to address industry-relevant questions. However, we concluded that important parameters to represent these scenarios are not available in published literature, meaning that additional work is needed to work with the industry to parametrize scenarios. This prompted us to engage with technical experts and plan a series of technical review meetings for the next phase of this project.

Background

Project need and challenge

The produce industry needs a tool to identify the most effective food safety management practices for mitigating risk. Currently, there is uncertainty around the variability of the initial contamination, which management practices better control contamination, and where in the process they are most effective, posing a challenge for the industry on how to make science-based decisions for requirements and guide future research priorities.

Current available technology and limitations for produce models

Produce supply chains have been modeled in the past to answer very specific questions such as the fate of microbial travelers for tomatoes, the effect of cross-contamination during processing of leafy greens, or the effect of processing and retail interventions (Mokhtari et al., 2021; Pang et al., 2017; Zoellner et al., 2018). Typically, these models are very intricate, often answering a single, very specific question. It is often difficult to get access to the models to adapt them and to assess other scenarios, and doing so usually requires expert modelling knowledge. A solution to this problem is to build a flexible model that the industry can use, but this is currently not available for produce. However, other food industries, such as poultry, have these types of models. One such example is the FAO/WHO released flexible risk model that incorporates standardized process stages and mathematics to model changes in contamination with *Salmonella* and

Campylobacter throughout the chicken meat supply chain (Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA), 2009). This tool has been used by academics to gain insights of interventions to reduce residual risk in poultry from *Salmonella* contamination (González et al., 2019).

Current challenges in selecting parameters to represent industry practices

In the past, published models of produce supply chains have sought to answer very specific research questions. While these models and risk assessments can provide a detailed understanding of a specific process (e.g., a wash step), the presentation of parameters and assumptions is not always clear and/or transparent. If one wants to model new industry practices, one needs to find data and express the input in math, a process known as parametrization, to make assumptions. One way to make this easier is to develop a library of parameters used in recent, peer-reviewed produce risk assessments and models so that one could select previously used parameters that meet their needs, which would also allow for evaluation of the quality and bias that may be introduced by these parameters, if used. In this way, it is also critical to review and collect available parameters to identify data gaps that could guide the areas where expert opinion will be needed to correctly parametrize a scenario.

Solution: develop a supply chain risk model

To address the main challenge and work towards providing the produce industry with a useful decision-making tool, a supply chain risk model (SCRM) needs to be developed. This tool will use standardized process stages and mathematics to address many industry-relevant scenarios. The model needs to be flexible to address challenges for different commodities and contamination scenarios. As a first step towards the development of this tool, we developed the framework for the SCRM, and generated a few relevant comparisons that show the potential that this model has, and what can be achieved as the model continues to evolve.

Solution: literature review to select parameters to represent industry practices

To gather parameters to represent industry practices, we conducted a literature review of risk assessments and process models for *E. coli* O157:H7 (further referred to as STEC) and *L. monocytogenes* in leafy greens. We constructed a library of parameters from the reviewed literature and selected parameters to be used in the baseline SCRM. In addition, we identified gaps in the literature where parameters are not available to represent industry-relevant scenarios, or where these parameters may introduce bias into the model due to low quality or inadequate (redundantly used, old) data.

Research Methods and Results

We divided the work performed in the first year of this project into two main sections: (i) the literature review section, and (ii) the supply chain risk model (SCRM) section.

Literature Review – Methodology

Search Strategy and Parameter Extraction

To identify risk assessment-relevant parameters for STEC and *L. monocytogenes*, a set of pre-defined search terms was entered into the Web of Science (WOS) and PubMed databases, **Table A** and **Table B**. The searches were conducted for STEC and *L. monocytogenes* separately, the inclusion criteria for which are described in **Fig. 1**. A total of 9 and 7 peer-reviewed articles were identified for STEC and *L. monocytogenes*, respectively (see **Table C**).

Table of parameters with main supply chain stages

Parameters were organized for five standard supply chain stages organized for (i) primary raw material production, (ii) harvest, (iii) manufacturing, (iv), presentation to consumers and (v) consumer handling. The parameters for each of the reviewed articles were extracted and organized into an Excel spreadsheet. From this, a table of key parameters for each pathogen was developed to include any parameters which were necessary for generic risk assessments and/or used by 2 or more articles. For each process stage, subcategories were defined to further organize parameters. See **Table D** for STEC key parameters and **Table E** for *L. monocytogenes* key parameters.

Table of references with main supply chain stages

Data sources for the identified parameters were also organized into an Excel spreadsheet. A table of the source(s) of the original data used to create parameter estimates was created for the identified key parameters. A parameter estimate could be: (i) an assumed value (not based on data or expert opinion), (ii) self-generated (when data was collected by the authors to create the parameter), (iii) directly taken from a data source (no modifications to the value from the original primary source), or (iv) fitted from data source(s) (parameter created by modifying a data source or fitting multiple data sources to a distribution). Data sources were most often from peer-reviewed literature but could also be from reports and databases. When data sources were not publicly available, they were indicated as such by an * symbol. See **Table F** and **Table G** for STEC and *L. monocytogenes* key parameter sources, respectively.

Expanded Search

For some of the parameters which were assessed as either being (i) only appropriate for risk assessment under certain conditions or (ii) without good estimates that exist, an expanded search was conducted to investigate if better data sources for parametrization existed. While this was not performed for all parameters which were assessed as such, this provided examples of potential alternative data sources for future produce safety models and risk assessments. Search terms specific to a given parameter were entered into the WOS and PubMed databases. Search terms and dates of search were recorded into an Excel spreadsheet for any candidate alternative data sources from the search.

Literature Review – Results

The results of the literature review are organized by the five basic process stages. Each section below will provide an overview of the key parameters extracted for STEC models (tables for *L. monocytogenes* provided, but not described in text), and an *example* of parameter analysis and results of any expanded searches performed.

Primary Raw Material Production Parameters

Five of the identified models for STEC include the primary raw material production process stage. No models for *L. monocytogenes* include this stage. We defined seven relevant subcategories (1.1 to 1.7) for key parameters and information for this process stage (**Table D**).

In some cases, parameters originating from one model were used in subsequent publications from either the same or different author. For example, two of the models reviewed here, Allende et al. (2018) and Bozkurt et al. (2021), used the parameter developed by Allende et al. (2017) for the amount of soil transferred to plants (m_{IWS} ; see **Table D**, representing a parameter appropriate for generic use in risk assessment. The use of the same parameter across these three models was also seen in the transfer coefficient for the amount of *E. coli* or STEC in soil transferred to the plant (TR_{S-P}); Allende et al. (2017) modified data from a published literature source on *Listeria* in soil transferred to parsley leaves (Girardin et al., 2005) to scale the transfer coefficient to *E. coli* transfer to spinach leaves. While this parameter is appropriate for use in risk assessment for spinach, it may need to be adjusted for other leafy green commodities with different surface areas, or new data may need to be collected.

Most notably, **there is very little data for initial levels of STEC in soil, manure amended soil, or irrigation water**, as all models determine initial STEC levels based on generic *E. coli* measurements that are converted to STEC levels using a generic ratio, R , based on data from Ottoson et al. (2011) (**Table F**). Use of this ratio may represent best practices for estimating STEC levels in agricultural soils and irrigation water, but future risk assessments should investigate any available data for STEC levels and may need to collect data to characterize *E. coli* levels in soil and irrigation water for the specific conditions which they are attempting to model.

Harvest Parameters

Two of the identified models for STEC include the harvesting process stage. No models for *L. monocytogenes* are included in this stage. Parameters identified for this stage were defined by two subcategories (2.1 & 2.2, **Table D**).

Just as during primary raw material production, future risk assessments may need to consider alternative data for *E. coli* and STEC levels in soil, depending on the conditions that they would like to model. Further, current models only represent a *manual* harvesting

cross-contamination scenario. Future risk assessments interested in cross-contamination from mechanical harvesting methods, or the effect of sanitation on harvesting blades or mechanical harvesting equipment will need to create parameters for these scenarios.

Manufacturing Parameters

Six of the nine process models identified for STEC included the manufacturing (packinghouse) process stage. For the identified key parameters, we defined 11 parameter subcategories (3.1 to 3.11, **Table D**).

Across all six models for the manufacturing process stage, estimating transfer of STEC from lettuce to equipment and equipment to lettuce was done using two sets of data (**Table F**), demonstrating sufficient data exist for these parameters. Pang et al. (2017) and Bozkurt et al. (2021) used a simple approach to determine the amount of cells on finished product by adding and subtracting cells transferred from and to equipment. As well, subtracting the reduction which occurs from washing the product with water alone or with other agents. All other reviewed models have more complex dynamics during the wash step, for example, dosing of chlorine and maintained free chlorine levels. As a result, these models are designed to allow cross-contamination during washing; a more complex approach than assuming washing is only a microbial reduction process. The associated spatial complexities of the models by Mokhtari et al. (2018), Madamba et al. (2022), Mokhtari et al. (2022), and Pang et al. (2022), therefore, require extensive modelling to calculate the final concentration of STEC in lettuce product. Future risk assessors should consider these complexities when scoping objectives for models. Finally, for transportation time and temperature to retail, the conditions of data collection should be considered. Data from Zeng et al. (2014), used by two of the models reviewed here, is appropriate for generic risk assessment. However, collecting data, as was done by Bozkurt et al. (2021), may be necessary for certain conditions.

Presentation to Consumer (Retail, Food Service) Parameters

Four of the nine STEC process models included the presentation to the consumer (retail) process stage. For the identified key parameters, we defined one relevant subcategory: storage, which includes time and temperature data (**4.1, Table D**).

Overall, we observed repeated use of data from Zeng et al. (2014). Zeng et al. (2014) collected data on the retail display temperature of salad greens across two 3-month periods (summer and winter seasons) at nine supermarkets in the U.S. The distribution for retail display temperatures ranged from 1.0 to 14.1°C, with most data approximately between 2–6°C. While this data is appropriate for use in generic risk assessment, utilizing retail storage temperature profiles representative of modern retail displays for leafy greens is important, as time and temperature abuse may meaningfully influence microbial growth. Sensitivity analysis for the baseline models presented by Bozkurt et al. (2021) and Pang et al. (2017), for example, revealed that the predicted number of illnesses (their

measure of risk) attributed to STEC was most sensitive to retail storage temperature. Therefore, we completed an expanded search for this parameter.

Newer data suggests that depending on retail display setup, that different temperature profiles may be more appropriate for use in risk assessment. Xie et al. (2021) measured retail display temperatures in a major retailer in Florida prior to and after retrofitting doors to a fresh-cut lettuce retail display case. This study found that the mean temperature prior to retrofitting doors was 5°C (range: 0–14°C), whereas after retrofitting the door was 2.6°C (range: -2– 6°C). Monge Brenes et al. (2020) also measured retail display temperatures in ten U.S. retail stores, representing four major retailers across five states. The overall mean temperatures in the top front and under front positions of retail displays without doors were 8.1°C (2.5–14.1°C) and 8.6°C (3.3–13.3°C), respectively. In retail displays with doors, the overall mean temperatures in the top front and under front positions were 5.7°C (2.6–6.7°C) and 2.5°C (1.1–4.8°C), respectively. Future risk assessors may be able to use these temperature profiles to better estimate the growth or die-off that occurs during retail storage.

Consumer Handling Parameters

Four of the nine STEC process models included the presentation to the consumer (retail) process stage in their model. For the identified key parameters, we defined three relevant subcategories: transport to home (**5.1, Table D**) and home storage (**5.2, Table D**), which includes time and temperature data.

As with the temperature profiles used for retail, there is repeated use of one source across STEC, the EcoSure (2007) report for consumer home storage temperature. The EcoSure (2007) report includes temperature monitoring at retail, during transportation to home and consumer home temperatures, doing so by probing various food products (e.g., deli meats). Importantly, there was no temperature monitoring of produce vegetables done in this report, suggesting that future risk assessors should consider alternative data sources for these temperature profiles.

Upon an expanded search, there were very limited data available on domestic refrigeration temperatures in the U.S. However, data from other countries were available. Biglia et al. (2018) found that the overall mean temperature of all domestic refrigerators surveyed (n=671 appliances) was 5.3°C. The maximum overall mean temperature in a single refrigerator was 14.3°C and the overall minimum mean temperature was -4.1°C, but appliance type (e.g., fridge-freezer, fridge with ice box, larder fridge) had a significant effect on temperatures recorded. Another study by Ovca et al. (2021) surveying domestic refrigerators (n=50 appliances) in Slovenia found that the mean temperature was 6.1°C. While refrigerator characteristics may drive the maintained internal temperature ranges of domestic refrigerators, future risk assessors should consider data with higher average

refrigeration temperatures than previously reported, as pathogens like STEC and *L. monocytogenes* may grow under temperature abuse conditions.

Flexible Supply Chain Risk Model (SCRM) Methods

SCRM Model Framework Description

The SCRM consists of 5 main process stages. (i) *Primary raw material production*, (ii) *Harvesting*, (iii) *Processing*, (iv) *Presentation to the consumer*, and (v) *Consumer handling*. An initial *contamination event*, which is the step where contamination is introduced into the system, occurs and a *retail testing step*, which represents a regulatory test at the retail whose probability of detection gives our model output, the risk of observing a positive test at retail, **Figure 2**.

Contamination in the system is quantified as the concentration of cells in Log_{10} (CFU/g). When contamination is introduced into a system, the concentration is drawn from a normal distribution, with a given mean (μ), and standard deviation (σ). In addition, a third parameter, the probability of occurrence (PO), denotes if the contamination event will occur for each iteration. The contamination concentration in the system may change at each of the 5 main process stages. The change in concentration at each stage is also drawn from a normal distribution, in this case, we define the parameters as, a change mean ($\Delta\mu$) and a change standard deviation ($\Delta\sigma$). Like the contamination event, the change in concentration has a probability of occurrence (PO), which denotes if a change in concentration will occur at a given process stage. The retail testing step provides the probability of a test being positive given the mass of the test (M), and the concentration in the product tested.

Description and parametrization of process stages in the base system

The parameters used to represent $\Delta\mu$, $\Delta\sigma$, and the PO at each of the stages are shown in **Table H**. At each of these process stages the contamination concentration in the system may change (increase or decrease) due to aggregated events that occur at each process stage. The baseline system represents a system that follows standard practices: contamination may occur at primary raw material production, then the product is harvested and taken into a processing facility for processing (shredding, washing), and bagged product is transported and displayed at retail (where our current analysis ends).

Retail testing

A *retail testing* step was added to the system to simulate a market basket test. A 300g test was chosen as this was the average mass for the subsamples taken for the FDA 2021 Yuma, AZ, microbial surveillance sampling assignment (United States Food and Drug Administration, 2021). For the model, we assumed one 300g test is taken every iteration. This was assumed as in the FDA sampling assignment there were a total of 540 tests (5,040, 300g subsamples) taken. Based on our calculations 4,132 10-acre lots (160,000 lb. per lot) were produced. While in the Arizona sampling exercise the tests were

performed after harvest at coolers (and very few finished products were sampled), we assumed that a retail test was more representative of recall producing event.

Contamination Scenarios

High Variability Contamination Event: The mean (μ) hazard contamination level was chosen as $-2.65 \log_{10}(\text{CFU/g})$ ($\sim 1 \text{ CFU/lb.}$), parametrized from a reverse engineering exercise of the 2018 romaine lettuce outbreak performed by a United Fresh Workgroup (United Fresh Produce Association, 2021). The standard deviation (σ) of $0.8 \log_{10}(\text{CFU/g})$ was chosen as this has been the standard deviation used by ICMSF to determine the stringency of sampling plans, as used in the FSO example in “Microorganism in Foods 7” (Microbiological Specifications for Foods & International Commission on Microbiological Specifications for Foods (ICMSF), 2018). The probability of occurrence (%) was tuned to **8.1%** for the likelihood of observing a positive test at retail to be 1 per **4,136** lots (**0.000242**). We chose this likelihood from calculating the risk of positive results based on the results of the FDA sampling assignment. The testing location for this scenario is assumed to be at the end of presentation to consumer (retail), however for the FDA sampling exercise, tests were taken at commercial coolers before processing. Currently, this represents the best estimate for testing protocol at retail.

Low Variability Contamination Event: In addition to the high variability contamination event, we included in the analysis a low variability contamination event. Contamination in these produce systems is very difficult to characterize, more specifically the variability of a contamination event may be an indication of different systems. To address this uncertainty, we change the standard deviation ($\Delta\sigma$) of the initial contamination to $0.2 \log_{10}(\text{CFU/g})$. This represents a low variability system as shown by ICMSF through their system analysis.

What-if Scenarios

Finished Product Testing (testing every 1 hr.): For this scenario, it was assumed that the product from previous steps is carried out through processing. As the whole lot is produced, testing is assumed to take place every hour, under this model it is assumed that the lot is processed in 8 hours. Therefore, we simulated 8 total 375g tests.

Improved Process Controls: To represent improved processing practices, we modeled a step that simulated an improved wash. To represent this, we used data from Bozkurt et al, 2021. In this paper, they evaluate different produce wash strategies. In our scenarios, we are using the parameters for chlorinated wash. This step adds reduction to our generic wash from Pang et al. (2017). This additional reduction is parameterized by a mean reduction in contamination of ($\Delta\mu$) $-0.87 \log_{10}(\text{CFU/g})$ and the standard deviation change in concentration ($\Delta\sigma$) of $0.12 \log_{10}(\text{CFU/g})$ based on Bozkurt et al. (2021).

Presentation of Results

The main output of the model is the probability of a positive test at retail. To better understand the results, we categorized the likelihood of a positive test into six different bins, where highest risk is defined by >1 in 10 chance of a positive test, and lowest risk being <1 in 100,000. Intermediate bins decrease 10-fold for risk of a positive test from highest to lowest risk.

Case studies identified as part of meeting with industry partners, Y2 preview

To get additional insight on the developed SCRM framework and its use for industry, we hosted a 2-day meeting with industry collaborators at UIUC in November 2023. During the meeting we generated additional scenarios based on industry case studies. Details for parametrization of one of these case studies, implanting rodent control, is in **Table I**.

Flexible Supply Chain Risk Model Results

Improved process controls manage food safety more effectively than finished product testing.

The results (found in **Table J**) show two patterns: the ability of a mitigation strategy to reduce high-risk lots, and the ability of a mitigation strategy to reduce the overall risk of a positive test at retail. Process controls more effectively reduced the overall risk of a positive test at retail for both high and low variability contamination scenarios. For the high variability scenario, the likelihood was reduced from 1 in 4,020 to 1 in 20,063 and for the low variability scenarios from 1 in 20,065 to 1 in 111,178, in both cases approximately a 5-fold reduction. Implementing finished product testing was only effective for the high variability scenario, reducing the overall risk from 1 in 4,020 to 1 in 11,178. For the low variability scenarios, finished product testing had negligible effects reducing the overall risk from 1 in 20,065 to 1 in 21,431.

Finished product testing reduces high-risk lots under high variability contamination scenarios. However, under low variability contamination scenarios with few high-risk lots, finished product testing has little effect.

For the high variability scenario, the highest risk lots (likelihood greater than 1 in 10) are predicted to be best managed by finished product testing, which reduced the highest risk lots from 23 to <1. Improved process controls reduced the highest risk lots from 23 to 3. For all other risk bins (1 in 100 – 1 in 10,000) improved process showed to be more effective than finished product testing.

Under the low variability scenario, no lots were in the 1 in 10 or 1 in 100 risk bins. For the 1 in 1,000 bins (medium high-risk lots), we see that improved process controls are a lot more effective than finished product testing, reducing the number of lots in this bin from 1,213 to 41, while finished product testing only reduced it to 1,102. And as we move to the 1 in 10,000 bins, the effects of finished product testing are negligible reducing these lots from 6,760 to 6,221, while improved process controls reduced this number down to

2,573. Showing that as the risk of a lot goes down, the effect of finished product testing also goes down.

Finally, we compared the percent relative reduction in risk categories for these lots under the two additional scenarios relative to the baseline, which can be found in **Table K**. Where positive values indicate reduction in lots per category, and negative values indicate increase in lots per category, e.g., for improved process controls under the high variability scenario there are 87% fewer highest-risk lots, 86% fewer high-risk lots, 72% fewer medium-high risk lots, and 26% fewer medium-low risk lots relative to the baseline. There are 105% and 3% more low and lowest-risk lots, resembling a shift of the higher risk lot categories to low and lowest-risk categories.

Finished product testing may still reject many lower-risk lots that would rarely be detected by a retail sample.

Beyond calculating the probability of detection of a retail test, we calculated the test result (detected not detected), **Table L**. As part of this model, we quantified the number of retail tests that detected contamination (that would result in a recall) for each of our risk bins (1 in 10 ... 1 in 100,000). The goal of this was to quantify the number of predicted recalls that would be generated for each bin, and more importantly, the goal was to see how many lots would finish product testing detection, compared to the number of lots that a retail test would detect. The results predict that finished product testing would detect, therefore reject products far more often than a retail test. For the highest and higher variability scenario, as seen in our previous results, the finished product would detect most of the loss, while the retail test would detect some, but fail to detect most. The interesting part is when we get to medium and low-risk lots, we see that product testing is detecting a lot more lots, compared to those that would result in a recall: 538 vs 5 for the medium-high risk lots, 114 vs 0 for the medium-low risk lots, and 5 vs 0 for the very-low risk lots. Similarly, we see the same pattern for the low variability contamination event, with the only difference being the absence of the highest and very-high risk lots. Finished product testing detects a lot more lots than a retail test would.

The model can represent industry-relevant case studies developed during in-person workshop, showing value to build out the model and improve in Year 2.

An example of an industry-relevant scenario developed from our industry workshop was parametrized: rodent control, **Table I**. The model predicted that controls, such as implementing rodent traps, have small effects at reducing the likelihood of a positive test at retail across both high- and low-variability contamination scenarios (see **Table K**).

Outcomes and Accomplishments

Literature Review

- A literature review was conducted where we identified 9 *E. coli* O157:H7 (STEC) and 7 *Listeria monocytogenes* process models and risk assessments.
- Parameters for 5 process stages were extracted and evaluated.
- A total of 50 (of 188 total) and 20 (of 162 total) key parameters were identified for STEC and *Listeria monocytogenes*, respectively.
- The literature review identified that there is a gap in the literature for preharvest STEC contamination events, and their distributions.
- For harvest, the literature review identified no information about cross-contamination between mechanical harvesting equipment and produce and the efficacy of sanitation 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 Process 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.

Other

One unexpected outcome from this year was successfully pulling together a group of produce safety experts to help us perform a technical review of our current model. So far, we have met twice to get their buy in and to provide a detailed explanation on the way the model engine works. At the technical review, we plan to have breakout sessions utilizing the expertise of participants to determine if the model can address industry-relevant inputs and scenarios. Currently, we are working on planning a meeting series for February or March 2024.

Summary of Findings and Recommendations

Summary of Findings

- We developed a flexible field-to-consumer model capable of evaluating the impacts of additional food safety practices (interventions) on our industry-guided indicator of risk, which is “a positive pathogen test from a market basket sample taken at a retail store.”
- Our model meaningfully demonstrates the potential tradeoffs of implementing different interventions, identifying that:
 - Process controls applied during processing that reduce pathogen levels will meaningfully reduce the risk of a positive test at retail under virtually all systems with low and high contamination levels.
 - Finished product testing is only effective at removing the most highly contaminated lots, and so is only effective if the system has lots with high contamination levels.
- Through interaction with industry partners, we identified potential interventions to apply to the system for which this model could be used to determine if they are likely worth studying further.
 - For example, preliminary results suggest one preharvest intervention, improved rodent control, would provide only small food safety gains as compared to other practices, suggesting it should be considered low priority for future studies and for food safety investments. This illustrates how our model can help prioritize future research as well as, ultimately, help with comparative assessment of different interventions.
- We completed a comprehensive literature review of previous process models and risk assessments for STEC and *L. monocytogenes* in leafy greens; this provides valuable data for our risk assessment, further scenario analyses, and other future risk assessments.
- By combining the model results and literature review, this project can help prioritize future research by identifying those parameters with large data gaps that also have a large impact on model outcomes.

Recommendations

- We identified that further interactions with industry are needed to collect relevant scenarios and test our model’s ability to address these scenarios, which we will prioritize in the second year of our project.

APPENDICES

Publications and Presentations

Publications

Two manuscripts will be submitted for the first year of this project: (i) literature review and (ii) an original research paper describing the framework and findings of the model.

The literature review has a working title of: A critical review of leafy greens risk assessments on Shiga toxin-producing *Escherichia coli* and *Listeria monocytogenes* to evaluate modelling parameters and identify gaps to promote improved produce safety risk assessments for the future. Target: Journal of Food Protection. The manuscript will be outlined such that we will discuss parameters within each of the five process stages.

The model research paper has a working title of: Developing the framework of a flexible supply chain risk model for leafy greens, comparing the effectiveness between improved process controls and finished product testing. Target: Journal of Food Protection.

Presentations

- 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].
- 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., 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. (2023, November 8-9). *Residual Risk Modelling* [Workshop]. University of Illinois at Urbana Champaign, Urbana.
- Stasiewicz, M. J., Wiedmann M., Pinto, G., Reyes G.A. (2023, December 7). *Technical Review Committee Meeting* [PowerPoint presentation].
- Pinto, G. Stasiewicz, M. J. (2024, January 8). *Technical Review Foundational Content and Model Walkthrough Meeting*.

Budget Summary

This project was awarded \$151,802 in funds. We have spent ~\$145,100; some of the remaining funds will be spent on travel to the CPS Research Symposium in June 2024. We did have the necessary funds to fully implement the project.

Tables A–L and Figures 1–2

Table A. Search terms applied on Web of Science and PubMed for *L. monocytogenes* risk assessment models on leafy greens dating back from 2007

Criteria #	Search Terms
1	Title or Abstract contained any of the following: <ul style="list-style-type: none"> • <i>Listeria</i> spp.; <i>L. monocytogenes</i>; <i>Listeria monocytogenes</i>; <i>Listeria</i>; <i>L.mono</i>; <i>L. spp</i>
2	Title or Abstract contained any of the following: <ul style="list-style-type: none"> • Leafy Green; Leafy Vegetables; Romaine; Lettuce; Spinach
3	Title or Abstract contained: <ul style="list-style-type: none"> • Risk Assessment; Model
Final Search	Criteria #1, #2, and #3 and publication year in the range any of the following: <ul style="list-style-type: none"> • 2007 to 2023

Table B. Search terms applied on Web of Science and PubMed for STEC risk assessment models on leafy greens dating back from 2017

Criteria #	Search Terms
1	Title or Abstract contained any of the following: <ul style="list-style-type: none"> • <i>E.coli</i>; STEC; shiga; <i>Escherichia coli</i>
2	Title or Abstract contained any of the following: <ul style="list-style-type: none"> • Leafy Green; Leafy Vegetables; Romaine; Lettuce; Spinach
3	Title or Abstract contained: <ul style="list-style-type: none"> • Risk Assessment; Model
Final Search	Criteria #1, #2, and #3 and publication year in the range any of the following: <ul style="list-style-type: none"> • 2017 to 2023

Table C. Commodity type and modeled process stages covered in the selected publications for STEC and *L. monocytogenes*

Organism	Modeled process stages	Commodity	Author	Abbreviation
<i>L. monocytogenes</i>	Post-harvest	Baby spinach	Omac et al. (2017)	OM17
	Post-harvest	Lettuce	Sant'Ana et al. (2014)	SA14
	Post-harvest	Ready-to-eat lettuce salad	Ding et al. (2013)	DG13
	Post-harvest	Ready-to-eat leafy vegetables	Carrasco et al. (2010)	CO10
	Post-harvest	Leafy green vegetables	Franz et al. (2010)	FZ10
	Post-harvest	Fresh-cut iceberg lettuce	Rijgersberg et al. (2010)	RB10
	Post-harvest	Leafy green vegetables	Tromp et al. (2010)	TP10
STEC	Preharvest	Baby spinach	Allende et al. (2018)	AL18
	Preharvest	Baby spinach	Allende et al. (2017)	AL17
	Preharvest	Leafy greens	Mishra et al. (2016)	MS17
	Pre-harvest & Post-harvest	Lettuce	Bozkurt et al. (2021)	BZ21
	Preharvest & Post-harvest	Lettuce	(Pang et al., 2017)	PG17
	Post-harvest	Lettuce	Madamba et al. (2022)	MD22
	Post-harvest	Lettuce	Mokhtari et al. (2022)	MK22
	Post-harvest	Lettuce	Pang et al. (2022)	PG22
Post-harvest	Lettuce	Mokhtari et al. (2018)	MK18	

Table D. Key parameters estimates and key information for STEC risk assessment

Parameter or Information (symbol)	Value	Unit	Papers with parameter
1. Primary Raw Material Production			
<i>1.1 General parameter(s)</i>			
Generic <i>E. coli</i> to <i>E. coli</i> O157:H7 ratio (R)	$10^{\text{Norm}(-1.9, 0.6, \text{Truncate}(0))}$	unitless	PG17, BZ21
<i>1.2 Soil and Feces Contamination</i>			
<i>E. coli</i> concentration in manure-amended soil (EC_{MAS})	Norm(0.549, 0.816) In positive MAS: Cumul(0, 229, {0, 5.29, 44.61, 229}, {0.11, 0.22, 0.58, 1}) In negative MAS: Unif(0, 100)	log(CFU/g) CFU/g	AL17, AL18 BZ21
<i>E. coli</i> O157:H7 concentration in feces (EC_{feces})	Norm(μ , σ)	log(CFU/g)	MS17
Prevalence of <i>E. coli</i> O157:H7 in soil (Prev_{MAS})	0.4166	unitless	BZ21
<i>1.3 Soil Splashing</i>			
Amount of soil transferred by irrigation water splash (m_{IWS})	Betagen(D_{season} , 0.4, 0.8, 0.05, 16.4)	g soil/g produce	AL17, AL18, BZ21
<i>E. coli</i> O157:H7 concentration on plant after irrigation with contaminated water ($EC_{\text{IWS-P}}$)	$(EC_{\text{IW}}/100) \times R \times m_{\text{W-P}}$	CFU/g	PG17
Daily <i>E. coli</i> increase on plant due to rain splashing (ΔEC_{Rain})	$10^{\text{Norm}(EC_{\text{MAS}})} \times m_{\text{IWS}} \times \text{Tr}_{\text{OH-P}} \times P_{\text{Rain}} \times (1 - \text{Sun})$	CFU/g	AL17, AL18, BZ21
<i>1.4 Soil and Feces Transfer</i>			
Transfer coefficient for <i>E. coli</i> from soil to plant ($\text{Tr}_{\text{S-P}}$)	Unif(D_{season} , 0.35, 0.9)	%	AL17, AL18, BZ21
	Transfer = $(RN-0)/(0.619-0) \times 1.3$, for $RN \leq 0.619$ Transfer = $1.3 + (RN-0.619)/(0.946-0.619) \times (340-1.3)$, for $0.619 \leq RN \leq 0.946$ Transfer = $340 + (RN-0.946)/(1-0.946) \times (230,000-340)$, for $0.946 \leq RN \leq 1$ Transfer ratio = Transfer/ (1.29×10^8)	unitless	MS17
<i>1.5 Water Contamination</i>			
Prevalence of <i>E. coli</i> in irrigation water (Prev_{IW})	0.35	unitless	AL17
	Water reservoirs: 0.95 Drainage ditches or canals: 1.0 0.049	unitless	AL18 BZ21
<i>E. coli</i> concentration in irrigation water (EC_{IW})	$(10^{\text{Norm}(D_{\text{season}}, 0.604, 0, 0.357)})/100$	CFU/ml water	AL17
	Baseline: Unif(1, 235) LGMA recommendation: Norm(-0.51, 1) Scenarios: Unif(235, 500), Unif(500, 1000), Unif(1000, 5000), Unif(5000, 10000)	CFU/100 ml water	PG17

Parameter or Information (symbol)	Value	Unit	Papers with parameter	
Prevalence of <i>E. coli</i> O157:H7 in irrigation water ($Prev_{IW-OH}$) <i>E. coli</i> O157:H7 concentration in irrigation water (EC_{IW-OH})	Water reservoirs: $(10^{(Norm(D_{season}, 1.270, 0.567))})/100$	CFU/ml water	AL18	
	Drainage ditches: $(10^{(Norm(D_{season}, 4.289, 0.544))})/100$			
	Canals: $(10^{(Norm(D_{season}, 2.972, 0.459))})/100$			
	Cumul(0,829.19, {0,4,31.6236.38,829.19}, {0.8,0.87,0.95,0.99,1})	CFU/100 ml water	BZ21	
	Tap water: 0 Surface water: 0.25 Reclaimed water: 0.60	%	BZ21	
Baseline: $(If(IW > Prev_{IW}, 0, EC_{IW}) \times R) \times 100$ Tap water: 0 Surface water: Pert(7, 96, 390) Reclaimed water: Pert(260, 860, 10, 1300)		CFU/ml water	BZ21	
	1.6 Water Transfer			
	Amount of water transferred to the plant by irrigation (m_{W-P})	Unif(1.8, 21.6)	ml/g produce	AL17, AL18, BZ21
		Drip Irrigation: 0 Norm(0.108,0.019, Truncate(0,)) Drip Irrigation: Unif(0.0000006, 0.00000088) Furrow Irrigation: Unif(0.00007, 0.00011)	ml/g produce ml/g produce ml/g produce	AL17 PG17 BZ21
1.7 Die-off				
<i>E. coli</i> decay in plant (k_{plant})	Winter: $-0.48 \times (h_{sunny}/24)$ Spring: $-0.52 \times (h_{sunny}/24)$ 0.433	log()	AL17, AL18	
	Winter: $P_{sunny} \times D_{season} \times (0.45 \times h_{sunny}/24)$ Spring: $P_{sunny} \times D_{season} \times (0.61 \times h_{sunny}/24)$ Summer: $P_{sunny} \times D_{season} \times (0.65 \times h_{sunny}/24)$ Autumn: $P_{sunny} \times D_{season} \times (0.47 \times h_{sunny}/24)$	log(CFU/plant/day) log(CFU/g produce)	PG17 BZ21	
	Conventional farm: 0.1744 Organic farm: 0.1528	log(CFU/g/day)	MS17	
2. Harvest				
2.1 Contamination at harvest				
<i>E. coli</i> concentration in soil at harvest ($EC_{soil-Harvest}$)	$10^{Norm(0.928, 1.11, Truncate(0, 3.67))}$	CFU/g	PG17	
2.2 Contamination from harvesting blade				
Mass of soil attached to harvesting blade (m_{S-B})	10.22	g	PG17, BZ21	
No. of <i>E. coli</i> O157:H7 cells in soil attached on blade (N_b)	$EC_{soil-Harvest} \times R \times m_{S-B}$ $EC_{MAS} \times m_{S-B}$	CFU log(CFU/blade)	PG17 BZ21	
Transfer coefficient from harvesting blades to lettuce (Tr_{B-P})	0.0013	unitless	PG17, BZ21	

Parameter or Information (symbol)	Value	Unit	Papers with parameter
No. of <i>E. coli</i> O157:H7 transferred from blade to lettuce (N_{B-P})	$N_b \times Tr_{B-P}$	CFU	PG17, BZ21
3. Manufacturing (Packinghouse)			
<i>3.1 General parameter(s)</i>			
Transfer coefficient from facility surfaces to lettuce (Tr_0)	Triang(9.9, 15.33, 18.83)	%	PG17, BZ21
<i>3.2 Processing Inputs</i>			
Prevalence of <i>E. coli</i> O157:H7 on incoming lettuce heads ($Prev_0$)	0.1 D(5, 25, 50, 75, 100) Winter: 0.23 Spring: 0.21 Summer: 0.27 Autumn: 0.28	% % %	PG17 MK18 BZ21
<i>E. coli</i> contamination level on incoming lettuce heads (EC_0)	D(0.02, 0.05, 0.075, 0.1)	%	MK22
	D(1, 2, 3, 4, 5, 6)	log(CFU/g)	MK18
	D(25,50,75,100)	CFU/head	MK22
	D(-1, 0, 1, 2, 3, 4, 5)	log(CFU/g)	PG22
<i>3.3 Manual Trimming - Knives</i>			
Transfer coefficient from lettuce to knives (Tr_{L-K})	Triang(0, 2.5, 5.0)	%	MK18, MD22, PG22
Transfer coefficient from knives to lettuce (Tr_{K-L})	Triang(0, 29.6, 59.2)	%	MK18, MD22, PG22
<i>3.4 Manual Trimming - Hands</i>			
Transfer coefficient from lettuce to hands (Tr_{L-H})	Triang(3, 10, 30)	%	MK18, MD22, PG22
Transfer coefficient from hands to lettuce (Tr_{H-L})	Triang(0, 1, 3)	%	MK18, MD22, PG22
<i>3.5 Shredding</i>			
Transfer coefficient from lettuce to shredder (Tr_{L-S})	Triang(0, 0.02, 0.02)	%	PG17, BZ21
	Triang(0, 0.25, 0.53)	%	MK18, MD22, PG22
Transfer coefficient from shredder to lettuce (Tr_{S-L})	Triang(16, 20, 28)	%	MK18, MD22, PG22
<i>3.6 Washing</i>			
Log reduction using water alone (d_w)	Pert(0.6,1,1.4)	log(CFU/g)	PG17
	Unif(0.29, 0.67)	log(CFU/g)	BZ21
	1.0	log(CFU/g)	MD22
Log reduction using periacetic acid (d_{PAA})	Pert(0.46, 1.12, 1.34)	log(CFU/g)	BZ21
Log reduction using chlorine (d_C)	Norm(0.87, 0.32, Truncate(0.36, 1.38))	log(CFU/g)	BZ21
Transfer coefficient from lettuce to flume tank (Tr_{L-FT})	Triang(0,0.01,0.02)	%	PG17, BZ21
<i>E. coli</i> O157:H7 concentration after washing (EC_{wash})	$EC_{Harvest} - d_w$	CFU/g	PG17, BZ21
<i>3.7 Conveying</i>			
	Triang(0, 0.10, 0.24)	%	PG17, BZ21

Parameter or Information (symbol)	Value	Unit	Papers with parameter
Transfer coefficient from shredded lettuce to conveyor belt (Tr_{L-C})	Triang(0, 0.62, 1.39)	%	MK18, MD22, PG22
Transfer coefficient from conveyor belt to shredded lettuce (Tr_{C-L})	Triang(15, 18, 22)	%	MK18, MD22, PG22
3.8 Shaker Table			
Transfer coefficient from shredded lettuce to shaker table (Tr_{L-ST})	Triang(0, 0.01, 0.02) Triang(0, 0.06, 0.38)	% %	PG17, BZ21 MK18, MD22, PG22
Transfer coefficient from shaker table to shredded lettuce (Tr_{ST-L})	Triang(6, 28, 30)	%	MK18, MD22, PG22
3.9 Centrifuge			
Transfer coefficient from shredded lettuce to centrifuge (Tr_{L-CF})	Triang(0.01, 0.04, 0.08) Triang(0, 0.35, 1.59)	% %	PG17, BZ21 MK18, MD22, PG22
Transfer coefficient from centrifuge to shredded lettuce (Tr_{CF-L})	Triang(23, 27, 31)	%	MK18, MD22, PG22
3.10 Finished Product			
Spread of contamination due to cross-contamination (S)	Pert(1, 1.2, 2)	unitless	PG17, BZ21
Prevalence after cross-contamination ($Prev_F$)	$Prev_0 \times S$	%	PG17, BZ21
Lettuce <i>E. coli</i> O157:H7 concentration after processing (EC_{final})	$N_{Final} / Prev_F$	log(CFU/g)	PG17, BZ21
3.11 Transport			
Transportation to retail time (t_{Trans})	Triang(6, 12, 24) Triang(30, 64, 85)	h h	BZ21 MK22, PG22
Transportation to retail temperature T_{Trans})	Beta(1.5217, 1.3470, 2.8376, 4.9987) Randomized profile	°C °C	BZ21 MK22, PG22
4. Presentation to Consumer (Retail)			
4.1 Storage			
Retail storage time (t_R)	Triang(0.5, 4, 7) × 24 Triang(0.5, 4, 10) × 24 Triang(12, 96, 168)	h h h	PG17 BZ21 MK22, PG22
Retail storage temperature (T_R)	Norm(4.4441, 2.9642, Truncated(0, 20.56)) Norm(3.8, 1.4, Truncated(9, 13.56)) Randomized profile	°C °C °C	PG17 BZ21 MK22, PG22
5. Consumer Handling			
5.1 Transport			
Transportation to home time (t_{R-H})	Lognorm(1.421, 0.46478, Truncate(0.1833, 3.8667),	h	PG17, BZ21

Parameter or Information (symbol)	Value	Unit	Papers with parameter
Transportation temperature (T_{R-H})	Shift(-0.24609) $\frac{1}{2} \times (T_R + T_{bH})$	°C	PG17, BZ21
<i>5.2 Storage</i>			
Home storage time (t_H)	$\frac{1}{2} \times (t_F + t_L)$	h	PG17, BZ21
Home storage temperature (T_H)	$T(0, 0.3 \times [24 \times SL - (t_{Trans} + t_R)], [24 \times SL - (t_{Trans} + t_R)])]$	h	MK22, PG22
	Normal(3.4517, 2.4442, Truncate(-5, 17.22))	°C	PG17, BZ21
	Random value	°C	MK22, PG22

Table E. Key parameters estimates and key information for *L. monocytogenes* risk assessment

Parameter or Information (symbol)	Value	Unit	Papers with parameter
3. Manufacturing (Packinghouse)			
<i>3.1 Processing Inputs</i>			
Prevalence of LM on incoming lettuce heads (Prev ₀)	Cumulative(0.01;0.5; {0.016;0.018;0.023;0.036;0.07;0.078;0.106;0.227}; {0.1;0.2;0.3;0.5;0.6;0.7;0.8;0.9})	unitless	CO10
	Pert(0, Average(P), Max(P)) where P =Beta(23, 2945), Beta (2,63), Beta(21,341)	%	OM17
Concentration of LM on positive samples (LM _{pos})	Cumulative(3, 4, {3, 3.04, 3.08, 3.23}, {0.2, 0.4, 0.6, 0.8})	log(CFU/g)	DG13
	Cumulative(-1.4,3, {-1,0,1,2,3}, {0.77,0.82, 0.86,0.95,1})	log(CFU/g)	OM17
Concentration of LM on nondetectable samples (LM _{neg})	Cumulative (-6.9, 2.5, {-6.9, -2.2, 2.5}, {0.01, 0.5, 0.99})	log(CFU/g)	DG13
	Cumulative(-5.18, -1.4, {-5.18,-3.29,-1.4}, {0.01, 0.5, 0.99})	log(CFU/g)	OM17
Concentration of LM incoming lettuce heads (LM ₀)	Cumulative(0; 5.39; {0.4;1.4;2.4;3.4;4.4}; {0.773;0.818;0.864;0.955;1})	log (CFU/25g)	CO13
	Discrete(LM _{pos} :LM _{neg} , Prev _{pos} :Prev _{neg})	log(CFU/g)	DG13, OM17
<i>3.2 Washing</i>			
Log reduction using water alone (d _w)	Uniform(0.274,0.83)	log(CFU/g)	OM17
Log reduction using periacetic acid (d _{pAA})	Pert(0.306,0.8,1.293)	log(CFU/g)	OM17
Log reduction using chlorine dioxide (d _{ClO2})	Pert(1.21,1.53,3.38)	log(CFU/g)	OM17
Log reduction using chlorinated water (d _{chl})	Normal(1.96; 0.35; Truncate(1; 3))	log (CFU/25g)	CO10
	Normal(0.96,0.29,Truncate(0.41,1.61))	log(CFU/g)	OM17
<i>3.3 Finished Product</i>			
Concentration LM after processing (LM _{FP})*	Poisson(250)	CFU/g	FZ10, TP10
	Scenario 0: 1	CFU/g	RB10
	Scenario 1,2,3,4,5,6: 10		
	RiskPert(-3,-1.4,1.1)	log (CFU/g)	SA14
	log ₁₀ ((10 ^(LM₀-d_w))/25) and fit distributions to LM _{FP} ≥ 0: BetaGeneral(1.045; 2.6407; 0.0010267; 1.8458)	log (CFU/g)	CO13
Prevalence of LM after processing (Prev _{FP})	0.00037864 (1/2641)	Unitless	FZ10, TP10
	RiskBeta(27,1181)	%	SA14
<i>3.4 Storage</i>			
Storage time at processing facility (t _{storage})	Distribution Center: 9.5	h	RB10

Parameter or Information (symbol)	Value	Unit	Papers with parameter
Storage temperature at processing facility (T_{storage})	Value drawn from normal distribution of temperature profile at time t Norm(3.50, 0.33)	°C	FZ10, TP10
	Producer: $\mu = 4.5, \sigma = 0.25$ Distribution Center: $\mu = 4.0, \sigma = 1.0$	°C	RB10
3.5 Transport			
Transportation to retail time (t_{Trans})	Producer to Distribution Center: 3 Distribution Center to Retail: 2	h	RB10
	RiskPert(2,5,9)	h	SA14
	Uniform(4, 10) + PERT(12, 24, 72)	h	DG13
	Uniform(24,72)	h	OM17
Transportation to retail temperature T_{Trans}	Producer to Distribution Center: $\mu = 3.0, \sigma = 1.0$ Distribution Center to Retail: $\mu = 7.0, \sigma = 1.5$	°C	RB10
	RiskPert(3,7.6,10.3)	°C	SA14
	Pert(2, 4, uniform(15, 25))	°C	DG13
	Uniform(-0.3,7.7)	°C	OM17
4. Presentation to Consumer (Retail)			
4.1 Storage			
Retail storage time (t_{retail})	Triangular(1; Uniform(2; 9); 37)	h	CO10
	< 24	h	DG13
	Uniform(96,168)	h	OM17
Retail storage temperature (T_{retail})	$\mu = 5.2, \sigma = 1.8$	°C	RB10
	RiskDiscrete($\{5\ 7\ 8\ 9\ 10\ 11\ 12\ 13\ 15\}, \{0.017\ 0.051\ 0.33\ 0.10\ 0.17\ 0.12\ 0.16\ 0.017\ 0.017\}$)	°C	SA14
	Cumulative(-2;20;{0;1.6;3.3;5;6.6;8.3;10;11.6;13.3;15;16.6;18.3};{0.059;0.109;0.258;0.526;0.734;0.833;0.932;0.962;0.982;0.990;0.998;0.999})	°C	CO10
	Supermarket: 7-14 Traditional market: 15-25	°C	DG13
	Extvalue(4.9495,2.8227)	°C	OM17
5. Consumer Handling			
5.1 Transport			
Transportation to home time ($t_{\text{R-H}}$)	$\gamma(5.25, 8.17)$	h	RB10
	RiskGamma(5.24,8.17)/60	h	SA14
	Triangular(0; 1; 2.5)	h	CO10
	Uniform(4, 10) + uniform(0, 24) + Pert(12, 48, 168)	h	DG13
Transportation temperature ($T_{\text{R-H}}$)	Extvalue(0.87866,0.36216)	h	OM17
	$(4 + 21\beta(15/7,27/7))$	°C	RB10
	RiskPert (7,12,20)	°C	SA14
	$(-1.318 \times (t_{\text{R-H}}^2)) + (5.8701 \times t_{\text{R-H}}); R^2=0.97$	°C	CO10, OM17
	Pert(2, uniform(4, 8.32),uniform(15, 25))	°C	DG13
5.2 Storage			
Home storage time (t_{H})	RiskUniform(0,192)	h	SA14

Parameter or Information (symbol)	Value	Unit	Papers with parameter
	Triang(12; Uniform(72; 96); Uniform(192; 288))	h	CO10
	IF($t_{shf} = 0, t_{shu}, t_{shf}$)	h	OM17
Home storage temperature (T_H)	Normal(5.99, 1.83)	°C	RB10
	RiskPert(3.04,6,10.8)	°C	SA14
	Normal(6.78; 2.56; Truncate(1; 11.3))	°C	CO10
	$\mu = 4.06$	°C	OM17

Table F. Sources of key parameters estimates and key information for STEC risk assessment

Parameter or Information (symbol)	Parameter Source	Papers with parameter
1. Primary Raw Material Production		
Generic <i>E. coli</i> to <i>E. coli</i> O157:H7 ratio (R)	Distribution taken from Ottoson et al. (2011)	PG17, BZ21
<i>1.2 Soil and Feces Contamination</i>		
<i>E. coli</i> concentration in manure-amended soil (EC_{MAS})	Distribution fitted from data from Castro-Ibáñez et al. (2015) In positive MAS, in negative MAS: Distribution fitted from self-generated data	AL17, AL18 BZ21
<i>E. coli</i> O157:H7 concentration in feces (EC_{feces})	Distributions fitted from data from Cooley et al. (2013) and Hutchison et al. (2004)	MS17
Prevalence of <i>E. coli</i> O157:H7 in soil ($Prev_{MAS}$)	Calculated from local data*	BZ21
<i>1.3 Soil and Feces Transfer</i>		
Transfer coefficient for <i>E. coli</i> from soil to plant (Tr_{S-P})	Distribution fitted from modifying data from Girardin et al. (2005) Calculated from data from Atwill et al. (2015)	AL17, AL18, BZ21 MS17
<i>1.4 Water Contamination</i>		
Prevalence of <i>E. coli</i> in irrigation water ($Prev_{IW}$)	Value taken from Castro-Ibáñez et al. (2015) Values taken from Truchado et al. (2018) Calculated from data from local data*	AL17 AL18 BZ21
<i>E. coli</i> concentration in irrigation water (EC_{IW})	Calculated from data from Castro-Ibáñez et al. (2015) Baseline: Distribution fitted from data from LGMA (California Leafy Green Products Handler Marketing Agreement) (2013) LGMA recommendation: Distribution fitted from data from LGMA (California Leafy Green Products Handler Marketing Agreement) (2013) Scenarios: Distribution fitted from assumed values Water reservoirs, drainage ditches, canals: Calculated from data from Truchado et al. (2018) Distribution fitted from local data*	AL17 PG17 AL18 BZ21
Prevalence of <i>E. coli</i> O157:H7 in irrigation water ($Prev_{IW-OH}$)	Baseline, tap water, surface water, reclaimed water: Calculated from local data*	BZ21
<i>E. coli</i> O157:H7 concentration in irrigation water (EC_{IW-OH})	Baseline: Calculated from values defined in this study Tap water: Value taken from local data* Surface water: Distribution fitted from local data* Reclaimed water: Distribution fitted from local data*	BZ21
<i>1.5 Water Transfer</i>		
Amount of water transferred to the plant by irrigation (m_{W-P})	Distribution fitted from data from Allende et al. (2017) Drip Irrigation: Value taken from company information* Distribution taken from Hamilton et al. (2006) Drip Irrigation: Distribution fitted from Stine et al. (2005) Furrow Irrigation: Distribution fitted from Stine et al. (2005)	AL17, AL18, BZ21 AL17 PG17 BZ21

Parameter or Information (symbol)	Parameter Source	Papers with parameter
1.6 Soil Splashing		
Amount of soil transferred by irrigation water splash (m_{IWS})	Distribution fitted from data from Allende et al. (2017)	AL17, AL18, BZ21
<i>E. coli</i> O157:H7 concentration on plant after irrigation with contaminated water (EC_{IWS-P})	Calculated from values defined in this study	PG17
Daily <i>E. coli</i> increase on plant due to rain splashing (ΔEC_{Rain})	Calculated from values defined in this study	AL17, AL18, BZ21
1.7 Die-off		
<i>E. coli</i> decay in plant (k_{plant})	Winter, Spring: Calculated from values defined in this study and a value from Ottoson et al. (2011) Calculated from data from Erickson et al. (2010)	AL17, AL18 MS17
	Winter, Spring, Summer, Fall: Calculated from values defined in this study and a value from Ottoson et al. (2011)	BZ21
<i>E. coli</i> decay in soil (k_{soil})	Conventional farm, organic farm: Calculated from data from Ma et al. (2012)	MS17
2. Harvest		
2.1 Contamination at harvest		
<i>E. coli</i> concentration in soil at harvest ($EC_{soil-Harvest}$)	Calculated from data from Lenehan et al. (2005)	PG17
2.2 Contamination from harvesting blade		
No. of <i>E. coli</i> O157:H7 cells in soil attached on blade (N_b)	Calculated from values defined in this study Calculated from values defined in this study	PG17 BZ21
Transfer coefficient from harvesting blades to lettuce (Tr_{B-P})	Value taken from Yang et al. (2012)	PG17, BZ21
No. of <i>E. coli</i> O157:H7 transferred from blade to lettuce (N_{B-P})	Calculated from values defined in this study	PG17, BZ21
3. Manufacturing (Packinghouse)		
3.1 General parameter(s)		
Transfer coefficient from facility surfaces to lettuce (Tr_0)	Distribution fitted from data from Pérez Rodríguez et al. (2011)	PG17, BZ21
3.2 Processing Inputs		
Prevalence of <i>E. coli</i> O157:H7 on incoming lettuce heads ($Prev_0$)	Value taken from Danyluk and Schaffner (2011) Assumed values Winter, Spring, Summer, Fall: Calculated from local data*	PG17 MK18 BZ21
<i>E. coli</i> contamination level on incoming lettuce heads (EC_0)	Values taken from Versar (2021) Assumed values Values taken from Versar (2021) Assumed values	MK22 MK18 MK22 PG22
3.3 Manual Trimming - Knives		
Transfer coefficient from lettuce to knives (Tr_{L-K})	Distribution fitted from data from Zilelidou et al. (2015)	MK18, MD22, PG22
Transfer coefficient from knives to lettuce (Tr_{K-L})	Distribution fitted from data from Zilelidou et al. (2015)	MK18, MD22, PG22
3.4 Manual Trimming - Hands		

Parameter or Information (symbol)	Parameter Source	Papers with parameter
Transfer coefficient from lettuce to hands (Tr_{L-H})	Distribution fitted from data from Zilelidou et al. (2015)	MK18, MD22, PG22
Transfer coefficient from hands to lettuce (Tr_{H-L})	Distribution fitted from data from Jensen et al. (2017)	MK18, MD22, PG22
<i>3.5 Shredding</i>		
Transfer coefficient from lettuce to shredder (Tr_{L-S})	Distribution fitted from data from Pérez Rodríguez et al. (2011)	PG17, BZ21
	Distribution fitted from data from Buchholz et al. (2012a, 2012b, 2014)	MK18, MD22, PG22
Transfer coefficient from shredder to lettuce (Tr_{S-L})	Distribution fitted from data from Buchholz et al. (2012a, 2012b, 2014)	MK18, MD22, PG22
<i>3.6 Washing</i>		
Log reduction using water alone (d_w)	Distribution fitted from data from (Keskinen et al., 2009); Nou and Luo (2010); Stopforth et al. (2008); Zhang et al. (2009)	PG17
	Distribution fitted from self-generated data	BZ21
	Value taken from Luo et al. (2012)	MD22
Log reduction using periacetic acid (d_{PAA})	Distribution fitted from self-generated data	BZ21
Log reduction using chlorine (d_c)	Distribution fitted from self-generated data	BZ21
Transfer coefficient from lettuce to flume tank (Tr_{L-FT})	Distribution fitted from data from Pérez Rodríguez et al. (2011)	PG17, BZ21
<i>E. coli</i> O157:H7 concentration after washing (EC_{wash})	Calculated from values defined in this study	PG17, BZ21
<i>3.7 Conveying</i>		
Transfer coefficient from shredded lettuce to conveyor belt (Tr_{L-C})	Distribution fitted from data from Pérez Rodríguez et al. (2011)	PG17, BZ21
	Distribution fitted from data from Buchholz et al. (2012a, 2012b, 2014)	MK18, MD22, PG22
Transfer coefficient from conveyer belt to shredded lettuce (Tr_{C-L})	Distribution fitted from data from Buchholz et al. (2012a, 2012b, 2014)	MK18, MD22, PG22
<i>3.8 Shaker Table</i>		
Transfer coefficient from shredded lettuce to shaker table (Tr_{L-ST})	Distribution fitted from data from Pérez Rodríguez et al. (2011)	PG17, BZ21
	Distribution fitted from data from Buchholz et al. (2012a, 2012b, 2014)	MK18, MD22, PG22
Transfer coefficient from shaker table to shredded lettuce (Tr_{ST-L})	Distribution fitted from data from Buchholz et al. (2012a, 2012b, 2014)	MK18, MD22, PG22
<i>3.9 Centrifuge</i>		
Transfer coefficient from shredded lettuce to centrifuge (Tr_{L-CF})	Distribution fitted from data from Pérez Rodríguez et al. (2011)	PG17, BZ21
	Distribution fitted from data from Buchholz et al. (2012a, 2012b, 2014)	MK18, MD22, PG22
Transfer coefficient from centrifuge to shredded lettuce (Tr_{CF-L})	Distribution fitted from data from Buchholz et al. (2012a, 2012b, 2014)	MK18, MD22, PG22
<i>3.10 Finished Product</i>		
Spread of contamination due to cross-contamination (S)	Distribution fitted from data from FDA 2012	PG17, BZ21

Parameter or Information (symbol)	Parameter Source	Papers with parameter
Prevalence after cross-contamination (Prev _F)	Calculated from values defined in this study	PG17, BZ21
Lettuce <i>E. coli</i> O157:H7 concentration after processing (EC _{final})	Calculated from values defined in this study	PG17, BZ21
3.11 Transport		
Transportation to retail time (t _{Trans})	Distribution fitted from self-generated data Distribution fitted from Zeng et al. (2014)	BZ21 MK22, PG22
Transportation to retail temperature (T _{Trans})	Distribution fitted from self-generated data Values taken from Zeng et al. (2014)	BZ21 MK22, PG22
4. Presentation to Consumer (Retail)		
4.1 Storage		
Retail storage time (t _R)	Distribution fitted from assumed values Distribution fitted from self-generated data Distribution fitted from Zeng et al. (2014)	PG17 BZ21 MK22, PG22
Retail storage temperature (T _R)	Distribution fitted from EcoSure (2007) Distribution fitted from self-generated data Values taken from Zeng et al. (2014)	PG17 BZ21 MK22, PG22
5. Consumer Handling		
5.1 Transport		
Transportation to home time (t _{R-H})	Distribution fitted from EcoSure (2007)	PG17, BZ21
Transportation temperature (T _{R-H})	Calculated from values defined in this study	PG17, BZ21
5.2 Storage		
Home storage time (t _H)	Calculated from values defined in this study and (Pouillot et al., 2010)	PG17, BZ21
Home storage temperature (T _H)	Distribution fitted from values defined in this study Distribution fitted from EcoSure (2007) Value taken from EcoSure (2007)	MK22, PG22 PG17, BZ21 MK22, PG22

Table G. Sources of key parameters estimates and key information for *L. monocytogenes* risk assessment

Parameter or Information (symbol)	Parameter Source	Papers with parameter
3. Manufacturing (Packinghouse)		
<i>3.1 Processing Inputs</i>		
Prevalence of LM on incoming lettuce heads ($Prev_0$)	Distribution fitted from data from Arumugaswamy et al. (1994); Breer (1992); de Simón and Ferrer (1998); FDA-HHS and USDA-FSIS (2003); Harvey and Gilmour (1993); Legnani et al. (2004); Lin et al. (1996); Tang et al. (1994); Velani and Roberts (1991)	CO10
	Detectable levels: Distribution fitted from self-generated data from data from Bae et al. (2011); Choi et al. (2005); Kim et al. (2011)	DG13
	Below detectable levels: Calculated from values defined in this study	
	Distribution fitted from data from FDA-HHS and USDA-FSIS (2003); Gombas et al. (2003); Lin et al. (1996)	OM17
Concentration of LM on positive samples (LM_{pos})	Distribution fitted from data from farms in Korea*	DG13
	Distribution fitted from data from Gombas et al. (2003)	OM17
Concentration of LM on nondetectable samples (LM_{neg})	Distribution fitted from data from farms in Korea* Distribution fitted from values defined in this study	DG13 OM17
Concentration of LM incoming lettuce heads (LM_0)	Distribution fitted from data from Gombas et al. (2003)	CO10
	Distribution fitted from values defined in this study	DG13, OM17
<i>3.2 Washing</i>		
Log reduction using water alone (d_w)	Distribution taken from Omac (2014)	OM17
Log reduction using peracetic acid (d_{PAA})	Distribution fitted from data from Park and Kang (2015a, 2015b)	OM17
Log reduction using chlorine dioxide (d_{ClO_2})	Distribution fitted from data from Park and Kang (2015a, 2015b)	OM17
Log reduction using chlorinated water (d_{chl})	Distribution fitted from data from Brackett (1987); Zhang and Farber (1996)	CO10
	Distribution taken from Omac (2014)	OM17
<i>3.3 Finished Product</i>		
Concentration of LM after processing (LM_{FP})*	Distribution fitted from data from Pielaat et al. (2008)	FZ10, TP10
	Scenario 0: Assumed value	RB10
	Scenario 1,2,3,4,5,6: Assumed value Distribution fitted from data from Sant'Ana et al. (2012)	SA14
Prevalence of LM after processing ($Prev_{FP}$)	Calculated from values defined in this study	CO10
	Value taken from Pielaat et al. (2008)	FZ10, TP10
	Distribution fitted from data from Fröder et al. (2007); Maistro (2006); Oliveira et al. (2011); Oliveira et al. (2010); Porto and Eiroa (2001); Sant'Ana et al. (2011)	SA14
<i>3.4 Storage</i>		

Parameter or Information (symbol)	Parameter Source	Papers with parameter
Storage time at processing facility (t_{storage})	Assumed value	RB10
Storage temperature at processing facility (T_{storage})	Distribution fitted from self-generated data Producer: Self-generated values Distribution Center: Self-generated values	FZ10, TP10 RB10
3.5 Transport		
Transportation time from processing facility to retail (t_{Trans})	Producer to Distribution Center: Assumed value Distribution Center to Retail: Assumed value Distribution fitted from data from Pereira (2008); Pereira et al. (2010) Calculated from self-generated data Distribution fitted from data from Zeng et al. (2014)	RB10 SA14 DG13 OM17
Transportation temperature from processing facility to retail (T_{Trans})	Producer to Distribution Center: Self-generated values Distribution Center to Retail: Self-generated values Distribution fitted from data from Pereira (2008); Pereira et al. (2010) Distribution fitted from self-generated data Distribution fitted from data from Zeng et al. (2014)	RB10 SA14 DG13 OM17
4. Presentation to Consumer (Retail)		
4.1 Storage		
Storage time at retail (t_{retail})	Distribution fitted from data from Audits International (2000) Value taken from the Korea Agro-Fisheries and Food Trade Cooperation (2005)* Distribution fitted from Danyluk and Schaffner (2011)	CO10 DG13 OM17
Storage temperature at retail (T_{retail})	Self-generated values Distribution fitted from data from Audits International (2000) Distribution fitted from data from Maistro (2006) Values taken from the Korea Agro-Fisheries and Food Trade Cooperation (2005)* Distribution taken from Danyluk and Schaffner (2011)	RB10 CO10 SA14 DG13 OM17
5. Consumer Handling		
5.1 Transport		
Transportation time from retail to home ($t_{\text{R-H}}$)	Distribution fitted from data from Evans et al. (1991) Distribution fitted from data from Nauta et al. (2003) Distribution fitted from data from Audits International (2000) Calculated from self-generated data Value taken from data from Audits International (2000)	RB10 SA14 CO10 DG13 OM17
Transportation temperature from retail to home ($T_{\text{R-H}}$)	Calculated from Evans 1998* Distribution fitted from assumed values Calculated from data from Audits International (2000) Distribution fitted from self-generated data and data from EcoSure (2007)	RB10 SA14 CO10, OM17 DG13
5.2 Storage		
	Distribution fitted from assumed values	SA14

Parameter or Information (symbol)	Parameter Source	Papers with parameter
Storage time at home (t_H)	Distribution fitted from data from FDA-HHS and USDA-FSIS (2003)	CO10
	Calculated from data from Danyluk and Schaffner (2011)	OM17
Storage temperature at home (T_H)	Distribution taken from Nauta et al. (2003)	RB10
	Distribution fitted from data from Silva et al. (2008)	SA14
	Distribution fitted from data from Carrasco et al. (2007)	CO10
	Value taken from Danyluk and Schaffner (2011)	OM17

Table H. Description of inputs for the baseline system*

Symbol	Variable	Distribution, value, or formula	Unit	Source	Justification and assumptions
<i>Contamination Event (C)</i>					
C_{μ}	Contamination mean	-2.65 1 CFU/lb.	Log CFU/g	(United Fresh Produce Association, 2021)	The United Fresh workgroup performed a traceback for the 2018 romaine lettuce outbreak. They concluded that the contamination level that caused the outbreak was 0.81 CFU/lb.
$C_{\sigma_{HV}}$	High variability contamination standard deviation	0.8	Log CFU/g	(ICMSF (International Commission on Microbiological Specifications for Foods), 2018)	The 0.8 standard deviation was chosen as this high variability SD was chosen to calculate the ICMSF sampling cases. Also, ICMSF uses this standard deviation in their leafy green case study.
$C_{\sigma_{LV}}$	Low variability contamination standard deviation	0.2	Log CFU/g	(ICMSF (International Commission on Microbiological Specifications for Foods), 2018)	The 0.2 standard deviation is chosen as the low variability SD for ICMSF
C_0	Initial contamination	Normal (μ , σ)	Log CFU/g	calculated	
PO_{C0}	Probability of occurrence of the contamination event	8.16	%	Fitted Value	The value was fitted to obtain a positive test rate at retail of 1 in 4,136 lots produced.
<i>Primary Raw Material Production (PRMP)</i>					
$\Delta\mu_{PRMP}^*$	Mean change at PRMP	0	Log CFU/g	Assumed	For raw material production, we are assuming no change to the initial contamination due to the GAP implementation
$\Delta\sigma_{PRMP}$	Standard deviation changes at PRMP	0	Log CFU/g	Assumed	
$\Delta PRMP_{agg}$	Aggregated Total Change due to PRMP	Normal ($\mu\Delta PRMP$, $\sigma\Delta PRMP$)	Log CFU/g	calculated	
<i>Harvest</i>					
$\Delta\mu_H$	Mean change at H	0	Log CFU/g	Assumed	For Harvest, we also assume that if GAPs are being followed this results in no change.
$\Delta\sigma_H$	Standard deviation changes at H	0	Log CFU/g	Assumed	
ΔH_{agg}	Aggregated total Change due to H	Normal ($\mu\Delta H$, $\sigma\Delta H$)	Log CFU/g	calculated	
<i>Processing</i>					
$\Delta\mu_P$	Fitted Mean change at Processing	-2.25	Log CFU/g	Fitted from the processing module	This process consists of a prewash step, that gives a reduction between 1.1 – 1.4 log CFU/g. The washing step gives a reduction following a
$\Delta\sigma_P$	Fitted Standard Deviation change at Processing	0.17	Log CFU/g		

Symbol	Variable	Distribution, value, or formula	Unit	Source	Justification and assumptions
ΔP_{agg}	Aggregated total change due to Processing	Normal ($\mu\Delta P, \sigma\Delta P$)	Log CFU/g	calculated	(Pahariya et al., 2022; Pang et al., 2017) pert distribution with 0.6,1,1.4 parameters. Cross-contamination steps were not considered as these mainly affected the prevalence in our preliminary runs.
Presentation to consumer					
$\Delta\mu PC$	Fitted Mean change at presentation to the consumer	-0.92	Log CFU/g	Fitted from presentation to consumer module (Pang et al., 2017)	The presentation to consumer steps consists of the transport from retail to facility and the retail storage steps. To represent good practices, we truncated the distribution of temperature are retail to have a maximum temperature of °5 C.
$\Delta\sigma PC$	Fitted Standard Deviation change at presentation to the consumer	0.21	Log CFU/g		
ΔPC_{agg}	Aggregated total Change at presentation to the consumer	Normal ($\mu\Delta M, \sigma\Delta M$)	Log CFU/g	calculated	
Regulatory Testing at retail					
M	Mass of retail testing by sampling exercise	300	g	(U.S Food and Drug Administration (FDA), 2021)	A 300 g test was selected based on the FDA AZ sampling assignment.
N		1	samples		
Consumer Handling					
$\Delta\mu CH$	Fitted mean change in consumer handling	-0.57	Log CFU/g	Fitted from the consumer handling module	This module includes transport from the consumer to
$\Delta\sigma CH$	Fitted Standard Deviation change at consumer handling	0.38	Log CFU/g		
ΔCH_{agg}	Aggregated total Change in consumer handling	Normal ($\mu\Delta CH, \sigma\Delta CH$)	Log CFU/g	calculated	

**Code available in Excel supplement*

Table I. Case study description table

Parameters	Symbol	Value	Unit	Justification
<i>Rodent Control for Leafy Green Crops</i>				
General Description: Crop contamination by wildlife poses a food safety for leafy greens. Rodent control practices are often required to be implemented by growers. However, the risk reduction effect of implementing rodent control practices is unknown. Here we will look at the effect of implementing rodent traps along the field.				
Lb. of leafy greens per acre	$Weight$	32,000	lb.	From baseline scenario
Total acres per iteration	Acres	5	Acres	From baseline scenario
Total pounds of leafy greens produced in field	$Weight_{field}$	$Weight \times Acres$ 160,000	lb.	calculated
Baseline contamination in field	$Cont$	1	CFU/lb.	From baseline scenario
Total CFU in field	$Cont_{field}$	$Weight_{field} \times Cont$ 160,000	CFUs	calculated
Total production time	$Production_{Weeks}$	4	weeks	Expert opinion
Total Field Length (perimeter)	$Length_{field}$	572	m	Assuming we have a square 5-acre field with total area of 20,449m ²
Distance between taps	$Traps_{dist}$	45	m	Expert opinion 50 yards
Total Traps per field	$Traps_{Field}$	$Length_{field} / Traps_{dist}$ 15	traps	calculated
CFU prevented per trap per week	CFU_{Trap}	500	CFUs	Expert opinion (Key data need)
Total CFU prevented per season by implementing rodent control	CFU_{redRC}	$CFU_{Trap} \times Traps_{Field} \times Production_{Weeks}$ 30,918	CFUs	calculated
Total CFUs after implementing rodent control	$CFU_{totalRC}$	$Cont_{field} - CFU_{redRC}$ 129,081		calculated
Log reduction by implementing rodent control	ΔRC	$Log_{10}(129,081/ 160,000)$ -0.093	Log CFU/g	calculated

Table J. Results for the risk of a positive test at retail to the high and low variability baseline systems and added interventions scenarios

Added Intervention Scenario	Risk category						The overall risk of a positive retail sample
	The risk that a retail sample would test positive is greater than...						
	<i>Highest</i>	<i>High</i>	<i>Medium-High</i>	<i>Medium-Low</i>	<i>Low</i>	<i>Lowest</i>	
	1 in 10 lots	1 in 100 lots	1 in 1,000 lots	1 in 10,000 lots	1 in 100,000 lots	<1 in 100,000 lots	
<i>High variability contamination scenario</i>							
Baseline	23	442	2,389	3,551	1,585	93,595	1 in 4,020
Improved Process Controls	3	63	674	2,622	3,242	96,638	1 in 20,063
Finished Product Testing	<1	130	1,851	3,437	1,580	94,582	1 in 11,048
Rodent Control	16	356	2,163	3,599	1,801	93,866	1 in 4,902
<i>Low variability contamination scenario</i>							
Baseline	<1	<1	1,213	6,760	191	92,027	1 in 20,065
Improved Process Controls	<1	<1	41	2,573	5,201	97,386	1 in 113,178
Finished Product Testing	<1	<1	1,102	6,521	118	92,377	1 in 21,431
Rodent Control	<1	<1	787	7,023	354	92,190	1 in 24,853

Table K. Comparison by percent reduction in lots of a positive test at retail for added interventions scenarios relative to the high and low variability baseline systems

Added Intervention Scenario	% Reduction in lots per risk category relative to the baseline						Overall X fold reduction in risk
	<i>Risk category</i>						
	1 in 10 lots	1 in 100 lots	1 in 1,000 lots	1 in 10,000 lots	1 in 100,000 lots	<1 in 100,000 lots	
	<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</i>							
Baseline	-	-	-	-	-	-	-
Improved Process Controls	87%	86%	72%	26%	-105%	-3%	5.13
Finished Product Testing	100%	71%	23%	3%	0.3%	-1%	2.75
Rodent Control	30%	19%	9%	-1%	-14%	0.3%	1.22
<i>Low variability contamination scenario</i>							
Baseline	-	-	-	-	-	-	-
Improved Process Controls	-	-	97%	62%	-2623%	-6%	5.64
Finished Product Testing	-	-	9%	4%	1.6%	0%	1.07
Rodent Control	-	-	35%	-4%	-85%	-0.2%	1.24
<i>Comparing the effect of contamination variability</i>							
Low Variability (Relative to High)	100%	100%	49%	-90%	88%	2%	4.99

Table L. Predicted number of lots that would be detected by testing categorized by overall risk of a positive sample.

Scenario	1 in 10 lots Highest risk lots	1 in 100 lots High-risk lots	1 in 1,000 lots Med-H risk lots	1 in 10,000 lots Med-L risk lots	1 in 100,000 lots Low-risk lots
<i>High variability contamination scenario</i>					
Baseline retail test	7 / 23	14 / 442	5 / 2,389	0 / 3,551	0 / 1,585
Finished Product Testing	23 / 23	312 / 442	538 / 2,389	114 / 3,551	5 / 1,585
<i>Low variability contamination scenario</i>					
Baseline retail test	0 / 0	0 / 0	0 / 1,213	1 / 6,760	0 / 191
Finished Product Testing	0 / 0	0 / 0	111 / 1,213	239 / 6,760	3 / 191

Fig. 1: Literature review inclusion process

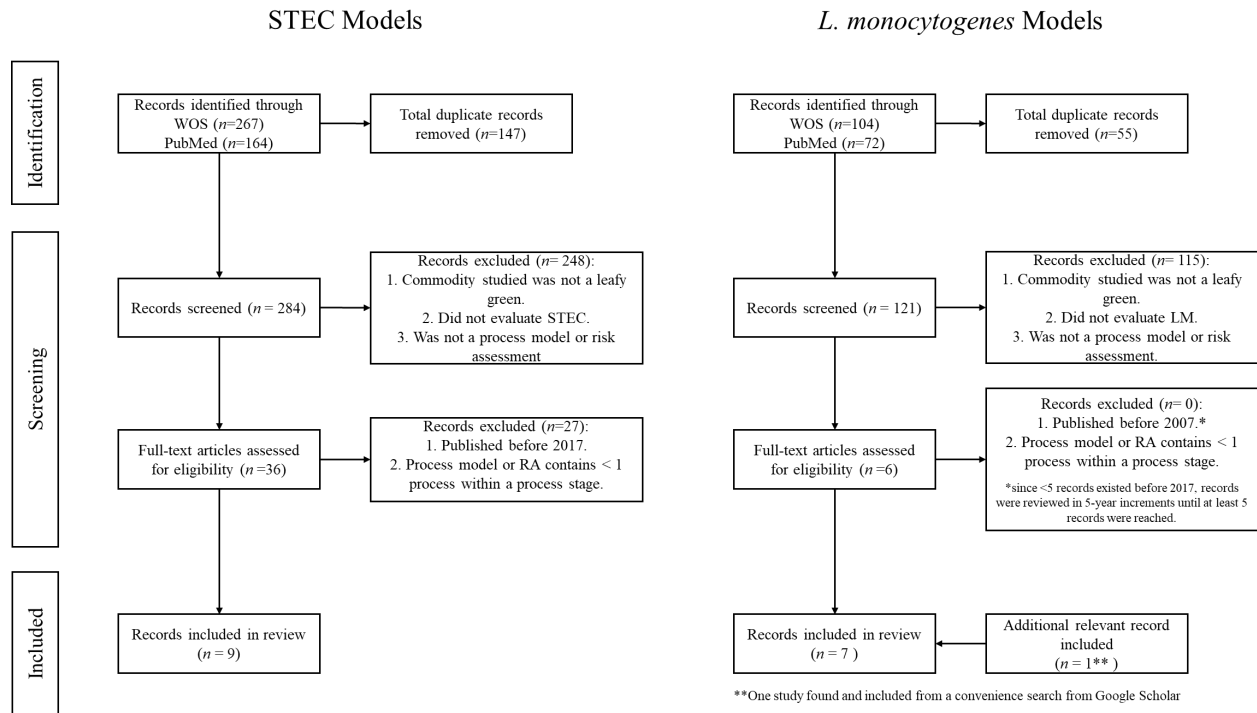


Fig. 1: Literature review inclusion process. Searches for STEC and *L. monocytogenes* models and risk assessments (RAs) were conducted separately. Searches were run through PubMed and Web of Science databases and results were exported for analysis for inclusion. During screening, the reviewers looked at the title and abstract to determine if the paper evaluated would meet inclusion criteria: (i) the commodity of interest (leafy greens), (ii) the pathogen of interest (STEC or *L. monocytogenes*), and (iii) whether it was a process model or risk assessment. Full text articles were then assessed for eligibility by (i) publication year and (ii) whether the process model or RA contained at least two processes within a given process stage in a leafy green supply chain. The results yielded 9 records for STEC and 6 records for *L. monocytogenes*. An additional record was identified for the *L. monocytogenes* literature search via Google Scholar, resulting in 7 total records included.

Fig. 2: Model and scenario analysis framework

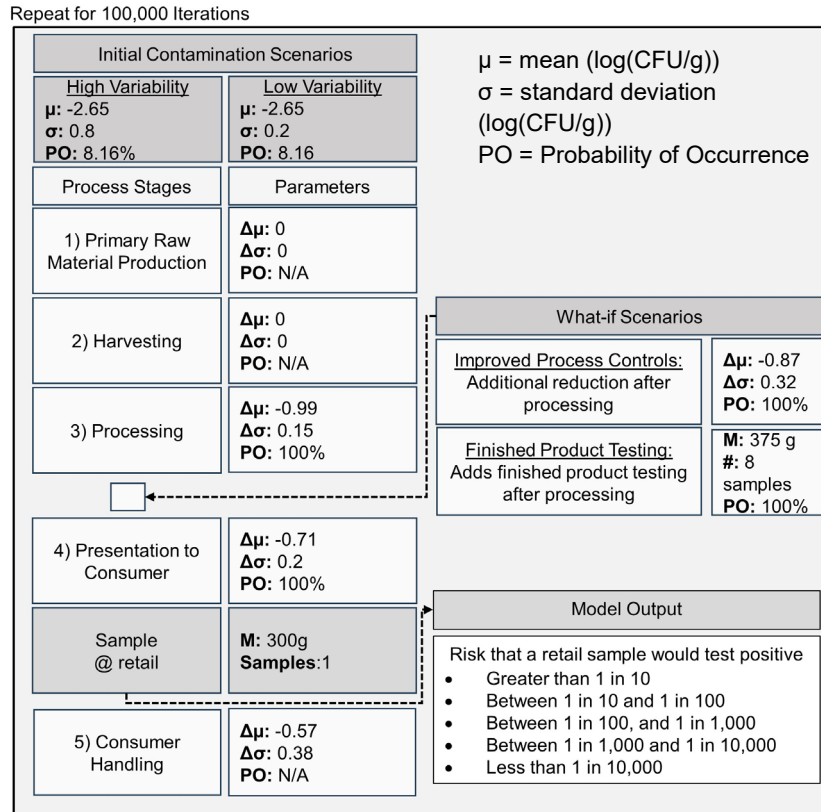


Fig. 2. Model framework. The model consists of 5 main process stages, contamination events, and a retail sample. For the analysis, two contamination events are evaluated with the same mean (μ) contamination levels and probability of occurrence (PO), but with different, high and low, variability (σ), generating two baseline scenarios. For each iteration, an initial contamination is drawn from the distribution. At each process stage, an increase or reduction may occur, introducing additional contamination or reducing existing levels of contamination in the system at that point. The contamination at the end of the Presentation to Consumer stage is used to determine the risk of a retail sample being positive for a given iteration and given this a risk category is assigned to the iterated lot. Two additional “What-If” scenarios are evaluated: improved process controls and finished product testing during the Processing stage. The resultant risk categories assigned to iterated lots are recorded for all scenarios to facilitate comparison of food safety gains from implementing different practices under both high- and low-variability systems.

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