CPS CENTER for PRODUCE SAFETY

CPS 2011 RFP
FINAL PROJECT REPORT

Project Title
Apple growing and packing microbial risk factors and their potential to lead to foodborne disease outbreaks

Project Period
January 1, 2012 – December 31, 2013

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Objectives
1. *Gather pathogen testing data and information about mitigation measures from apple growers.*
2. *Correlate pathogen levels in water used in fresh market apple production and packing operations at different points in the system to levels measured on apples before they leave the packinghouse.*
3. *Characterize potential exposure to pathogens from consumption of fresh market apples and describe potential human health effects associated with these exposure levels; combine the results to estimate the risk of becoming ill from eating contaminated apples.*
4. *Prepare a written risk assessment report about the findings of Objectives 1-3.*
5. *Submit the risk assessment model and report for review to an advisory panel consisting of the WTFRC, the Northwest Horticultural Council and other experts in the field of quantitative microbiological risk assessment.*

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Abstract

While quantitative microbial risk assessment (QMRA) has been conducted for apple cider, no QMRA model was available for the fresh-pack industry to quantify potential pathogen levels on fresh whole apples and the associated probability of illness (Duffy, 2001; Duffy 2002). To address this need, we developed a QMRA model using data from industry and scientific research that can be used by the industry to predict apple pathogen levels from the orchard through departure from the packinghouse, using various contamination scenarios. The model currently provides an initial risk estimate for consumption of apples that have been contaminated by pathogenic *Escherichia coli* (*E. coli)* in evaporative cooling water applied to apples in the orchard prior to harvest. The QMRA model estimates the potential for change in apple pathogen levels during various stages of primary production and packing using relevant orchard, storage, and packing facility parameters. The risk of foodborne illness associated with consumption of Washington apples contaminated by pathogenic *E. coli* predicted by the QMRA model is very low based on available data and current industry practices. During model development, data gaps were identified that need to be addressed in order to increase the model's ability to more accurately predict the potential risk of illness if contamination were to occur.

Background

Although there has been *E. coli* O157:H7 outbreaks in unpasteurized apple cider and juice products and recalls of fresh-sliced apples due to *Listeria monocytogenes* contamination, there has been no reported illness related to fresh whole apples (FDA, 2009; 2010; 2012c, 2012d, 2012e; 2013a). However, research using attenuated pathogenic and nonpathogenic stains of *E. coli* has demonstrated survival on apples under varying circumstances and, in some instances, growth. (Burnett, 2000 & 2002; Dingman, 2000; Janisiewicz, 1999a and 1999b; Jin, 2011; Kenney, 2002a, 2002b; Lee, 2005; Rodgers, 2004; Wang, 2009).

Fresh market apple packing operations constitute a significant process in the supply chain and are a potential source of contamination. To date, there is no published quantitative microbiological risk assessment of fresh market apple packing operations. After the 1996 *E. coli* O157:H7 associated foodborne illness outbreak attributed to unpasteurized apple juice, Duffy and Schaffner from Rutgers University used published data to model the ability of *E. coli* O157:H7 from various sources in the orchard environment to potentially contaminate apples and apple cider (Duffy, 2001; Duffy, 2002). Their model focused on fecal contamination through manure use in the orchard and bird feces and confirmed that certain orchard practices such as the use of dropped apples increased the risk of contamination in cider production (Duffy, 2002). Other research has investigated the effectiveness of various practices used to mitigate microbial pathogens on apples; however, these studies were primarily related to apple juice and not specifically related to the whole fresh apples for the fresh-pack market (Yuste, 2003; Reinders, 2001; Dingman, 2000).

The overall objective of this QMRA for fresh whole apples is to provide a systematic evaluation of the food safety risks and potential ensuing adverse health effects that could arise from the application of pathogenic *E. coli*-contaminated evaporative cooling water to apples prior to harvest. Growers in eastern Washington apply water to orchards via overhead sprayers to cool apples during high temperatures most often in the latter part of the season close to harvest. While there are other possible points of pathogenic *E. coli* contamination that can occur in an orchard, e.g. from animal and human contact, this QMRA focuses on evaporative cooling in response to industry questions following the release of the proposed *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (the Produce Rule). This QMRA seeks to address the following three questions: 1) What is the probability of illness from consumption of pathogenic *E. coli*-contaminated fresh market

apples? 2) What are the greatest sources of uncertainty (i.e., data gaps) in the input parameters used in the model? 3) What data do we recommend be collected in order to improve the model?

Research Methods and Results

Objective 1. Gather pathogen testing data and information about mitigation measures from apple growers.

In a previous CPS-funded data collection project (Wetherington, 2011),packinghouse data was collected for the years 2005-2010 from 17 companies and compiled into a Microsoft Excel (2010) database after removing all confidential record details (i.e., company names were replaced with numerical references; process identifiers such as line names and locations were also removed). Initially, the dataset consisted of approximately 3,000 records. In mid-January 2013, Intertox conducted a survey at a Washington grower-shipper meeting to obtain current practice information and solicit grower and packinghouse participation in the study. Based on survey results, Intertox Decision Sciences (IDS) visited packing companies on two separate occasions in 2013 to discuss data-sharing and collect information related to their food safety programs. From the contacts that were made, several companies agreed to share their data. With the addition of these new companies as well new data from previously participating companies, approximately 2,000 records were added to the dataset for the years 2011 and 2012. The current database consists of approximately 5,000 records for the years 2005-2012. In addition to data, the industry has supported this research by sharing information regarding their production and packing operation processes during site visits and conversations. The collective industry data and knowledge was used to build the risk assessment model.

Objective 2. Correlate pathogen levels in water used in fresh market apple production and packing operations.

Because water is used extensively in apple production and packing operations, water quality is a particularly important risk factor to consider when examining the risk of contamination in fresh market apples. Apples come in contact with water applied at various points from the orchard to the packing house including during irrigation and application of pesticides, in drench tanks and flumes, and from spray bars. For this project, we collected product test data and water quality data during packing and production operations which we had planned to examine for correlations. However, the use of product testing has decreased significantly in the past two years; therefore, we were unable to collect sufficient product test data to correlate with pathogen levels in water. We did, however, work closely with one packing facility and collected two years of temperature, pH, chlorine and ORP readings along with water test results. We used regression analysis to test for correlations between pathogen levels measured in water and the above parameters. This work is ongoing. While this does not reveal how microbial levels in water are affecting apple microbial levels, it does provide insight into potential process issues that could have an effect on apples.

Objective 3. Characterize potential exposure to pathogens from consumption of fresh market apples and describe potential human health effects associated with these exposure levels; combine the results to estimate the risk of becoming ill from eating contaminated apples.

This QMRA is based on methodology developed by the National Research Council (NRC) in the 1980's and is used by the U.S. Environmental Protection Agency, the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) in conducting their risk assessments (NRC, 1983). The generally accepted NRC methodology includes four elements – hazard identification, exposure assessment, hazard characterization/dose response assessment, and risk characterization.

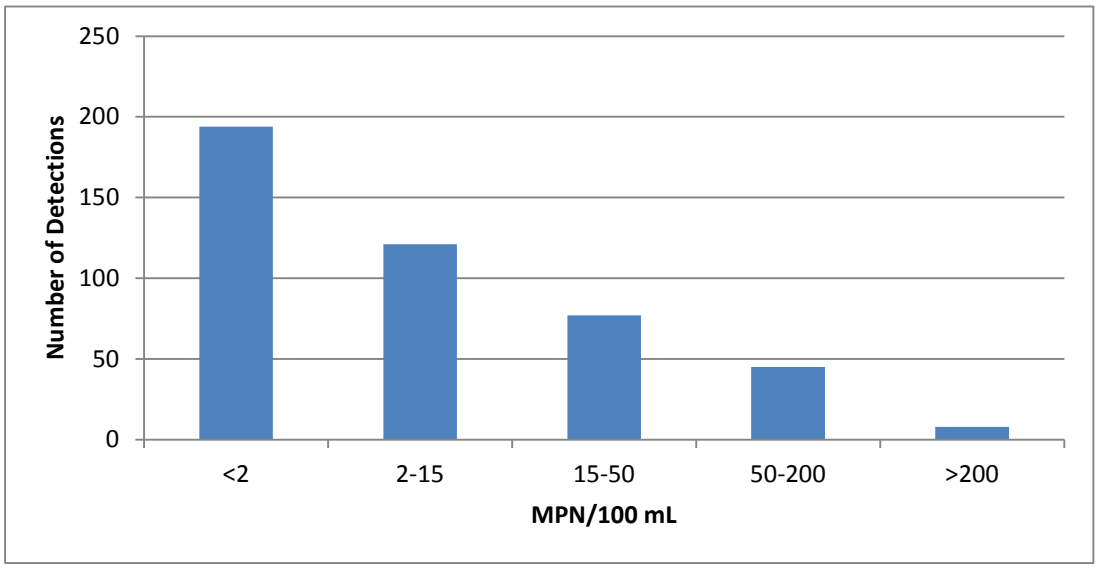
Research related to pathogen and apples identified studies for three pathogens – *E. coli* O157:H7,

Salmonella, and *Listeria monocytogenes* (*L. monocytogenes*). Currently the model only includes pathogen information for *E. coli* O157:H7 (also noted as the broader category of enterohemorrhagic *E. coli* (EHEC) of which *E. coli* O157:H7 is the dominant strain). An assessment of *Salmonella* and *L. monocytogenes* contamination was ruled out at this time due to a lack of data and research related to the behavior of these pathogens on apples.

As part of the exposure assessment, we analyzed industry testing results for generic *E. coli* in agricultural water and for packinghouse water and environment. Results are as follows:

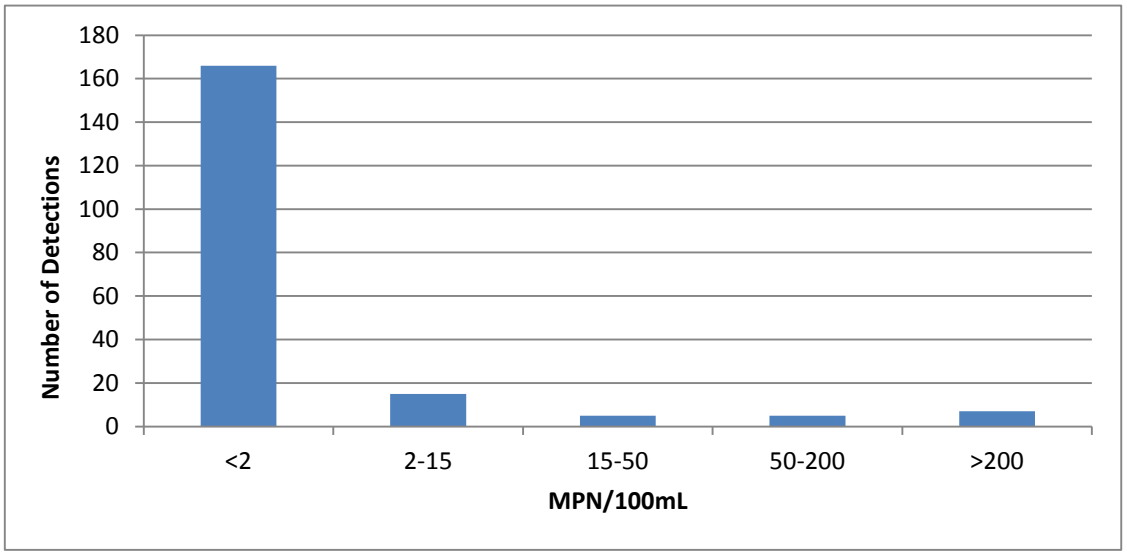
- The industry microbial test results for generic *E. coli* in agricultural water during production ranged from <1 to 2,400 MPN/100 mL - 44% had levels less than 2 MPN/100 mL, 55% had levels between 2 and 200 MPN/100 mL, and 2% exceeded 110 MPN/100 mL (Figure 1).

FIGURE 1. Quantities of generic *E. coli* detected in irrigation water, 2005-2012 (N=445)



- Of the 198 water samples at packing facilities, 84% had generic *E. coli* levels less than 2 MPN/100 mL (Figure 2). Water samples were taken from dump tanks (48%), flumes (17%), source water (11%), and other areas along the processing line (13%). The remaining samples were taken from hydrocoolers, drench tanks or were not specified. Four percent of dump tank samples and 7% of other process water samples had generic *E. coli* detections greater than 200 MPN/100 mL. Aside from the drench tank samples, no other packing line or facility water sample test result was greater than 200 MPN/100 mL.

FIGURE 2. Quantities of generic *E. coli* detected in packing line water, 2005-2012 (N=198)



- Packing companies performed a total of 575 tests for generic *E. coli* on food contact surfaces resulting in six positive tests: three detections on brush beds, two on plastic flaps along the line and one on clam shells. Four *E. coli* O157:H7 swab tests were conducted between 2005 and 2012, all with negative results.

A QMRA model was constructed in Microsoft Excel incorporating an Excel add-in (Palisade @Risk probability analysis software; Ithaca, NY). QMRA models are widely used for probability analysis and the approach Intertox took was similar to the approach used by other risk assessors when building models to estimate the risk of foodborne illness (Danyluk, 2006; Danyluk, 2011; Evers, 2010; Schroeder, 2006.) Parameters in the QMRA model are represented by a range of values that describes what is known about the uncertainty and variability in that parameter. Using probability analysis we computed the total uncertainty and variability in the output by quantifying the uncertainty and variability both in the inputs and in the models: i.e., where possible, data inputs used in the calculations are quantified not in terms of a single, discrete number, but as probability density functions that express the existing knowledge about alternative values for a parameter. This allows for statistical interpretation and incorporation of experimentally derived data for individual segments of the apple production and packing continuum into the model (Cassin, 1998b). The model can be revised and calibrated as additional data on pathogen levels at specific points in the process or additional information on the relationship between location-specific parameters and growth or decrease in pathogen concentrations are identified.

Based on industry input we evaluated the following three scenarios:

1) Best-case scenario, assuming all components of the system are properly working, as follows:

- Cooling – Apples are adequately cooled to remove the field heat and microbial populations are reduced (Janes, 2002).
- Dump tank – Water in the dump tank contains a sanitizer, and as a result there is a slight reduction of *E. coli* levels on apples (i.e., dump tank water is neutral) (Sapers, 2000).
- Washing – Washing apples with detergents to remove natural wax reduces contamination on the surface of the fruit (Kenney, 2002a).

- Spray bar – Contamination on apples is reduced using PAA in a spray bar (Killinger, unpublished).
- Waxing – Waxing reduces contamination on apples (Kenney, 2002b).
- Entire process – Growth of *E. coli* that has been deposited and internalized at the calyx and stem areas (Buchanan, 1999; Sapers, 2000; Janisiewicz, 1999b).

2) Worst-case scenario with waxing (to reflect apples that are typically waxed), assuming some components of the system are not working properly, as follows:

- Cooling – Apples are inadequately cooled to remove the field heat and as a result bacteria grow (Janisiewicz, 1999b).
- Dump tank – Water in the dump tank contains a sanitizer that prevents contamination of water, but there is no reduction of contamination on apples (i.e., dump tank water is neutral) (Annous, 2001).[1]
- Washing – Washing with detergents to remove natural wax reduces contamination on apples (Kenney, 2002a).
- Waxing – Waxing reduces contamination (Kenney, 2002b).
- Entire process – Growth of *E. coli* that has been deposited and internalized at the calyx and stem areas (Buchanan, 1999; Sapers, 2000; Janisiewicz, 1999b).

3) Worst-case scenario, without waxing (e.g., to reflect apples that are typically unwaxed such as Golden Delicious or organic apples), as follows:

- Cooling – Apples are inadequately cooled to remove the field heat and as a result bacteria grow (Janisiewicz, 1999b).
- Dump tank – Water in the dump tank contains a sanitizer that prevents contamination of water, but there is no reduction of contamination on apples (i.e., dump tank water is neutral) (Annous, 2001).
- Washing – Washing with detergents to remove natural wax reduces contamination on apples (Kenney, 2002a).
- Entire process – Growth of *E. coli* that has been deposited and internalized at the calyx and stem areas (Buchanan, 1999; Janisiewicz, 1999b; Sapers, 2000).

In developing the QMRA model, we used the following data:

- Industry data and input from industry members/experts:
  - Orchard
    - Amount of water for evaporative cooling applied per season (gallons/ acre) - 40 gallons/minute/acre for 11 hours
    - Mass of apples harvested per acre (kg/acre)- In 2012 WA produced 5.7 billion lbs on 146,000 acres = 39,041 lbs/acre or 17,710 kg/acre
    - Percentage of cooling water landing on apples (percent) – 35%
    - Minimum days in field after last cooling water applied (days) – 0.417 days
    - Maximum days in field after last cooling water applied (days) – 0.5 days

[1] The worst case scenario could include the possibility of wash water doing harm rather than remaining neutral; however, there are no studies nor data demonstrating this potential with apples.

  - Post-harvest Cooling
    - Minimum time in cooling (hours) – 3 hours
    - Maximum time in cooling (hours) - 16 hours
  - Spray Bar
    - Sanitizer used (Yes or No) - Yes
    - Wax applied (Yes or No) – Scenario dependent

- Pathogen concentration and prevalence – Concentration data are described by a distribution based on assumed or detected minimum, maximum, median, average, and standard deviation, where the minimum concentration is assumed to be the lowest concentration detected. In addition, the model requires input of an assumption about the "fraction contaminated" (i.e., the fraction of apples assumed to have a concentration of at least one microbe, or 1 CFU).

  The initial generic *E. coli* concentration on apples is estimated using industry irrigation water samples collected from orchards. In Washington orchards, water sources for evaporative cooling are typically the same as irrigation water sources. The assumed concentrations of *E. coli* in evaporative cooling water were 2,400 MPN/100 mL, which was the highest industry-reported level and 235 MPN/100 mL – the maximum acceptable level for a single sample put forward by the FDA in the Proposed Produce Rule as the agricultural water quality standard for water used during growing activities. As in the FDA's Draft *Quantitative Risk Assessment to Support the Proposed Produce Rule*, a ratio of 1:100 for EHEC to *E. coli* in irrigation water was used to estimate EHEC levels from generic *E. coli* levels (FDA, 2012f). The fraction contaminated – 12.5% was calculated from Lee and Kang (2005).

- Scientific studies
  - Data from Lee and Kang (2005), the only study investigating the survival of generic *E. coli* on apples in the orchard, were used to estimate *E. coli* concentration in the orchard environment after evaporative cooling and prior to harvest. In September and October close to harvest, generic *E. coli* was sprayed on apples in the orchard and measured at day 0, 1, and 3. Concentrations immediately after spraying were 4-5 log CFU. Populations were reduced to non-detectable levels (0.3 log CFU/apple) in apples collected 1 day after spraying. The estimated mean log reduction was 4.8 log CFU/ d, SD = 0.6; assume triangular distribution with mean = mode and min/max equal to $\pm$ 2 SDs.
  - No studies were identified that investigated the effect of temperature on *E. coli* growth on whole apple surfaces. Data from Janes et al. (2002) that investigated growth of *E. coli* O157:H7 in apple wounds at 4°C were used to estimate the effect on *E. coli* concentration during pre-packing cooling to remove field heat. Red Delicious, Jonathon, and Golden Delicious apples were inoculated with *E. coli* O157:H7 at 6-7 log CFU/g. After 7 days at 4°C, the log reduction ranged from 0.4 to 0.9 log CFU, or an average of 0.089 log CFU/ d (min= 0.057 log CFU/ d, max = 0.13 log CFU/d; assume triangular distribution with mean = mode and min/max of dataset.)
  - Data from an evaluation of five aqueous commercial cleaners and waxes by Kenney and Beuchat (2002a and 2002b) were used to estimate *E. coli* concentrations following application of cleaners and wax in the packing line. In Kenney and Beuchat (2002a), various aqueous commercial cleaners were evaluated for their efficacy in removing pathogens from fresh apples. Cleaners were used to wash apple, at the concentrations and exposure times recommended by the manufacturers. (Mean= 4.5 log CFU/apple; SD: 0.51; triangular with min = 3.8, mid = 4.5, max = 5.7 log CFU.) In Kenney and Beuchat (2002b), Red Delicious apples treated with commercial

waxes showed reductions after 30 min compared to untreated apples, at driving temperatures of 21 or 55°C (n=10). (mean = 0.32 log CFU/apple; min = no change, max =0.91; assume triangular distribution with mean = mode and min/max of dataset.)

- Reduction of *E. coli* due to exposure to sanitizers in spray bar water was estimated from unpublished data contributed by the Killinger laboratory at Washington State University. Killinger et al. measured log reduction of attenuated *E. coli* on apples from peroxyacetic acid in a double spray bar (min = 0.3, mode = 0.5, max = 0.7 log CFU/apple; assume triangular distribution with mean = mode and min/max of dataset.)
- Data from a study by Janisiewicz et al. (1999b) that measured the growth of *E. coli* in apple wounds was used to estimate growth during the packing process. These data were used to estimate the concentration of *E. coli* that may have been internalized in apples following an application of contaminated water. Janisiewicz et al., 1999b showed growth of pathogenic *E. coli* in apple wounds at 24°C for 48 hours. It is assumed that bad quality apples (wounded, bruised) are culled by workers along the packing line per industry practices, but that some growth occurs for apples that had pathogens internalized at the calyx and stem ends from application of contaminated water during overhead evaporative cooling. Experiments by Buchanan et al. (1999) and Sapers et al. (2000) showed that pathogenic *E. coli* were associated with the stem and calyx area when exposed to contaminated water. These areas are not readily accessible to the washing and rinsing processes in the packing line where pathogens may otherwise be removed or inactivated (Annous, 2001). In the Buchanan et al. study some *E. coli* were internalized inside the apple. Data for 6 hours calculated to simulate time apple spends at room temp during packinghouse activities. (Mean log growth: 0.21 log CFU/wound; SD: 0.11; assume triangular with min = 0.1, mid = 0.21, max = 0.32 log CFU/wound; assumes triangular distribution with mean = mode and min/max of dataset and the amount in one wound equals total internalized contamination in the whole apple.)

- Exposure estimates - Variables involved in calculating human exposure to pathogens from eating apples include population-specific estimates of body weight and apple serving size. Data on reported apple consumption and body weight from the 2009-2010 National Health and Nutrition Examination Survey (NHANES) was used to estimate exposure. Because of age-related variation in consumption patterns as well as adverse health effects, the model assesses the probability of illness for a child, an adult, and two adult subpopulations – pregnant woman and an elderly individual ($\underline{\geq}$65 years).
- Dose-Response estimates - Required user input includes parameter estimates to predict the number of illnesses assuming a given dose of the pathogen. The dose-response model used in this assessment is based on a model developed by Cassin et al. (1998a) for *E. coli* O157:H7 in ground beef and modified by Danyluk et al. (2011) for use in their QMRA for leafy greens. Cassin et al. proposed a beta binomial model that predicts the probability of illness from a particular dose, and Danyluk et al. simplified this binomial model by converting it back into a simple beta Poisson model that specifies a mean population risk.

The model calculates risk estimates predicting the number of people who could become ill from eating apples contaminated with EHEC at the orchard level. In the best case scenario, the model estimated 2.0 cases in 10 billion servings (one apple) for adult consumers. For child consumers, pregnant women, and the elderly the model estimated 1.5, 2.0, and 1.8 cases in 10 billion servings, respectively.

To test the influence of industry practices on model results, individual exposure-related parameters were evaluated while keeping all other assumptions the same. For measuring the sensitivity an increase

in evaporative cooling water volume would have on the model results, we changed the assumption of gallons of water applied per acre from 20,400 to 40,000 (i.e. as may occur with sustained elevated temperatures). With the increase in evaporative cooling water volume, the predicted probability of illness for adults increased from 2.0 cases in 10 billion servings to 4.1 cases in 10 billion servings.

To test the sensitivity of the time interval between application of evaporative cooling water and harvest, we increased the 10 to 12 hour interval to 24 hours. We also tested a decrease in the interval to 0 hours. When evaporative cooling water was applied up until harvest (0 hours), the probability of illness for adults increased from 2.0 cases in 10 billion servings to 3.2 cases in 100 million servings. If application was discontinued 24 hours before harvest the probability of illness decreased to 9.2 cases in 10 trillion servings. Lastly, to test the sensitivity of post-harvest cooling, we increased time in the cooler from 3 to 16 hours to 24 hours. When the cooling step is reduced to 0 hours, the probability of illness increases from 2.0 cases in 10 billion servings to 4.2 cases in 10 billion servings, and when increased to 24 hours, the probability of illness decreases to 1.8 cases in 10 billion servings.

We also tested the influence of these industry practices on model results for children. The results of this analysis are summarized below in Table 1.

Table 1. Sensitivity Analysis Results for Children

Input Changed	Parameter change	Mean Probability of Illness (after change)	Mean Probability of Illness (before change)
Amount of evaporative cooling water applied	20,400 gallons/acre to 40,000 gallons/acre	3.12×10^{-10}	1.54×10^{-10}
Time in field after evaporative cooling	10 – 12 hours to 0	2.43×10^{-08}	1.54×10^{-10}
Time in field after evaporative cooling	10 – 12 hours to 24 hours	6.87×10^{-13}	1.54×10^{-10}
Time spent in cooler	3 – 16 hours to 0	3.12×10^{-10}	1.54×10^{-10}
Time spent in cooler	3 – 16 hours to 24 hours	1.4×10^{-10}	1.54×10^{-10}

An analysis of the factors influencing the probability of EHEC-related illness in children was completed in @Risk. Washing with cleaners during packing is the most effective control step followed by the evaporative cooling water application interval prior to harvest. This suggests the importance of washing apples with appropriate cleansers and concentrations in order to ensure reduction of EHEC on apples.

Objective 4. Prepare a written risk assessment report about the findings of Objectives 1-3.
A comprehensive report describing the industry data analysis, the risk assessment process, the QMRA model developed by Intertox, Inc., the literature review, and the model risk estimates was written for the Washington apple industry.

Objective 5. Submit the risk assessment model and report for review to an advisory panel consisting of the WTFRC, the Northwest Horticultural Council (NHC) and other experts in the field of quantitative microbiological risk assessment.
The comprehensive report was submitted to the WTFRC, the NHC, and to Brian Zomorodi, Ready Pac Foods, Inc., Drs. Linda Harris, UC Davis and Donald Schaffner, Rutgers University. Following their individual review of the document, a conference call was convened with the reviewers to discuss their feedback. Reviewers also submitted written comments. Revisions to the risk assessment were made based on the reviewer feedback.

Outcomes and Accomplishments

Since 2010 Washington companies that grow and pack apples have participated in a NHC and WTFRC supported program to collect and compile microbial testing data (i.e., environmental, water, and product) in a common database for industry analysis. This data was contributory in producing this QMRA model. In addition to data, the fresh-pack apple industry has supported this research by sharing information regarding their production and packing operation processes during site visits and conversations. This expert knowledge was instrumental in building this risk assessment model where data was not available. This project would not have been possible without the support and industry knowledge and relationships of Deborah Carter at NHC and Ines Hanrahan at WTFRC. Both were instrumental in introducing us to key industry members providing the basis for the relationships necessary to gain industry support. Feedback from Drs. Linda Harris and Donald Schaffner and Brian Zomorodi was valuable and strengthened the report and analysis.

A QMRA can be supportive of operation-specific Hazard Analysis and Critical Control Point (HACCP) plans. Understanding how the production and packing processes affect pathogen levels, to the extent pathogens are present, provides the industry with a means to evaluate the practices they currently employ, and an opportunity for adjustments if QMRA results indicate that current practices are insufficient at reducing the potential for illness. The model also provides a tool for industry members to evaluate how effective a particular mitigation measure will be in reducing potential human health risks prior to implementation. Potential mitigation measures for improving food safety may require substantial financial commitments, and the results of a QMRA tool can provide the ability to estimate the potential human health impact of a measure under consideration prior to committing valuable and limited resources.

In conducting this QMRA, data gaps were identified indicating the need for further research in order to provide a better understanding of the overall risk from growing through packing. Research investigating the effects that various primary production and packing processes have on microbial levels on apples, food contact surfaces, and process water, are areas where insufficient data are available for assessing human health impacts. QMRA results can be used to focus future research efforts in a cost-effective manner. This is critical for efficiently managing valuable research monies.

Finally, with the concern surrounding the FDA's proposed agricultural water quality standard of 235 MPN/100 mL for a single sample during growing activities in the proposed Produce Rule, this QMRA provides the fresh-pack apple industry with a tool to evaluate the potential human health risks related to this level of contamination in irrigation and evaporative cooling water. If, as is expected, the FDA revises this standard based on submitted comments, it is unlikely that the final standard will be stricter than that which is currently proposed. Therefore, the risk estimates in this risk assessment provide conservative estimates of the effect of a federal standard on Washington apple production. When the Produce Rule is finalized, the model can be updated to evaluate the revised standard.

Summary of Findings and Recommendations

Key findings of this study include:

- The QMRA model results suggest that the risk of EHEC-associated illness from consumption of apples contaminated with EHEC through evaporative cooling water is low based on currently available data and industry practices. As more data becomes available, the model can be updated to more accurately predict the potential risk of illness if contamination were to occur.

- Sensitivity analysis indicates that washing with cleaners during packing is the most effective control step. This highlights the importance of washing apples with appropriate cleansers and concentrations in order to ensure reduction of EHEC on apples.
- The time interval between evaporative cooling water application and harvest is another effective control step as indicated by the sensitivity analysis. This QMRA indicates that maximizing the time between application and harvest reduces the probability of illness if water is contaminated with EHEC.
- The QMRA supports current practices such as those related to evaporative cooling and exclusion of bruised and dropped apples are protective of human health. While risk estimates from this QMRA suggest that consumption of an apple exposed when growers apply evaporative cooling water exposed to containing 2400 MPN/100 mL *E. coli* is unlikely to result in illness, , consideration should be given to water quality and time intervals between application and harvest as preventive controls in the orchard.[2]

[2] Although water quality is an important risk factor in food safety, published research does not consistently demonstrate a reliable correlation between generic *E. coli* presence or levels in agricultural water and human pathogen presence.

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APPENDICES

Publications and Presentations (required)

Poster presentation at Center for Produce Safety Research Symposium, June 27, 2012, Davis, CA.

Presentation and poster at Apple Hort and Postharvest/Apple Crop Protection Research Review, January 29 2013, Yakima, WA.

Presentation at Apple Hort and Postharvest/Apple Crop Protection Research Review, January 29-31, 2014, Yakima, WA.

Presentation at Blue Bird Pears Growers Meeting, February 24, 2014, Wenatchee (WA) Convention Center.

Budget Summary (required)

Category	**Budgeted**	**Expended**	**Remaining**
Salaries	$39,736	$39,736	0
Benefits	$18,278	$18,278	0
Travel	$1,700	$850	$850
Contractual	$7,092	$7,092	0
Total Costs	**$66,806**	**$65,956**	**$850**

Total budget expenditures include salaries and benefits (87%) associated with the development and delivery of the data collection, exposure assessment and risk assessment model. Travel costs were spent on visits to Yakima and Wenatchee to meet with the Washington Tree Fruit Research Commission and individual packinghouses and growers. Money remaining in the budget is for travel to attend the 2014 CPS Research Symposium. Contractual dollars of $7,092 were spent on acquired data from third party laboratories and time associated with data collection from individual packinghouses.